## Julie Stokes

**From:** Legislation
**Sent:** Friday, 3 October 2014 5:01 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: new 1080 poison regulations

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**From:** David Bacchiella [mailto:DBacchiella@hinchinbrook.qld.gov.au]
**Sent:** Friday, 3 October 2014 2:42 PM
**To:** Legislation
**Subject:** new 1080 poison regulations

I believe there is going to be changes to 1080 that will allow landholders to purchase and put out this poison.
As I am the officer in the Hinchinbrook shire council that does the baiting in the shire for feral pigs and dingoes I have concerns giving landholders in closely settled areas a 1080 licence.In large properties out west there would not be a problem as there are huge distances between properties.
But in shires like Hinchinbrook were the properties are much smaller and there is more dwellings I believe that local government officers should still be the ones to distribute and put out 1080.At least we make sure adjoining land holders are notified and that bating signs are put up.
But most importantly before we bait for feral pigs we make sure we pre-feed first and put up cameras to make sure there are no off target species eating the pre-feed .This is done to minimize any off target baiting.
I know for a fact that landholders if they get a 1080 licence will not adhere to the rules as some have told me if they do get a licence they will bait regardless .
I believe this be a recipe for disaster as there will be bait put out for no good reason and we will start getting off target baiting.
At the moment with proper monitoring there has been no off target baitings. I hope you think long and hard if there is going to be changes to the 1080 poison legislation.
Thanking You
David Bacchiella

**From:** Legislation
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Feedback New Medicines, Poisons and Therapeutic Goods Bill
**Date:** Thursday, 2 October 2014 10:45:10 AM
**Attachments:** FW New Medicines Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014 .msg

Please find questions and feedback below

Cheers,
Kelly

**From:** Ann Richards
**Sent:** Thursday, 2 October 2014 9:48 AM
**To:** Legislation
**Cc:** Lee Broad
**Subject:** Feedback New Medicines, Poisons and Therapeutic Goods Bill

Thanks for the opportunity to provide feedback.

Re: Information sheet for health professionals

It writes that there will be a requirement for a hospital etc to have a scheduled substance management plan and that staff working within the facility will work within the scope as written in the plan.

Questions:

1. Is it anticipated that each facility within a HHS has to have a scheduled substance management plan or can HHSs write one that overarches all of their facilities?
2. Will there be lead time for HHSs to develop this plan before enactment of the new legislation?
3. Will a template be provided to HHSs to ensure the document/s prepared by a HHS include all aspects of the compliance requirements?

Kind regards,
Ann

Ann Richards
Public Health Manager (Southern Sector)
Torres Cape York HHS
Floor 6, Building 2
William McCormack Place
Sheridan St, Cairns, Q 4870
Email: Ann.richards@health.qld.gov.au
Phone: 07 4226 3020
Mobile: [redacted]

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: APHS Packaging - [redacted]

Postcode: 4122

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☒ Industry - medicines
- ☐ Industry - poisons
- ☒ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes, a more user friendly act and regulations

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Yes

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

None

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

No

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Yes, current code of GMP

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

No changes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

No, it does not reduce the number of licenses required as we move from two Licences to Manfacture to two Wholesaling Licences and need to also be registered as a TGA facility. The increased timeframe for licencing will reduce the time and resources required to maintain licences. The introduction for electronic submission of licences and renewals should have a positive impact on increasing efficiency and hoepfully allow appropriate time-frames for reminders.

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes, could there be a single licence that covers restricted and controlled medicines - rather than two separate ones.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Yes - but we will stil require the wholesaling licence.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

No issue

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

n/a

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

No

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

Not at all

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Six months

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Approved procedures and we would add a section intio the Site Master File that is a requirement of our TGA licence

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

The site master file current cover smost and the update to it would be a minimal cost of a change control.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Six months

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Yes, if they have the appropriate skills to complete the audits - with also ensuring that there is uniformity between the auditors.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

If there was harminisation betweenTGA audits and Queensland Health audits.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

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September 2014

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## Personal details:

Given name:

Surname:

Organisation and/or Professional position: Queensland Police Service and Public Safety Business Agency

Postcode: 4000

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☒ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: PSBA CLLO Office

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

The objectives outlined in the draft Bill appear to appropriately address public health concerns.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Streamlining compliance regimes is a positive outcome for industry; however, care needs to be taken to ensure where compliance measures are required by Commonwealth Legislation, appropriate state represenation is available to monitor complaince at a state level.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

The Bill does not articulate the process required for the reporting and monitoring of pharmaceutical medications. The Bill does not define the requirements for recording the sales of S3 pseudoephedrine in a singular real time electronic recording system that is accessible to law enforcement and health officers. The current Health Drugs and Poisons Regulation 1996 provides that pseudoephedrine sales must be recorded by pharmacists on such a system. This system has been in place as a pilot in Queensland since 2005 and is an important tool to enable pharmacists to ensure customers or patients have a therapeutic need for S3 pseudoephedrine. This strategy is a key element in reducing domestic manufacture of methylamphetamine using pseudoephedrine in Australia and the public health harms associated with the unlawful manufacture and misuse of methylamphetamine (including ICE).

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

None identified

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Nothing further, other than what has already been identified in this document.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Nil

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

The scope of offences appear to adequately address the harms associated with the misuse, and illegitimate use of therapeutic medicines and poisons.

A question is raised as to the defence provision under each of the offence sections 'unless the person has a reasonable excuse e.g. s.23 'Offence to perform regulated activity for prohibited substances'. Reasonable excuse is not defined in the Bill and as such much interpretation may be applied. What is the intent of the reasonable excuse provision?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

The penalties are reasonable given the potential risks to public health and individual safety.

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Nil comment

11. Are the proposed licences, approvals and other authorisations appropriate?

The proposed licences and approvals appear appropriate

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

The Bill appears to address this issue adequately.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

The definition of 'criminal history' in the proposed Bill encompasses a wider range of information than currently defined in the Health (Drugs and Poisons) Regulations 1996. This would enable the chief executive to consider information not previously made available by the Commissioner of Police. There is also a new requirement on the Commissioner of Police to advise when a person's criminal history has changed. Such continuous monitoring of the criminal histories of persons of interest to Queensland Health cannot be done manually and will require the use of the QPS SCRAM computer system. This means that Queensland Health (QH) must be able to send electronic files in a suitable format to SCRAM with details of those persons and be able to update that 'list' with new persons and remove those persons whose licence, approval, or authority is no longer in force.

It is noted the Bill does not make specific provision for information exchange between QPS and QH. PSP strongly supports minimising the legislative burden and reducing red tape. However, QH may wish to consider the need for information sharing provisions in the context of any potential conflict with s.159 ‘Confidentiality of information’ of the Bill.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Nil comment

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

None identified

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Nil comment

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity’s processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Nil comment

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

Nil comment

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Nil comment

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

If the appointment of third party auditors promotes compliance with the legislation by industry and the findings from these auditors is actioned appropriately then engagement of third party auditors should be considered.

An avenue for the exchange of information to the QPS should be considered where the auditor finds evidence of serious or organised criminal activity relating to activities undertaken under the health legislation.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Nil comment

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

See question 3 regarding recording of S3 pseudoephedrine medications.

A number of pieces of legislation are not listed in the consequential amendments that will be affected by the assent of the Bill, including:

Police Powers and Responsibilities Act 2000;

Police Powers and Responsibilities Regulation 2012;

Police Service Administration Act 1990;

Drugs Misuse Act 1986; and

Drugs Misuse Regulation 1987.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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Read our privacy statement for details.

# PUBLIC SAFETY PORTFOLIO (PSP)

**(includes Public Safety Business Agency (PSBA), Queensland Police Service (QPS), Queensland Fire and Emergency Services (QFES) and Inspector General Emergency Management (IGEM))**

## DISCUSSION PAPER FEEDBACK

**Title of Submission:** *Medicines, Poisons and Therapeutic Goods Bill 2014*

The PSP requires further consultation or a meeting to discuss the following major issues:

- The Bill does not articulate the process required for the reporting and monitoring of pharmaceutical medications. The Bill does not define the requirements for recording the sales of S3 pseudoephedrine in a singular real time electronic recording system that is accessible to law enforcement and health officers. The current *Health Drugs and Poisons Regulation 1996* provides that pseudoephedrine sales must be recorded by pharmacists on such a system. This system has been in place as a pilot in Queensland since 2005 and is an important tool to enable pharmacists to ensure customers or patients have a therapeutic need for S3 pseudoephedrine. This strategy is a key element in reducing domestic manufacture of methylamphetamine using pseudoephedrine in Australia and the public health harms associated with the unlawful manufacture and misuse of methylamphetamine (including ICE).
- The definition of 'criminal history' in the proposed Bill encompasses a wider range of information than currently defined in the *Health (Drugs and Poisons) Regulations 1996*. This would enable the chief executive to consider information not previously made available by the Commissioner of Police. There is also a new requirement on the Commissioner of Police to advise when a person's criminal history has changed. Such continuous monitoring of the criminal histories of persons of interest to Queensland Health cannot be done manually and will require the use of the QPS SCRAM computer system. This means that Queensland Health (QH) must be able to send electronic files in a suitable format to SCRAM with details of those persons and be able to update that 'list' with new persons and remove those persons whose licence, approval, or authority is no longer in force.
- It is noted the Bill does not make specific provision for information exchange between QPS and QH. PSP strongly supports minimising the legislative burden and reducing red tape. However, QH may wish to consider the need for information sharing provisions in the context of any potential conflict with s.159 'Confidentiality of information' of the Bill.
- A number of pieces of legislation are not listed in the consequential amendments that will be affected by the assent of the Bill, including:

  *Police Powers and Responsibilities Act 2000;*

  *Police Powers and Responsibilities Regulation 2012;*

  *Police Service Administration Act 1990;*

  *Drugs Misuse Act 1986; and*

  *Drugs Misuse Regulation 1987.*

Please liaise with Acting Senior Sergeant Scott Raven on telephone no. 3364 3934 in the first instance on each of the above issues.

**Contact officer to be included in the consultation addendum:**

| | | | |
|---|---|---|---|
| PSP contact officer: | Acting Senior Sergeant Scott Raven, Strategy Officer, Policy Branch, PSBA | | |
| | Ph: 3364 3934 | Email: Raven.ScottF@police.qld.gov.au | Submitted on: 18/09/2014 |

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: First Response Australia Pty Ltd [redacted]

Postcode: 4870

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Not known at this stage. Will see how the Act and regulations work in practice.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

No

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

No

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

As an Emergency Training and Response organsiation we have our internal Codes of Conduct and Professional Ethics that govern our service delivery, patient care and safety.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes, more than adequate

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

On my copy of the Background Paper, under Appendices

Appendix 1, Offences and penalty units, 250 penalty points for an individual equals $284,625. I take it that this is a mistake?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Not known at this stage. Will see how the Act and regulations work in practice.

11. Are the proposed licences, approvals and other authorisations appropriate?

Not known at this stage. Will see how the Act and regulations work in practice.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

In relation to granting of a Commercial Paramedic Licence or Approval, we think it is now appropriate for that approval to include other levels as well, below Advanced Care Paramedic. For example, if an organisation has a system of quality assurance in realtion to patient care, including a Medical Director, we see no reason that other levels of patient care cannot be included. We would like to see the levels of First Aider, First Responder and EMT included as well, below that of Advanced Care Paramedic, so that when we provide an onsite service at a large event, we can deliver a more effective service. Each of the levels would be able to administer a certain amount of medications up to their level of training. The Clinical Practice Guidelines (CPGs) would reflect how far the practitioner could proceed. For example, a First Aider would be able to administer the Methoxyflurane Inhaler for pain relief, once trained; and the next level up would be able to do a few more skills. The FRA EMTs have undergone considerable training and have some Advanced Skills and our Advanced Care Paramedics undertake treatment at a higher level again. What levels we send and how many, would be influenced by a site risk assessment.

The above proposed system would be strictly managed under our Clinical Governance Framework which includes oversight by a Medical Director; Medical Advisory Panel; Clinical Audit Framework; Clinical Audit Procedure; and comprehensive Clinical Practice Guidelines.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

N/A

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Not known at this stage. Will see how the Act and regulations work in practice.

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

We have always complied with the TGA in relation to the approval of new medical devices. It is to be seen whether the combination of the State and Federal Acts increases our administrative work and costs. if the aim of the new QLD Act is to reduce these, then a certain amount of autonomy by organsiations should be allowed within reason.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Not known at this stage as we are unsure what the combined Acts will impose on us over and above what we already comply with.

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

At First Rsponse Australia (FRA) we already have a comprehensive Scheduled Substance Management Plan. This includes the following: our Clinical Governance Framework which includes oversight by a Medical Director; Medical Advisory Panel; Clinical Audit Framework; Clinical Audit Procedure; and comprehensive Clinical Practice Guidelines (CPGs). Also it includes the secure storage, purchasing, allocation, checking, restocking and administration of controlled medications under our CPGs. Our Management Plan also includes our quality assurance system as a Registered Training Organisation (RTO) which also addresses Workplace Health and Safety; including public safety, risk assessment and risk management.

There is no need for FRA to write a separate Management Plan because it is already very comprehensive and is reviewd regularly under Continuous Quality Improvement, including regular meetings of our Medical Advisory Panel which includes our Medical Director (Emergency Physician).

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

We envisage that our current system is more than adequate and is already under a Continuous Quality Assurance System

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

We already have this in place

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Any auditing needs to be done by regular professionals who are fair and reasonable, taking into account existing organisational systems.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Not known at this stage.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

FRA would like to see standards and regulations that reflect the intent of our views mentioned above; including those of points 12 and 18

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

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## Personal details:

Given name: Peter

Surname: Dyer

Organisation and/or Professional position: SCPHU

Postcode: 4558

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☒ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☐ Yes, keep me informed by email: _____

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Missing a primary objective - should be: To protect the health of the Queensland public. S4 does really pick up the criminal, illicit, deliberate acts involving scheduled substances. This Bill should promote an objective which is in place to prevent the above illegal acts. The current objectives promote the safe clinical apsects which is fine but no mention of an object to prevent delibertae illicit misuse etc.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

It will interesting to see how industry responds to the requirment for Schedued substance management plans. Yes I acknowledge similar accreditation requirments may assist in negating duplication but from a complaince aspect PHU inspectors visit premises which may already have accreditation plans/requirments already but are still found to be non compliant. An accrediatation document an accrediation body is only effective if monitoring is undertaken from an operational perpective of what is occuring on site at a premises and not just doing a desk top review or on site desk top document review of flicking and ticking check squares. We do not want dust collecting plans that are completed by paid consultants and then placed on a top shelf by an entity and not understood or complied with in terms of operational activities. Required documents in other areas of public health program areas invariable leads to contracted consulatnts at "interesting costs" Are third party auditors going to be involved - if so how is non complaince going to be addressed and whom by and whom will ensure 'independence".

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

See above

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

I have quickly gone trhu the BIll nad now working thru these questions and checking where time permits on specific sections of the bill - Is there a provision to allow an offence for attempting to commit an offence against the Act or Regulation - could be very useful.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

I couldn't enter data into Q6 below so here it is. Schedule substance defns S10-13 are excellent - well done

Does S15 (1) (a) allow for a possession offence against importers of substances, advertising of substances when the offending party (1st person) ie via internet etc may never take physical possession of the substance ie it is intercepted by Aust Customs or the substance goes straight from an overseas, interstate (2nd party) entity to the buyers (third party) address via mail and logistics companies. Can a possession charge be laid against the 1st party if they are advertising drugs or obtaining drugs and those drugs are stopped at the airport. Section 24 I see may pick this up but confirm please

Check S16(3) defn exemption to see if it actually does exempt self administartion as the instruction defn has linkage to administration and supply from one person to another not self administraion of your own prescribed medicine. I agree with intent but don't know if it is captured well.

Supply defn icks up sell but does defn of sell pick up giving away for free ie must not be limited to money. Previous offenders have often attempted to circumvent law by stating I will give it away for free.

Does the administer defn pick up apllication of topical medications ie other than entry into the body

Defn of instruction is linked to stated medicine to a stated person - is this limiting standing orders and flexibility where multiple persons may receive a varity of treatment regimens dependant on conditions and emergency.

Place defn - any issues with planes and vessels (they have drugs on board for passengers etc) slipping out of the defn -

Authorised way - want to make sure offending health professionals are covered by a breach for say having drugs etc at home ie contray to professional scope of practice issues.

S24 - Do we have a problem if a person is found with hundreds / thousands of S2, S3 and or S9 substances in their possession - do we leave them with the person particulalry if we cannot prove supply?

Are S9 prohibited substances missed in S25 and S26

S30 seems cumbersome

Does S28 pick up the dog baiting issues, ie it seems to pick up when an animal is baited but not if persons are found to be placing baits in certain areas to kill dogs ie illgeal baiting Does a S15(b) possess charge pick it up

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Possibly not obtaining offences but at initial consideration they seem to meet other major matters

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

yes for the majority - check to confirm if a licensee start to undertake criminal offences ie say selling substances illicilty is there appropriate fines or is it only a S98 offence over failure to comply with a plan.

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

How will issues of drugs going missing in transport be addressed. Do transport companies have exemptions? Can the loss of drug from a drug manufacturer / wholesaler etc via transport to a pharmacy be an offence against the licensee.

Are whole sale reps going to require general approvals

Will the Act cater for the endless problem of wholesale rep drug samples ending up with unauthorised possion by storage shed managers.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

S20 seems okay

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

S72 (1) wording isnt easy to read. There has been in the past criminal use of the drug licensing regimen ie I recall a person with a drug wholesaler licence carrying out sales of steroids and facing minimal fines when discovered. ie it was worthwhile until caught to commit offences as the profits were vastly more than the fines. This is also covered in are the fines appropriate in question 9 above.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Minimal, Sorry I thought S7 poions manufacturers are already licenced and stock feed manufacturesr could have probable commonwealth or other state accredidation / licenicng

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Are sole traders in Qld now picked up by Commonwealth law ie does an indiviual not a company only carrying out activites within Qld picked up by the new Bill ie Health regulation matters

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

If outside consultants are brought in for ease of production of plans then it is highly likely users of the plans will not fully uunderstand and may in fact place away as dust collectors and simply obtain to mee the requirments of this Bill.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Will depend on what frequency does the DG of DoH require monitoring. And what will occur when non complainces are idnetified. Who will enforce? Will there be enforcement? Who will receive third party audit reports and risk assess for what level of enforcment if non complainces identified. Will a third party just audit against the plan / processes or in fact undertake count drug stocks and get down to specific checks. Will there be conflicts of interest. If I were to choose pharmacies it is very common for non complainces to be identiifed. How will these be actioned. Will PHU Inspectors be required to enforce non complainces, will non complainces be actioned? will check audits of third part auditors be required to be udnertaken.

If consideration is given to some of the already in place Commonwealth or accrediation schemes in place already then this would suggest DoH is going to have a large problem as non compliances are often identified within accredited entities that would have received visits from "third party" persons. Will inspectors of PHUs takle action against the entity for non complaince and action against the third party auditor.

If third party auditors are implemented then there will need to be offences put in place for if those persons are not seen to be moniotirng and promoting compliance.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Inspectors of PHUs should be undertaking yearly audits. Existing schemes are often coming from a different angle of intent..

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

Department of Health

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: Sole Trader : Dr Veras Formulations

Postcode: 4009

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☒ Industry - therapeutic goods
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Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

See response to questions 15,16,17

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

See response to questions 15,16,17

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

See response to questions 15,16,17 ..... please see responses to questions 15,16,17 as my response to question 6

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

See response to questions 15,16,17

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

SOLE TRADER COMPLEMENTARY MEDICINES

- Queensland is in a unique position of having Sole Trader Complementary Medicines available under the guidance of Queensland Health and not the TGA

- Through Sole Trader products, Queensland has access to a number of ingredients / nutrients that are unavailable through TGA listing and this offers Queenslanders true benefits : including access to nutrients that are proven world wide as safe and effective in patients care / employment in research & development, sales, marketing, technical support, manufacturing & packaging / creation of government income through taxation
Everyday, Sole Trader products that contain nutrients like 5 Hydroxytryptophan ( 5HTP ) , L Theanine and Nicotinamide Adenine Dinucieotide are dispensed to many patients by qualified Healthcare Practitioners to assist them with their healthcare conditions.

- Many products that are now "mainstream" complementary medicines, such as CoQ10, Lipoic Acid and Acetyl-L-Carnitine started their Australian lives as Sole Trader products. Over time due to their health properities and their safety, plus some lobbying, the TGA gazetted these nutrients for Listing.

- I agree that a reduction in red government tape and the aligning of state and federal regulations has its benefits and I fully support that all manufacturing of all Sole Trader Complementary Medicines can only be conducted in a TGA licensed facility and under all the manufacturing, sourcing and packaging regulations set by the TGA

RECOMMENDATION 1 : Sole Trader Complementary Medicines Exemption
- that Queensland Health offers an exemption for Sole Trader Complementary Medicines to maintain current business practices with the proviso that all Sole Trader Complementary Medicines are manufactured in a TGA licensed facility under the rules and regulations set by the TGA

RECOMMENDATION 2 : Sole Trader Complementary Medicines Governance
- that within the new Queensland Health Medicines, Poisons & Therapeutic Goods Bill that there is a separate section, clearly defined and entitled Sole Trader Complementary Medicines Governance
- within this section of the Bill, it will clearly articulate who in Queensland Health is responsible for Sole Trader brands, what is their authority and what are the conditions by which a Sole Trader can operate.
It should also clearly communicate the exemption that has been granted by Queensland Health and highlight any boundaries associated to the exemption

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

If Queensland Health fully adapts the TGA Act as law in Queensland, without an exemption for Sole Trader products, then my company Dr Veras Formulations would be forced to close as all the products formulas include nutrients that are not recognised by the TGA and therefore an Aust L listing is unavailable. It would then be illegal for any Dr Vera Formulations to be sold. This has a significant personal financial impact, but this decision has a far wider consequence :

- If products with ingredients / nutrients like 5HTP, L Theanine and Nicotinamide Adenine Dinucieotide were not available the negative effect on people's health and lives would be significant. Not just the patient, but their families, friends and colleagues will be negatively impacted.

- If Sole Trader products were not available patients and practitioners will simply go to the internet and buy overseas brands with similar formulations. These products are not listed with the Australian TGA and there is no knowledge of their manufacturing process and raw material sourcing. This adds risk to the user of the products. They will not go without, because they need these products to function.

- Innovation into the Australian market will be lost if Sole Trader products are not available. The Australian consumer should have access to the latest knowledge and most efficacious formulas available across the world

- Sole Trader brands employ Queenslanders across many functions : research and development, manufacturing, marketing, technical support and sales. Jobs will be lost if Sole Trader products are lost

- Sole Trader products add revenues and profits into companies and any lost of margin will see a reduction in human resource and marketing activities. This has a flow on effect through manufacturing, labels, packaging and printers just to name a few.
Also, taxation income will be reduced.

- The Queensland government would need to be able to explain to its people, why they have made a decision that negatively impacts the health of the sick, decreases jobs, increases unemployment and reduces taxation income

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

This is difficult to respond to as it is compliant on the TGA actions.

If Queensland Health adopted the TGA processes without any exemptions for Sole Traders and the TGA started to recognise a wider variety of nutrients then the process could be implemented quite quickly. Unfortunately, the TGA is not well known for its speed.

If no exemptions were available , then a transition period of no less than 36 months would be required to attempt to minimise the effect on patients health, peoples employment and loss of personal income.

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Would this be required in TGA became the law in Queensland ?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

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Regulatory Policy Unit

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Your comments may be moderated according to our acceptable use policy.

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# CONSULTATION FEEDBACK FROM MNPHU

## *Medicines, Poisons and Therapeutics Goods Bill 2014*

### GENERAL QUESTIONS

***1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?***

Objectives "a" - "c" and how they are proposed to be achieved are relevant to protecting and promoting public health. However, objective "d" "to minimise compliance costs for industry by—…" does not appear relevant to protecting and promoting public health.

Clause 146 should not exempt individuals and businesses (sole traders) operating within Queensland from TGA requirements.

***2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?***

This will be more identifiable on the release of the regulation and standards.

Proposed third party auditors will add to regulatory costs.

Yes. With the exception of individual businesses in Qld if not captured by TGA legislation including e.g. the manufacture and/or sale of products currently under Part 16 Therapeutic goods and other drugs of the Health Regulation 1996. This may result in an inconsistent regulatory burden on Qld businesses not under the TGA versus those that are. Businesses under TGA will generally have higher compliance costs.

***3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.***

Concern about the burden imposed each child care centre and school will be required to apply for authority and create and maintain a scheduled substance management plan.

Yes. To keep up to date with innovation and lessen regulatory burden organisations such as the Pharmacy Guild that have adopted consistent standards and practices should be supported, assessed and endorsed by the Chief Executive QH for the purposes of the Act e.g. computer programs relating to Controlled Drugs and other medicines and poisons records etc. Electronic alternatives to outdated "ink" signature requirements for medicines and poisons records such as Purchase Orders etc.

However, this question is difficult to answer definitively without perusal of the associated regulation, standards and guidelines that industry will be required to follow.

***4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?***

Please refer to table at the end of this document.

***5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?***

Yes, refer to item 1. Individuals and businesses not under TGA need to have legislative controls that mirror TGA to equitably and consistently protect public health and safety.

Clause 14 - What is a regulated activity states that "A person performs a regulated activity for a scheduled substance if the person does any of the following…" The gap is that if the substance

**CONSULTATION FEEDBACK FROM MNPHU**

*Medicines, Poisons and Therapeutics Goods Bill 2014*

is not SCHEDULED in the SUSMP such as many of the products under the Health Regulation 1996, Part 16 Therapeutic goods and other drugs not currently under TGA control it is not considered a "regulated activity" and the protection of public health will not be consistent with TGA. The definition of an "eligible person" is linked to a "regulated activity".

Does the legislation provide the ability to monitor obtaining of drugs of diversion, eg controlled drugs, pseudoephedrine obtained from intrestate wholesalers or is this something to be considered in the regulation?

The Bill does not provide for an offence for non-compliance with the Poisons Standard, even though all associated documents refer to the adoption of components of the standard not already referenced in Qld legislation. This would be considered an over-arching and non-specific offence and as such should be included in the Act, rather than any regulations, as is the case for the other similar broad offences.

In reference to Part 7 - Monitoring and enforcement and sections relating to functions and powers of authorised persons. It is noted that authorised persons will have powers as outlined under Chapter 9 of the Public Health Act. The current powers relating to 'Forfeiture of seized things' under the Public Health Act do not correlate to those outlined under the current Health Act 1937. A thing seized under the Health Act can be forfeited to the State if the inspector who seized the thing reasonably believes it is necessary to keep the thing to prevent it being used to commit an offence against a relevant provision. This provision enables the inspector to seize without having to proceed to prosecution. This provision is not captured under the forfeiture provisions in the Public Health Act when seizing a thing at a place that may be entered without consent or a warrant and does not give the authorised person the option to seize without prosecution. There maybe occasions when seizure of a thing from a person is enough of a deterrent and causes the person not to re-offend. The loss of income (for the offender) from the sale of a product that has been seized and the added burden of costs of a prosecution also needs to be taken into consideration. This provision should be included in the new bill when an authorised person acts under Section 403 of the Public Health Act 2005. Further, if a thing is seized under Section 403 of the Public Health Act (seizing without consent or a warrant), Section 414 - Return of seized things does not stipulate any parameters for the return of the seized thing to its owner.

Under Section 413 ( c) of the Public Health Act, there is reference to the term 'public health risk'. When examining the definition of 'public health risk' under Section 11 of the Public Health Act, it does not appear to capture a medicine or poison, unless a medicine or poison could be considered a 'substance' under 11 (xi) and would have to be prescribed under a regulation. This may need to be addressed to ensure a medicine or poison is included under these provisions.

Under Section 112 - Power of destruction of the Medicines Bill, it references a thing posing an immediate risk to the health or safety of a person or animal. There needs to be some clarity/defintion around what is considered an immediate risk to the health and safety of a person.

Section 108 - Power to Enter a Place of Business, currently excludes an authorised persons' powers to enter a premises to investigate alleged contraventions of the act by a person who does not have 'an authority' for medicines and poisons.

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

The solution is to consider amending section 108 to delete the mention of 'a person who holds an authority' and replace with 'a person who possesses, manufactures, supplies, administers or applies a medicine or poison' as shown below:

Section 108 - Power to Enter a Place of Business

In addition to the powers under the Public Health Act, section 385, an authorised person may also enter a place to perform a function under this Act if it is the place of business of a person who possesses, manufactures, supplies, administers or applies a medicine, poison or therapeutic good and the place is—

(a) open for carrying on the business; or

(b) otherwise open for entry; or

(c) required to be open for inspection under an authority.

Secondly, reference to the word 'obtain' is omitted from the new bill. If not addressed, this may have unintended consequences where persons who have an authority to possess and administer a medicine, such as nurses, may inadvertently receive the authority (or not be restricted) to 'obtain' schedule 8 medicines. This detail would normally be addressed in the regulation however there may be a need to reference to the word 'obtain' in the Bill.

***6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?***

The definition of wholesale does not appear to be provided in the Bill. Clause 41 refers to "supply the medicine or poison, primarily by wholesale." However, a further explanantion or definition does not appear to be provided. It would be prudent to consider what is intended to be captured under the definition of wholesale, eg whether a pharmacy supplying to a nursing home is considered to be a wholesale transanction.

Does the definition of wholesale now apply to pharmacies selling controlled and restricted drugs to doctors for their doctor's bags?

The definition of "manufacture" appears to capture dispensing by repacking into webster packs. Under the current HDPR, this is exempt from the definition of manufacture. Will this be managed under the new regulation or another way?

Could examples be provided of 'reasonable excuse' and define 'lawfully supplied'.

Acts Interpretation Act 1954 (Qld) "entity" includes a person and an unincorporated body.

A "regulated activity" should include the manufacture and/or sale of products currently under Part 16 Therapeutic goods and other drugs of the Health Regulation 1996. The definition of an "eligible person" is linked to a "regulated activity".

The Bill should provide a definition for “obtain” and “prescribe”.

Does the definition of possess now include obtain i.e. receives and takes custody of the substance?

The definitions provided in the Bill do not seem comprehensive in reference to terms used. For example 'eligible person' refers to 'registered health practitioners', however no definition is given for this and no reference is made to other pieces of legislation. There is also no definition provided for some terms used in the legislation i.e. 'entity', 'institution', 'facility'. It is understood 'entity' is used in the Bill as a generic term that can include individuals or a group of individuals and businesses that include those with a physical building or not. It is necessary to define (or

refer to other current legislation) the different businesses involved in scheduled substances so as to distinguish each type and provide clarity around the application or non-application of the proposed Act in certain circumstances i.e. a pharmacy, a nursing home, a support accommodation facility, a hospital, a business that sells poisons etc.

Does Clause 14 (f) in relation to the definition of a regulated activity include prescribe?

***7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?***

No comments.

**OFFENCES AND PENALTIES**

***8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?***

Should Clause 21 (Meaning of "authorised way" for pt 2) include reference to 20 re the meaning of "authority" so this is not ambiguous and similarly with authorised person in 22?

With regard to restrictions on Clause 27 will there be a provision to allow e.g. panadol to be administered in child care and school settings like s256A HDPR.

Clause 28 - also consider whether this is overly encompassing? A parent giving panadol to their child seems to be covered by 2b, but this relies on the general purchase of simple analgesics being 'lawfully supplied for the treatment or use' of that child. Also it appears a person is committing an offence if they give drugs intended for humans to animals? Is this warranted?

The Bill should fully adopt the SUSMP and have associated offence provisions for non compliance with the SUSMP.

The Bill does not make it an offence to possess a S3 medicine. However, S3 Pseudoephedrine is a substance subject to diversion. Hence, it is recommended consideration be given to making unauthorised possession of S3 Pseudoephedrine an offence.

No. Part Significant Offence provisions of the Bill primarily centre on "medicines" (clause 11) and "poisons" (clause 12) that are "scheduled substances" (clause 10). If the substance is not a "scheduled substance" it does not come under a "regulated activity" (clause 14) or a "schedule substance management plan" (clause 42). If an unscheduled therapeutic substance is not covered by the TGA (as with those therapeutics currently under Health Regulation 1996 - Part 16 Therapeutic goods and other drugs) what Qld offence provisions will apply should Qld decide to regulate under clause 146 of the Bill?

***9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?***

Existing Health Act/HDPR offences such as keeping medicines and poisons OUT OF REACH OF CHILDREN need to be referenced by virtue of SUSMP etc requirements.

The proposed penalties appear to be commensurate with the levels of potential harm associated with each offence.

Without knowledge of what is proposed in any associated Regulations; in relation to the offences for scheduled substance management plans it is unclear whether offences for various specific activities (storage, record keeping, self-prescribing etc) will be dealt with individually (and penalties provided for each) or whether it is proposed that these offences will be dealt with

as a generic offence for not complying with a scheduled substance management plan. If the latter is the case, there will be great difficulty in distinguishing between numerous systematic breaches or single administrative-type breaches by entities and providing for parity in how legal action may be taken in response each.

**LICENCES, APPROVALS AND OTHER AUTHORISATIONS**

***10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?***

Overall. However, clause 100 refers to the requirement for a Commonwealth scheme manufacturer to notify the CE and include the prescribed fee by regulation. If the objective is to reduce compliance costs, then attaching a prescribed fee for notifying the CE would appear contrary to this objective.

***11. Are the proposed licences, approvals and other authorisations appropriate?***

In general, yes. However, it is not clear what advantage is gained by changing retail licenses, ie. "C" and "K" licenses to general approvals.

***12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?***

Yes.

***13. In your view are the provisions in the draft Bill for criminal history checking and recall powers, appropriate?***

Yes.

***14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?***

Unless it is envisaged that the new legislation will be vastly different or more prescriptive than the current legislation, compliance with the new legislation should be sooner, rather than later, for matters other than the development of scheduled substance management plans.

This will be more identifiable on the release of the regulation.

**THERAPEUTIC GOODS ACT 1989 (COMMONWEALTH)**

***15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?***

Regulatory burden needs to be consistent between businesses whether they are an individual, sole trader or a corporation or selling within Qld or outside the state. It cannot be assumed that a corporation will have higher income than an individual or sole trader selling only in QLD.

***16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?***

No comments.

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

***17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?***

No comments.

**SCHEDULED SUBSTANCE MANAGEMENT PLANS**

***18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?***

Would we be required to have a scheduled substance management plan as we keep vaccines on site? We have state-wide vaccine management guidelines that we work to and our health management plan would cover some of the likely requirements. All the areas likely to be required in a scheduled substance management plan do not currently exist in any of our documentation as far as I am aware.

Section 93 (3)(c) refers to signing a plan and states an individual is to sign it if the 'entity' the plan applies to is an individual, and if they are a body corporate then referencing back to another section they refer to the individual responsible for the plan. The use of body corporate is not used anywhere else in the legislation and is a sub-category of a 'corporation' as provided in the Acts Interpretation Act. An issue I could see is if a person does not identify with either of these two definitions (individual or body corporate) there could possibly be some confusion about who should sign the plan.

***19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?***

Staff time and potential consultancy costs would be the expense and resulting loss of opportunity costs.

***20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?***

A transitional period for development of these plans will need to consider the number and nature of persons/businesses impacted as this level of detail does not appear to be provided in any documents.

Perhaps 6-12 Months, depending on the prescribed activity undertaken might be considered reasonable.

**MONITORING AND ENFORCEMENT**

***21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?***

There is no detail provided in the proposed Bill or associated documentation in relation to the scope, application or use of third party auditors for medicines, poisons and therapeutic goods legislation, therefore it is difficult to provide detailed comments on this activity as it relates to the proposed regulatory framework.

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

Besides the manufacturing of medicines, poisons and therapeutic goods, the operations involved in other businesses (Hospitals, retailers, small practices etc) are usually not as black and white in their detail of the systems involved in the management of medicines, poisons and therapeutic goods. For some businesses, dealing with scheduled substances is an ancillary practice associated with the running of their business. Given that these businesses involvement with scheduled substances is quite simple and straight forward, any system that is introduced to review and audit systems would likely be over the top and unnecessary. The introduction of third party auditors would add an increased regulatory burden on businesses as well as an additional economic burden.

Medicines, poisons and therapeutic goods use in Queensland relies largely on the quality/safety of these products. Other major issues related to these substances involve the diversion of certain substances into illegal markets and the appropriate prescribing and use of substances in the community. With controls in place to address manufacturing, the remainder of controls will relate to having legislation in place to deal with the latter two concerns. By looking into the introduction of a system that relies on documenting and auditing a system that has a tangible outcome (i.e. manufacturing of quality medicines) and trying to make it fit a system that does not have easily measured outcomes, or readily identifiable systems that lead to an outcome (diversion of medicines, prescribing practices etc), it is not appreciating that third party auditor schemes are not a one-size-fits all approach.

If third party auditors were introduced for manufacturers it could be similar to (or possibly make use of) the current system in place for the TGA.

The third party auditor system can create issues as described in a recent study[1]:

- Moving regulatory models to involve third party auditors (aka private industry, which is driven by dollars) can lead to the quoting of unrealistic prices by auditors keen to obtain work, which in turn leads to poor quality of work leading to the removal of robustness in the system and a poor level of compliance monitoring that is not readily identified.
- Once an auditor has gained work with a business, it is in their best interest (to keep the work) to provide a favourable report. This has the potential to lead to corruption and collusion amongst businesses and auditors. The only way to ensure this does not occur is to introduce a level of regulation around this system that involves resources from the regulator that could possibly be better used addressing the original issue of compliance by those businesses.
- Third party auditors are introducing a level of activity into a regulatory model that someone must pay for, and in many cases this is a cost burden that is worn by the business.

In the associated document provided, it was suggested that functions of an auditor could be to advise licensees, approval holders and eligible persons about what they may need to do to ensure compliance with the requirements of the legislation. Given the major groups of professionals (pharmacists, nurses etc) involved in the use of medicines, poisons and therapeutic goods there are already well established representative bodies that could, and currently do, provide this service. There is also the option to engage a private consultant with expertise in this area (which has little to do with development of a regulatory framework).
If the role of a third party auditor is to carry out this function, that essentially is a consultancy-type function, then there would be a conflict of interest in then providing an independent third party auditor role. If this role is undertaken by two different auditors then the cost to business is increasing again.

Appointing third party auditors would appear to provide an additional compliance cost to industry as they would charge a fee for their service. Currently, all monitoring and advice around

[1] Truth Telling by Third Party Auditors: Evidence from a Randomised Field Experiment in India (Esther Duflo, Michael Geenstone, Rohini Pande and Nicholas Ryan (March 2, 2012)

compliance to industry is provided free-of-charge by Inspectors/authorised persons under the Health Act and by Officers of the Department of Health. Hence, introducing third party auditors would increase compliance costs, which is contrary to one of the objectives of the Bill.

***22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?***

The legislation as it currently stands is not contemporary so as to easily recognise and allow for changes in business practices that have occurred since the legislation was introduced. This is particularly of note in relation to record keeping, storage requirements and the modernisation of some administrative practices e.g. electronic transactions and signatures.

**STANDARDS AND REGULATIONS**

***23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.***

Please see attached table of highlighted issues that should be addressed.

The current HDPR regulation has a number of requirements pertaining to record keeping for controlled drugs. It is noted under the new bill that a management plan will be required to be kept by entities for regulated activities. It is not clear whether there will be further details included in a regulation or relevant standards/guidelines in relation to recording transactions relating to controlled drugs or is this something that will just be addressed in an entity's management plan?

Under Chapter 2, Part 2, Division 1 of HDPR 1996 a Veterinary Nurse does not have any endorsements pertaining to controlled drugs. It is recommended that consideration be given to including endorsements for Veterinary Nurses (who have completed a certified course of training relating to the use of controlled drugs with animals) to be in possession of and administer controlled drugs under the direct supervision of a Veterinary Surgeon. This could be captured in the regulation. Details would also need to be included as to what constitutes a certified course of training.

To keep up to date with innovation and lessen regulatory burden organisations such as the Pharmacy Guild that have adopted consistent standards and practices should be supported, assessed and endorsed by the Chief Executive QH for the purposes of the Act e.g. computer programs relating to Controlled Drugs and other medicines and poisons records etc. Standards set by industry organisations and endorsed/approved by QH will help promote a contemporary regulatory regime approved and adopted statewide in pace with technology and innovation. This will help address outdated regulatory requirements in a more timely manner to reduce regulatory burden e.g. allowing electronic alternatives to outdated "ink" signature requirements for medicines and poisons records such as Purchase Orders etc. It is unclear whether provisions in relation to this will be covered under a management plan.

Legislative inconsistencies not necessarily based on risks to public health should be addressed e.g. the current HDPR requires locked storage of S7 poison by retail (K licence under s284 (3) HDPR) whilst the same S7 product under a Wholesaler Licence (G Licence) requires “inaccessible to the public” storage only (s284 (5) HDPR).

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

### Table - Highlighted Issues - For Consideration in the Making of Regulations

| Issue | Comment |
|---|---|
| Discrepancies | What are requirements for reporting and management of this issue? |
| QOTP | Will requirements for these programs rely on current clinical guidelines or newly developed standards etc? |
| Prescription details | * Requirements for scripts, what will they be i.e. who can prescribe what, hand written components of S8 scripts, expiry dates, interstate scripts recognition.<br>* Is there a requirement under National Health legislation that could be referred? |
| Self-prescribing | Is this to be addressed in the Regulation, in particular in relation to health practitioners that have authority to write scripts? |
| Self-administration | * Particularly in relation to health practitioners self-administering substances they have restricted access to i.e. a doctor using morphine from his doctor's bag?<br>* s30 of Bill addresses self-administering animal meds |
| Storage | * S4's & S8's as well as imprest v dispensed of these medicines in certain facilities.<br>* S2 & S3 substances addressed in SUSMP (Clause 43 & 44) - will this clause be adopted in the new legislation? |
| Labelling | Provided for in SUSMP (Part 2) General and Dispensed Meds (Appendix L) - will these sections be adopted in the new legislation? |
| Camphor/Naphthalene | Exemptions provided in SUSMP (Clause 17) - will this clause be adopted in the new legislation? |
| Record keeping | Requirements for record keeping for various scheduled substances, in particular S8 substances and means of recording i.e. bound & sequentially numbered books, electronic means of recording etc |
| Ship's master | How will this requirement be acknowledged and addressed in new legislation? |
| Clinical trials | Will there be storage/record keeping exemptions for CTX/CTN trials, as well as those that require HREC approval but do not fit into these two categories? |
| Responsible person | How will certain issues be addressed in facilities where the responsible person is not clearly defined i.e. issues with a safe in a pharmacy where the pharmacist on at the time is a locum and not responsible for the safe mounting etc |
| Dispensed meds | How will management of these be addressed in terms of possession, supply (carers) & use i.e. dispensed meds being distinguished from imprest stock in facilities and subsequent |

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

| Issue | Comment |
|---|---|
| | controls around each being appropriate |
| Imprest Stock | Will these be recognised in legislation (and definition provided), specifically in relation to 'starter packs' that nursing homes quite often keep |
| Scheduled substance management plan | Bill currently applies requirement to ALL scheduled substances. Clause 94 is written this way with exemptions only being provided for in Regulation - who is it proposed will be exempt from keeping these plans and will it be inclusive or exclusive? |
| S3 meds | Warnings in relation to sale, establishment of therapeutic need requirements to supply etc. Provided in SUSMP (Clause 37). Will this clause be adopted in the new legislation? |
| Restrictions on certain professions | i.e. Vets, dentists, podiatrists and restrictions around certain types of scheduled substances and regulated activities they can perform. |
| Expiration dates of medicines | Restrictions on sale and use of expired scheduled substances? |
| Authorities in certain facilities | Nursing homes for example and who can obtain etc i.e. Med Super, DON etc |
| Emergency supply | Provisions in Poisons Standard for S4's only (clause 39). Will this clause be adopted in the new legislation? |
| Emergency situations | Public health emergency powers in relation to disposal or dealing with scheduled substances. |
| Oral prescription | Will these be allowed, what will the requirements and rules be around this practice? |
| Strychnine & Cyanide | Provided in SUSMP (Clause 41), also includes Arsenic, 1080 etc. Will this clause be adopted in the new legislation and how will the 'authorities' referred to be managed? |
| Purchase orders | What will the requirements be for these and will this process recognise use of electronic medium for transactions? |
| Transport, couriers | Allow for exemptions for possession under certain circumstances. |
| Disposal/destruction | Restrictions on who, how and under what circumstances. |
| Display of certain meds | Out of reach of children - not addressed. |
| Containers | Provided in SUSMP (Clause 20). Will this clause be adopted in the new legislation? |
| Details to be forwarded to CE | Will there be requirements for certain records for certain substances i.e. S8's etc to be sent to CE for monitoring? |

## CONSULTATION FEEDBACK FROM MNPHU

*Medicines, Poisons and Therapeutics Goods Bill 2014*

| Issue | Comment |
|---|---|
| | |
| Use of electronic medium for records | In pharmacies, nursing home etc |
| Stock checks by locum pharmacist | Will there be a requirement for stock checks for persons taking over management of an entity i.e. locum pharmacists and S8's |
| Keeping records | Requirements on length of time records are to be kept. |
| Advertising medicines | Provided for in SUSMP (clause 32). Will this clause be adopted in the new legislation or will the Price Information Code of Practice be adopted as in the current HDPR? |

**Medicines, Poisons and Therapeutic Goods Bill 2014**
http://www.getinvolved.qld.gov.au/gi/consultation/2122/view.html

**Discussion Paper Feedback**

**Title of Submission:** *Medicines, Poisons and Therapeutic Goods Bill 2014*

The Department of Education, Training and Employment (DETE) supports the submission with no changes but notes the following:

*Licences, approvals and other authorisations*

- DETE is not aware of any incidents in the early childhood or state schooling sectors under the current regulatory framework that would suggest the need for greater regulation of the sectors with respect to possessing and administering scheduled substances.
- DETE will need to work closely with Queensland Health to ensure that schools can continue to purchase and administer routine and emergency medications including adrenaline auto-injectors for anaphylaxis and medications for asthma.
- As details of the new regime are yet to be developed in regulation, it is difficult to ascertain the level of impact at this time.
- It is proposed, through regulation, to authorise staff of entities such as education and care service providers and schools as eligible persons to perform regulated activities to the extent necessary to carry out their functions. This includes, for example, administering certain medicines.
- Under the current legislation, education and care services already hold an endorsement and are authorised to administer S2 or S3 medicines to a child with the written consent of a parent or guardian.
- It is understood that existing authorities made under the *Health (Drugs and Poisons) Regulation 1996*, specifically to obtain, possess and administer S3 adrenaline auto-injectors for anaphylaxis emergency response, will be maintained for a "transition period". Following this transition period, authorisation to education and care services and schools would need to be reissued by Queensland Health.
- Currently, **without specific approval**, schools are able to purchase S3 salbutamol (Ventolin) or S3 terbutaline (Bricanyl) for the purpose of administering emergency medication for the treatment of asthma. Under the *Medicines, Poisons and Therapeutic Goods Bill 2014* (the Bill), schools would be required to have an approval and develop a Scheduled Substance Management Plan (SSMP) to purchase these medications.
- The proposed alterations to the licence and approval process to purchase and administer these medications will require sufficient transition periods to ensure no interruption to education and care service providers and schools' ability to maintain and administer routine medication and emergency first aid supplies.

*SSMPs and Standards*

- The proposed requirement in the Bill for a SSMP specific to the needs of each service could place significant additional burden on education and care service providers and schools in terms of cost (depending on the prescribed fee), administration and regulation.
- The Bill provides for detail of the new regime, as it relates to DETE interests, to be prescribed in regulations, including relevant standards which entities must comply with.
- Under existing policy, including the Administration of Medications in Schools and Management of Students with Specialised Health Needs procedure, state schools have requirements for the safe storage, disposal and possession of medicines and poisons. It is understood that existing requirements and risk management processes may satisfy the need for schools to develop a SSMP.

*Further consultation*

- DETE requests further opportunities to provide input into the Bill's supporting regulation including:
  - the requirements for SSMPs; and
  - the level of specificity required for nominated contact persons under each SSMP in light of the turnover and movement of staff in the school environment.
- DETE also recommends a fact sheet specific for state and non-state schools be developed explaining the potential impact of the Bill, particularly the licence, approval and authorisations process. The existing information sheets for 'Educational and Childcare Services' and 'Entities' are unclear as to their application in a school environment.
- DETE can work with officers from Queensland Health to consult with key stakeholders (particularly in the early childhood and care sector) and help to ensure education and care service providers and schools are aware of any revised obligations under the Bill.

## Name of contact officers to be included in the consultation addendum:

**Name:** Louise Pellow
**Title:** Principal Advisor, State Schools - Operations
**Phone:** 3513 5957

**Name:** Carolyn Hildebrand
**Title:** Director, Monitoring and Compliance
Regulation Assessment and Service Quality and Early Childhood Education and Care
**Phone:** 3328 6798

**Name:** Christine Loos
**Title:** A/Director, Organisational Health
**Phone:** 3513 6564

**Name:** Catherine McTavish
**Title:** Principal Advisor, Office of Non-State Education
**Phone:** 3513 6744

**Name:** Kirsten Law
**Title:** Senior Advisor, Portfolio Services and External Relations
**Phone:** 3513 6768

**Date:** 29 September 2014
**Trim Ref:** 14/324483

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name:

Surname:

Organisation and/or Professional position: Sage Centred Natural Therapies Clinic

Postcode: 4518

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email:

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Mostly

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Unsure

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Only insofar as it applies to Natural Therapies use Herbs and Nutrients used in Supplments

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

Ensure that the person who is prescribing use of these products is trained appropriately with ongoing training to keep them up to date.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Unsure

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

My professional body insists we conduct a thorough case history including the current use of medicines and ensure that we check all possible contra-indications wtih these and the supplements or herbal mixtures we prescribe. This is part of code of practice to ensure that the person's optimal health and wellbeing is always paramount.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Unsure

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Unsure

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Unsure

11. Are the proposed licences, approvals and other authorisations appropriate?

Unsure

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Unsure

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Unsure

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

36 Months

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

SOLE TRADER COMPLEMENTARY MEDICINES

Queensland is in a unique position of having Sole Trader Complementary Medicines available under the guidance of Queensland Health and NOT the TGA.

Through Sole Trader products, Queensland has access to a number of ingredients / nutrients that are unavailable through TGA listing and this offers Queenslanders true benefits: including access to nutrients that are proven world wide as safe and effective in patients care / employment in research and development, sales, marketing, technical support, manufacturing & packaging / creation of Government income through taxation.

Everyday, Sole Trader products that contain nutrients like 5-Hydroxytryptophan (HTP), L-Theanine and Nicotinamided Adenine Dinucleotide are dispensed to many patients by qualified Healthcare Practioners to assist them with their healthcare conditions.

Many products that are now "mainstream" complementary medicines, such as CoQ10, Lipoic Acid and Acetyl-L-Carnitine started their Australian Lives as Sole Trader Products. Over time due to their health properties and their safety, plus some lobbying, the TGA gazetted these nutrients for Listing.

I agree that a reduction in Government Red Tape and the aligning of State with Federal Regulations has its benefits and I fully support that all manufacturing of all Sole Trader Complementary Medicines can only be conducted in a TGA licenced facility and under all the manufacturing, sourcing and packaging regulations as set by the TGA.

RECOMMENDATION 1: Sole Trader Complementary Medicines Exemption: That Queensland Health offers an exemption for Sole Trader Complementary Medicines are to maintain their current business practices with the priviso that all Sole Trader Complementary Medicines are manufactured in a TGA licenced facility under the rules and regulations as set by the TGA.

RECOMMENDATION 2: Sole Trader Complementary Medicines Governance: That within the new Queensland Health Medicines, Poisons & Therapeutic Goods Bill that there is a speparate section, clearly defined and entitled Sole Trader Complementary Medicines Governance: within this secion of the Bill, it will clearly articulate who in Queensland Health is responsible for Sole Trader Brands, what their authority is and under what conditions by which a Sole Trader can operate.

It should also clearly communicate the exemption that has been granted by Queensland Health and highlight any boundaries associated to the exemption.

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

If Queensland Health fully adopts the TGA Act as law in Queensland, without the exemption for Sole Trader products, then my business would be seriously affected, as would the health of my clients/patients, already I find my clients sourcing their supplments from overseas companies - companies offering products with ingredients that are not regulated in either their source or manufacture. Products with ingredients / nutrients such as 5HTP, L Theanine and Nicotinamide Adenine Dinucleotide were not available, this would only encourage these people to purchase even more unregulated products from overseas companies, usually via the internet or from overseas network marketing companies. These companies are not listed with the Australia TGA and there is no knowledge of their manufacturing processes and raw material sourcing. This adds risk to the end user of the products. These people will not go without as they feel better and function better with these nutrients (as well as others that they purchase on-line but are unavailable here in Australia).

Innovation into the Australian market will be lost if Sole Trader Products are not available. The Australian consumer has the right to access to the latest knowledge and most efficious formulas available across the world.

By losing these Sole Trader products, we are actually putting the public at risk, as they will not search out any drug / herb / nutrient interactions, thier neigbour or friend uses it so I will too. The TGA would be more effectual in baning the imports from overseas of these overseas nutrients instead of restricting their manufacture here in Queensland.

Sole Trader brands employ Queenslanders across many functions: research and development, manufacturing, marketing, technical support, and sales. Jobs will be lost if Sole Trader products are lost, as well as the flow on effects into other areas that are involved in these processes. Ultimately taxation revenue will be reduced from a wide range of sources.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

At least 36 months if this was to go ahead.

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Does not apply to me

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

This is just one more 'nail in the coffin' to me as a Naturopath as little by little my rights are being eroded, and as I said, the clients instead simply find other ways to source their products. Ultimately, I will not be able to do my job and will end up with the rest of the unemployed, before I have an opportunity to make the cost of my university degree in Health Science (Complementary Medicine) a total waste of my time and money.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Unsure

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Yes, by all means, but at least be reasonable about the behaviour; not simply turn up unannounced like the mafia - while working with a client.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Unsure but would like to see restrictions on what comes in from overseas.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

Irrespective of whether it is the manufacturer or the person who ultimately sells the product, there is a duty of care to the consumer of the product. So all care needs to be taken to give the best possible product, have it stored and delivered in a safe manner, as well as provide appropriate instructions to the end users. For example, when to consume the product, what possible consequences could be, what drug / herb / nutrient interaction may occur and so on - this cannot take place when a product is ordered online.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: 360 degree wellness - [redacted]

Postcode: 2040

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

No

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

NO

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Yes

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

yes, the right of individuals to seek health providing nutrients to enable a better quality of life

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

No

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Queensland is in the unique position of haning sole trader Comlementary medicines available under the guidance of Queensland Health and not the TGA

Through sole trader products, queensland has access to a number of ingredients/nutrients that are unavailbel through TGA listing and this offers Queenslanders true benefits: including access to nutrients that are proven world wide as safe and effective in patient care/employment in research/development, Sales, marketing, technical support, manufacture and packaging/ creation of government income through taxation.

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

If products with ingredients /nutrients like 5HTp, L Theanine and nicotinamide adenine were not available the negative impact on people's health would be significant.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

**From:** Jennifer Gamble
**Sent:** Tuesday, 30 September 2014 9:19 PM
**To:** Hazel Brittain; Cathie Nesvadba
**Cc:** Sarah Stewart; Mary Sidebotham
**Subject:** Re: Consultation on New Medicines, Poisons and Therapeutic Goods Bill

Dear Cathie

From Dr Kirsten Small on behalf of ACM Q

Take home message

"1. That midwives should have access to the full list of drugs available in Australia, within their scope of practice as defined by current industry standards, rather than having a restricted list of drugs. No one can predict what women will need so the list will always be inadequate to meet women's needs.

2. That registered midwives who have completed an ANMAC accredited training course should be legally able to prescribe in Qld, both in the community and in hospital, regardless of whether they are Medicare eligible and working in private practice or not. "

Further detail from Dr Kirsten Small,

"My reading of this is that rather than listing separate types of health care providers as was the case in the previous Act - this lumps every health care provider who is registered with AHPRA together as 'eligible' persons who may perform a regulated activity which is defined as -

(a) possesses the substance;

(b) manufactures the substance;

(c) supplies the substance;

(d) administers the substance;

(e) applies the substance;

(f) gives a lawful direction to, authorises or asks another person to supply or administer the substance.

It looks like there will be a set of standards developed independently of the Act, but which must be complied with, that will be developed by the DoH and in some cases they may adopt existing standards to determine what activities specific health care providers are able to perform.

The devil will be in the detail of these standards which are not outlined in the draft Act. Who knows! It might open up midwifery prescribing to all midwives, or we may end up with a drug formulary like Vic or WA that have the potential to get in the way of good practice. We'd need to get lobbying so that we don't end up with something disastrous."

Regards J

Secretary - ACM Q

**Professor Jenny Gamble**
**Acting Head, School of Nursing and Midwifery**
Professor of Midwifery, Maternity and Family Unit
Centre for Health Practice Innovation | Griffith Health Institute
School of Nursing and Midwifery | Griffith University
Ph: +61 7 338 21083 | M:
Email:

Address: Office 3.29 - Academic 1 (LO5), University Drive, Meadowbrook. QLD. Australia. 4131
Executive Support Officer: Sue Gibbons | Ph: +61 7 555 28733 |
Email:

Griffith University Midwifery Facebook - Midwifery@Griffith

On 30 September 2014 21:02, < > wrote:
Thanks Sarah, Kirsten Small looked at it for us. Haze

Sent from my BlackBerry 10 smartphone.

## Julie Stokes

**From:** Magistrate RyanT <[redacted]
**Sent:** Thursday, 2 October 2014 9:59 AM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** Medicines, Poisons and Therapeutic Goods Bill
**Attachments:** NCIS Fact sheet_Opioid Related Deaths in Australia 2007-2009_Update August 2014.pdf

Dear Dr Stokes

Thank you for the opportunity to review the draft Medicines, Poisons and Therapeutic Goods Bill.

I have reviewed the clauses relating to confidentiality and information sharing and appreciate the inclusion of an express provision enabling confidential information to be shared with a coroner or the Health Ombudsman.

As the attached fact sheet demonstrates, coroners have seen a significant increase in the number of deaths resulting from multiple drug toxicity in recent years. These are mostly unintentional and often involve opioids such as Fentanyl and Oxycodone in combination with alcohol and benzodiazepines. The capacity to monitor prescription patterns and share this information with the Health Ombudsman and coroners will assist in the timely investigation of these deaths and early intervention where inappropriate prescribing has been identified.

Regards

Terry Ryan
State Coroner
Ph: (07) 3898 0360
Mob[redacted]
Fax:(07) 310 99617

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**From:** Medicine Poisons and Therapeutic goods Bill [mailto:mptg.bill@health.qld.gov.au]
**Sent:** Wednesday, 1 October 2014 1:43 PM
**To:** Coroner State
**Subject:** Attention Stephen - new Medicines, Poisons and Therapeutic Goods Bill

Hi Stephen,

Here is the email that was sent to the State Coroner. The links to the Bill and the documents can be found via the Get involved website, but I have attached key documents here.

Apart from the features of the model (how to be authorised to do things with medicines and poisons and in what circumstances, standards and management plans) I would like to draw attention to sections 158-161 about confidentiality and information sharing, where we have tried to be clear about releasing of information to the health ombudsman.

Thank you for bringing this matter to the attention of John Lock. We would be grateful for a response by 10am tomorrow if at all possible.

Kind regards
Julie

**Dr Julie Stokes**
Consultant Pharmacist

Medicines Regulation & Quality | Chief Health Officer Branch | Health Services and Clinical Innovation Division
Department of Health | Queensland Government
Locked Bag 21 Fortitude Valley BC QLD 4006
t. 07 3328 9225
e. julie.stokes@health.qld.gov.au | www.health.qld.gov.au


## New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

The Department of Health has released a draft of the proposed new Medicines Poisons and Therapeutic Goods Bill intended to provide a modern framework to regulate how medicines and poisons are used in our community.

You are receiving this email as a stakeholder in the regulation of medicines and poisons.

As you or members of your organisation deal with medicines or poisons that are currently regulated under the Health (Drugs and Poisons) Regulation 1996, we would like to know how the proposed new Act may affect you or members of your organisation.

The draft of the Bill and consultation questions can be found at:

- Get Involved
  or
- a copy can be provided on request by contacting the Department of Health via email at legislation@health.qld.gov.au or by phone on 07 3234 1793

**How to provide feedback**
The consultation questions ask for feedback about some specific aspects of the proposed regulatory scheme as well as the Bill itself. You can respond to the consultation questions by:

- using the online survey at Get Involved
- downloading the consultation feedback template form, and emailing the completed form to the Department of Health at legislation@health.qld.gov.au
  or
- posting the completed consultation feedback form to:
  Medicines, Poisons and Therapeutic Goods Consultation Process
  Regulatory Policy Unit
  Department of Health
  PO BOX 48 BRISBANE QLD 4001

Feedback may also be provided by way of a written submission, if preferred.

Please forward this email to colleagues or members of your organisation who may wish to be informed of the proposed change and to provide feedback.

Thank you for your participation in modernising our legislation.

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Please think about the environment before you print this message.



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NCIS Fact Sheet. August 2014

# Opioid related deaths in Australia (2007-2011)

ISSN 2201-2192

## PURPOSE

The data contained in this report is provided by the National Coronial Information System (NCIS). The NCIS is a data repository for mortality data from all Australian State and Territory Coroners and from New Zealand[1]. The NCIS produces publicly available *NCIS Fact Sheets*[2] to provide information to the community about mortality trends and changes over time. *NCIS Fact Sheets* are intended for wide use by the public, including media outlets, to raise awareness of mortality risks and for the development of strategies for the prevention of death. NCIS Fact Sheets are generated for the purpose of presenting statistical evidence only and the NCIS does not seek to provide interpretation of the data.

*NCIS Fact Sheets* do not contain identifying information.

Any data used from this report must be cited as originating from the NCIS. All NCIS Fact Sheets are available from the NCIS website www.ncis.org.au

## NCIS DISCLAIMER

This dataset does not claim to be representative of all relevant cases within the time period specified. This may be due to; cases still under coronial investigation, missing data, occasional processing and coding errors. The Department of Justice accepts no liability for any loss or damage that may arise from any use of or reliance on the data.

The data entered into the NCIS is collected from source material such as the police report of death, autopsy reports, toxicology reports and coronial findings from nine jurisdictions. It is acknowledged that quality and consistency of these documents may vary between and within each jurisdiction. There are also differences between jurisdictions as to legislation governing the reporting of a death to a coroner, which can impact on the type, quality and quantity of the information collected and reported by each jurisdiction. These differences will have an impact on the information available in the NCIS. It should also be noted the NCIS is the result of an administrative data set and data collection is the result of operational processes which differ between jurisdictions. Contributing data to the NCIS is not the primary purpose of the operational processes which can result in data limitations.

[1] Data collection commenced in July 2000 for all Australian jurisdictions expect Queensland which commenced in January 2001. New Zealand data is collected from July 2007.
[2] ISSN 2201-2192

## Key Findings

An opioid drug was found to have made a primary contribution to death in 4,102 fatalities reported to an Australian Coroner across a 5 year period (2007-2011). This equates to an average of over 820 deaths each year[3]. The previous fact sheet published in February 2013 included data over a three year period (2007-2009), showing an average of approximately 800 cases per year.

The identified opioid drug deaths had the following characteristics:

- The majority of deaths were deemed unintentional (71.2%), while almost one-sixth were due to an act of intentional self-harm (15.8%).
- Over two-thirds of deaths involved males (67.1%), deceased aged between 35-44 years had the highest proportion (28.4%).
- A slightly higher proportion of females compared with males were involved in deaths involving codeine-containing products.
- Heroin was the opioid drug most frequently involved in death (particularly in cases of sole drug involvement), with 84.4% of all heroin-related deaths involving males. 87.6% of all heroin related deaths were unintentional in nature.
- Methadone and oxycodone were the second and third most frequently identified opioids involved in death.
- Almost three quarters of opioid drug deaths occurred in combination with non-opioid drugs (74.5%). Of the drug classes examined[3], benzodiazepines and alcohol were the non-opioid drug classes most frequently identified.
- Codeine-containing products, morphine, oxycodone and tramadol were more likely to be involved in intentional self-harm deaths than heroin or methadone.



[3] Only cases completed with the Coroner and closed on the NCIS as at 29th March 2014 were included

From 2007 to 2009, the number of opioid drug deaths identified on the National Coronial Information System (NCIS) increased by 25.0% (744 deaths in 2007 compared to 934 in 2009), with an apparent subsequent decrease in opioid related fatalities in 2010 and 2011 (Table 1).

## Table 1: National opioid drug deaths, by year of death (n=4,102)

| Year of Death | Opioid as sole drug | Opioid one of multiple drugs | Total |
|---|---|---|---|
| 2007 | 221 | 523 | 744 |
| 2008 | 230 | 633 | 863 |
| 2009 | 249 | 685 | 934 |
| 2010 | 219 | 630 | 849 |
| 2011* | 128 | 584 | 712 |
| ***TOTAL*** | ***1,047*** | ***3,055*** | ***4,102*** |

*The number of opioid related death in 2011 is likely to be an underestimation due to comparatively low case closure rates. Several cases are still open under coronial investigation and not included in this report. Numbers are to be interpreted with caution. Please refer to the 'Limitations' section of this fact sheet for further information.

The majority of opioid drug deaths were unintentional (71.2%; Table 2), however a higher proportion of deaths involving codeine-containing products, morphine, oxycodone and tramadol were deemed intentional compared with those involving other opioid drugs, especially amongst females

For detailed data on intentional self-harm deaths please see Appendix 1

## Table 2: National opioid drug deaths 2007-2011, by intent and opioid drug *

| Intent of deceased | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | (N=1,127) | (N=845) | (N=762) | (N=328) | (N=630) | (N=573) | (N=515) | (N=769) | (N=4,102) |
| **Unintentional** | 87.6% | 78.6% | 63.9% | 62.8% | 70.3% | 53.8% | 70.5% | 59.7% | **71.2%** |
| Intentional Self-Harm | 4.6% | 6.4% | 23.6% | 24.1% | 15.1% | 31.4% | 15.3% | 26.5% | **15.8%** |
| Other | 0.0% | ≤1% | ≤1% | ≤1% | 1.1% | ≤1% | 0.0% | ≤1% | **≤1%** |
| Natural Causes (no intent) ^ | ≤1% | 3.2% | 3.7% | 4.0% | 4.8% | 4.2% | 5.4% | 4.5% | **3.6%** |
| Undetermined / Unlikely to be known | 6.8% | 11.6% | 8.4% | 8.5% | 8.6% | 9.9% | 8.3% | 8.7% | **9.0%** |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

* – Not mutually exclusive for each opioid drug when multiple opioids were involved (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

^ – Natural cause deaths were deaths resulting from a natural disease but considered to be primarily contributed to by an opioid drug

Heroin was the most frequently identified opioid drug, found in 1127 deaths during this period (Table 3). Multiple drugs were identified in more than half of the deaths involving heroin (676 of 1127 deaths; 60.0%; Table 3). Heroin was also the most commonly detected opioid drug in deaths attributed to one drug only (451 of 1127 deaths; 40.0%; Table 3).

Methadone and oxycodone were the next most frequently identified opioid drugs (Table 3).

## Table 3: National opioid drug deaths 2007-2011, by opioid drug (n=4,102)

| Opioid drug * | Opioid as sole opioid and sole drug | Opioid one of multiple drugs | Total |
|---|---|---|---|
| Heroin | 451 | 676 | **1127** |
| Methadone | 146 | 699 | **845** |
| Oxycodone | 92 | 670 | **762** |
| Morphine (without codeine detected) | 141 | 489 | **630** |
| Codeine (without morphine detected) ^ | 42 | 531 | **573** |
| Morphine and codeine detected together ^ | 79 | 436 | **515** |
| Tramadol | 36 | 292 | **328** |
| (Dextro)propoxyphene | 13 | 110 | **123** |
| Other # | 13 | 48 | **61** |
| Fentanyl | 26 | 104 | **130** |
| Buprenorphine | 5 | 49 | **54** |
| Hydrocodone | 0 | 15 | **15** |
| Pethidine | 3 | 11 | **14** |

* – Not mutually exclusive for each opioid drug when multiple opioids were involved (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

^ – A proportion of cases (n=769) involved the possible use of a codeine combination product with paracetamol, ibuprofen, aspirin or doxylamine detected alongside the presence of codeine

# – "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

The majority of deaths involved only **one** type of opioid drug[4] (3,161 of 4,102 deaths; 77.1%; Table 4), whilst 19.5% involved two opioids.

Oxycodone, methadone and codeine-containing products were most commonly identified in deaths involving multiple opioid drugs. Combinations of methadone/heroin, codeine/oxycodone and codeine/tramadol were frequent, as was morphine (with or without codeine) in combination with oxycodone or tramadol (Table 5).

## Table 4: National opioid drug deaths 2007-2011, by number of opioid drugs detected together

| Number of opioid drugs detected together | Frequency | Percentage [%] |
|---|---|---|
| Solitary opioid drug (1) | 3162 | 77.1 |
| 2 | 800 | 19.5 |
| 3 | 123 | 3.0 |
| 4 or more | 17 | 0.4 |
| ***TOTAL*** | ***4,102*** | ***100*** |



[4] With or without non-opioid drugs

## Table 5: Multiple opioid drug deaths 2007-2011, by opioid drug

| Opioid drug | Oxycodone | Methadone | Codeine (without morphine detected) | Heroin | Tramadol | Morphine (without codeine detected) | Morphine and codeine detected | (Dextro)-propoxyphene | Fentanyl | Buprenorphine | Hydrocodone | Other* | Pethidine |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **372** | **346** | **286** | **211** | **225** | **181** | **162** | **72** | **74** | **38** | **15** | **26** | **10** |
| *Used with 1 other opioid drug* | **284** | **286** | **232** | **183** | **157** | **153** | **131** | **55** | **53** | **26** | **8** | **16** | **5** |
| *Used with 2 other opioid drugs* | **73** | **53** | **44** | **25** | **56** | **26** | **26** | **12** | **17** | **10** | **5** | **8** | **5** |
| *Used with 3 other opioid drugs* | **13** | **7** | **8** | **<3** | **11** | **<3** | **5** | **4** | **3** | **<3** | **<3** | **<3** | **0** |
| *Used with 4 other opioid drugs* | **<3** | **0** | **<3** | **<3** | **<3** | **0** | **0** | **<3** | **<3** | **0** | **<3** | **<3** | **0** |
| Oxycodone | | | | | | | | | | | | | |
| Methadone | 59 | | | | | | | | | | | | |
| Codeine (without morphine detected) | 119 | 51 | | | | | | | | | | | |
| Heroin | 27 | 95 | 46 | | | | | | | | | | |
| Tramadol | 70 | 45 | 61 | 31 | | | | | | | | | |
| Morphine (without codeine detected) | 71 | 66 | <3 | <3 | 34 | | | | | | | | |
| Morphine and codeine detected | 62 | 62 | <3 | <3 | 39 | 0 | | | | | | | |
| (Dextro)propoxyphene | 18 | 8 | 24 | 14 | 9 | 11 | 5 | | | | | | |
| Fentanyl | 27 | 11 | 13 | <3 | 10 | 15 | 13 | <3 | | | | | |
| Buprenorphine | 5 | 5 | 9 | 14 | 3 | 4 | <3 | <3 | <3 | | | | |
| Hydrocodone | 5 | 0 | 10 | <3 | 0 | 0 | 4 | 0 | <3 | <3 | | | |
| Other* | 7 | 7 | 4 | 4 | <3 | 4 | 3 | 0 | <3 | 5 | <3 | | |
| Pethidine | 3 | 0 | 5 | 0 | 0 | <3 | <3 | <3 | 3 | 0 | 0 | 0 | |

* – "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

More than three-quarters of opioid drug deaths occurred amongst persons aged between 25 and 54 years (3,229 of 4,102 deaths; 78.8%; Table 6), with death most frequent in the subset of 35 and 44 year olds (28.4%). Deaths involving heroin were most frequent amongst 25-34 year olds, whilst opioid drug deaths involving oxycodone, tramadol and codeine-containing products more frequently occurred amongst older age groups (35-54 year olds; Table 6).

## Table 6: National opioid drug deaths 2007-2011, by age and opioid drug

| Age of deceased | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product * | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | **(N=1,127)** | **(N=845)** | **(N=762)** | **(N=328)** | **(N=630)** | **(N=573)** | **(N=515)** | **(N=769)** | **(N=4,102)** |
| 15-24 | 7.1% | 6.3% | 4.9% | 2.7% | 4.3% | 5.1% | 5.8% | 4.7% | **5.8%** |
| 25-34 | 41.3% | 29.6% | 20.3% | 20.1% | 21.1% | 15.3% | 25.9% | 17.9% | **27.2%** |
| 35-44 | 32.7% | 30.2% | 26.2% | 26.5% | 26.5% | 27.7% | 24.9% | 25.6% | **28.4%** |
| 45-54 | 14.8% | 26.2% | 26.5% | 25.3% | 26.0% | 28.7% | 25.3% | 28.2% | **23.2%** |
| 55-64 | 4.2% | 6.4% | 13.9% | 15.5% | 13.2% | 14.5% | 13.5% | 15.6% | **10.0%** |
| 65+ | 0.0% | 1.3% | 8.0% | 9.5% | 8.6% | 8.5% | 4.4% | 7.7% | **5.3%** |
| Other | 0.0% | <1% | <1% | <1% | <1% | <1% | <1% | <1% | **<1%** |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

* – The possible use of a codeine combination product has been identified where paracetamol, ibuprofen, aspirin or doxylamine was detected or mentioned (within toxicology reports or Coronial documentation) alongside the presence of codeine

Males outnumbered females at a ratio of around 2:1 overall (2,754 to 1,348 deaths, respectively), with pronounced difference between the sexes noted for deaths involving heroin, methadone and morphine (Table 7). There was a slightly higher proportion of females than males in deaths involving codeine-combination products.

## Table 7: National opioid drug deaths 2007-2011, by gender and opioid drug

| **Gender of deceased** | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | **(N=1127)** | **(N=845)** | **(N=762)** | **(N=328)** | **(N=630)** | **(N=573)** | **(N=515)** | **(N=769)** | **(N=4,102)** |
| Male | 84.4% | 66.5% | 60.8% | 52.4% | 67.3% | 47.9% | 57.3% | 49.4% | 67.1% |
| Female | 15.6% | 33.5% | 39.2% | 47.6% | 32.7% | 52.1% | 42.7% | 50.6% | 32.9% |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

Opioid drug deaths generally followed population rates in terms of frequency (i.e. New South Wales and Victoria with the highest proportions, followed by Queensland, Western Australia and South Australia; Table 8).

Noted differences to this trend were seen in relation to tramadol (comparatively high proportion in Western Australia and Tasmania), morphine without codeine and oxycodone (highest proportion in Queensland). The highest proportion of heroin deaths and deaths involving codeine (without morphine) were reported in Victoria (40.8% and 28.9%, respectively; Table 8).

## Table 8: National opioid drug deaths 2007-2011, by investigating jurisdiction and opioid drug

| Jurisdiction | Heroin[5] | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | **(N=1127)** | **(N=845)** | **(N=762)** | **(N=328)** | **(N=630)** | **(N=573)** | **(N=515)** | **(N=769)** | **(N=4,102)** |
| NSW | 24.9% | 31.1% | 24.8% | 22.9% | 23.0% | 26.0% | 34.7% | 28.2% | 27.8% |
| VIC | **40.8%** | 25.7% | 22.4% | 22.6% | 21.9% | **28.9%** | 14.9% | 26.2% | 26.3% |
| QLD | 11.2% | 13.4% | **25.3%** | 20.4% | 25.7% | 17.2% | 29.9% | 21.2% | 19.5% |
| WA | 14.6% | 12.8% | **16.4%** | **22.0%** | 11.9% | 15.9% | 13.7% | 15.1% | 13.9% |
| SA | 6.4% | 10.8% | 5.5% | 5.2% | 10.3% | 5.1% | 2.7% | 2.5% | 7.6% |
| TAS | 0.0% | 3.8% | 3.3% | **6.4%** | 3.2% | 4.5% | 2.7% | 4.8% | 2.6% |
| ACT | 2.1% | 1.7% | 2.1% | <1%% | 1.9% | 2.3% | <1% | 1.7% | 1.7% |
| NT | 0.0% | <1% | <1% | 0.0% | 2.1% | <1% | <1% | <1% | <1% |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

[5] Jurisdictional breakdowns of heroin deaths may have been influenced by the proportion of cases where police reports or finding reports were attached on the NCIS database. This is due to the manner in which heroin deaths were determined, heavily relying on attached documentation. NSW had attachment rates of 57% at the time of data analysis, which is substantially lower than other jurisdictions included in this report. This may have influenced the ability to identify heroin deaths in NSW in particular.

The majority of opioid drug deaths occurred at a home (3,478of 4,102 deaths; 84.4%; Table 9). Heroin was the only opioid drug analysed that showed fatal overdoses occurring outside a home in a notable sense (280 of 1127 deaths; 24.8%). Commercial areas, transport areas and recreational areas were often the non-home locations for heroin deaths.

## Table 9: National opioid drug deaths 2007-2011, by incident location and opioid drug

| Incident Location | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | (N=1127) | (N=845) | (N=762) | (N=328) | (N=630) | (N=573) | (N=515) | (N=769) | (N=4,102) |
| Home | 75.2% | 89.8% | 89.5% | 90.2% | 87.1% | 87.3% | 86.4% | 87.5% | **84.8%** |
| Commercial Area (Non-Recreational) | 6.3% | 1.4% | 2.0% | 2.1% | 2.7% | 2.8% | 3.7% | 2.6% | **3.5%** |
| Transport Area: Public Highway, Freeway, Street Or Road | 5.6% | 1.9% | 1.2% | 1.2% | 0.8% | 1.2% | 2.5% | 1.7% | **2.5%** |
| Recreational Area, Cultural Area, Or Public Building | 5.2% | 1.8% | 1.8% | <1% | 1.3% | 2.1% | 1.7% | 1.6% | **2.5%** |
| Medical Service Area | 1.1% | 1.2% | 2.4% | 2.4% | 4.6% | 2.6% | 2.3% | 2.9% | **2.2%** |
| Transport Area: Other | 3.9% | 1.3% | 1.0% | <1% | 1.3% | 1.0% | 1.2% | <1% | **1.8%** |
| Other* | 2.8% | 2.6% | 2.1% | 2.4% | 2.2% | 3.0% | 2.1% | 3.1% | **2.7%** |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

*'Other' – involves areas such as School and Educational Areas, Sports and Athletic Areas, or Industrial or Construction Areas

When opioid drugs were found in combination with other drug classes, the most common (of the classes examined) involved benzodiazepines or alcohol.

Benzodiazepines were most commonly combined with hydrocodone, methadone, oxycodone and fentanyl whilst amphetamines and cocaine were most frequently found in combination with heroin (Table 10).

Alcohol was also most commonly identified in deaths involving heroin and buprenorphine, and was not as frequent in deaths involving tramadol, dextropropoxyphene or methadone (Table 10). Alcohol was either rarely or not noted amongst deaths involving fentanyl, pethidine or "other" opioid drugs[6].

***NOTE: Additional NCIS searches indicate that there are at least an additional 121 deaths during this time period still under investigation with the Coroner which could be opioid drug deaths (101 of these deaths directly refer to an opioid within the cause of death).***



[6] "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

## Table 10: National opioid drug deaths 2007-2011, with drug combination (with categorised drug groups)

| Opioid drug * | Number of cases involving opioid drug in combination with categorised group | Alcohol [%] ^ | Amphetamines [%] | Benzodiazepines [%] | Cocaine [%] | Other non-opioid drug [%]ⁿ | Detected cannabis [%] # |
|---|---|---|---|---|---|---|---|
| Heroin | **676** | 28.1 | 17.8 | 54.1 | 5.8 | 19.5 | 9.8 |
| Methadone | **699** | 11.9 | 15.5 | 66.8 | 1.1 | 29.5 | 14.7 |
| Oxycodone | **670** | 19.0 | 7.0 | 65.7 | 0.7 | 30.4 | 10.3 |
| Morphine (without codeine detected) | **489** | 18.0 | 12.1 | 64.8 | 1.2 | 24.1 | 12.7 |
| Codeine (without morphine detected) @ | **531** | 17.7 | 4.0 | 59.3 | 0.2 | 49.9 | 5.6 |
| Morphine and codeine detected together @ | **436** | 18.6 | 10.1 | 67.0 | 2.1 | 24.3 | 14.2 |
| Tramadol | **292** | 11.0 | 9.6 | 64.0 | 0.7 | 42.1 | 8.9 |
| (Dextro)propoxyphene | **110** | 11.8 | 4.5 | 62.7 | 0.9 | 34.5 | 8.2 |
| Other £ | **48** | 4.2 | 4.2 | 83.3 | 0.0 | 22.9 | 14.6 |
| Fentanyl | **104** | 4.8 | 7.7 | 63.5 | 0.0 | 17.3 | 17.3 |
| Buprenorphine | **49** | 20.4 | 6.1 | 55.1 | 0.0 | 18.4 | 6.1 |
| Hydrocodone | **15** | 13.3 | 13.3 | 73.3 | 0.0 | 60.0 | 13.3 |
| Pethidine | **11** | 0.0 | 0.0 | 54.5 | 0.0 | 36.4 | 0.0 |

* – Not mutually exclusive for each opioid drug (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

^ – 'Alcohol' = external cause deaths involving alcohol concentration equal to or greater than 0.05%

# – Detection of cannabis was identified when cannabis was listed as one of the drugs under the object code of Pharmaceutical Substance for Human Use (PSHU)

@ – A proportion of cases (n=769) involved the possible use of a codeine combination product with paracetamol, ibuprofen, aspirin or doxylamine detected alongside the presence of codeine (674 of these cases involved a combination with another categorised drug group)

£ – "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

ⁿ - 'Other non-opioid drug' includes compounds such as antipsychotic drugs, antidepressants and non-opioid analgesics

## Coronial recommendations about opioid drug deaths

There were thirty-five opioid drug deaths reported during 2007 to 2011 where Coroners made recommendations pertaining to these cases. Common themes to these recommendations included:

- Improved recordkeeping, security and checking of opioid medication held in hospitals
- Recording of patient medication in Ambulance records and subsequent checking and recording of this medication by the hospital/facility receiving the patient
- Increased oversight and training for doctors about the prescription of opioid drugs (including dangers and practices surrounding the prescription of take-away methadone)
- Medical practitioners such as registered clinical psychologists and emergency medicine staff being vigilant about identifying patients with possible overmedication
- Improved warnings on medication about the dangers of combining opioid drugs with each other
- Changing the product information for fentanyl transdermal patches to ensure that it contains no potential anomalies
- Appropriate warnings for prisoners identified as suffering from drug dependency issues that are to be released from Corrective Services as to the danger of using illicit substances where their tolerance to such substances has been reduced by their period of incarceration
- Other mechanisms to reduce the abuse of Schedule 8 drugs such as:
    - tightening and auditing the prescription of opioid drugs
    - sharing of patient information amongst practitioners for patients who are suspected of abusing such prescriptions
    - a real-time prescription monitoring system accessible to prescribers and disseminators
    - a periodic review of patients with chronic non-malignant long term pain by a pain management specialist

## National Coronial Information System (NCIS)

65 Kavanagh Street
Southbank
VIC 3006
Telephone: +61 3 9684 4414
Fax: +61 3 9684 4475

Web-site: http://www.ncis.org.au
E-mail: ncis@ncis.org.au

# Appendix 1: Detailed data about opioid drug deaths

## Table A: National opioid drug deaths 2007-2011, by year of death and opioid drug (n=4,102)

NOTE: The possible use of a codeine combination product has also been estimated where paracetamol, ibuprofen, aspirin or doxylamine was detected or mentioned (within toxicology reports or Coronial documentation) alongside the presence of codeine.

| Opioid drug * | 2007 | | 2008 | | 2009 | | 2010 | | 2011[7] | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Sole drug | Multiple drug | Sole drug | Multiple drug | Sole drug | Multiple drug | Sole drug | Multiple drug | Sole drug | Multiple drug |
| Heroin | 85 | 101 | 101 | 161 | 113 | 165 | 98 | 130 | 54 | 119 |
| Methadone | 31 | 134 | 28 | 137 | 38 | 149 | 36 | 134 | 13 | 145 |
| Oxycodone | 7 | 109 | 18 | 115 | 16 | 156 | 28 | 136 | 23 | 154 |
| Morphine (without codeine detected) | 42 | 93 | 36 | 95 | 31 | 105 | 24 | 110 | 8 | 86 |
| Codeine (without morphine detected) ^ | 12 | 111 | 9 | 124 | 12 | 145 | <3 | 82 | 7 | 69 |
| Morphine and codeine detected together ^ | 22 | 62 | 19 | 102 | 24 | 90 | 11 | 102 | 3 | 80 |
| Tramadol | 7 | 62 | 8 | 61 | 6 | 75 | 10 | 49 | 5 | 45 |
| (Dextro)propoxyphene | 6 | 17 | 3 | 24 | <3 | 31 | <3 | 30 | 0 | 8 |
| Other # | 6 | 13 | 3 | 13 | 3 | 4 | 0 | 5 | <3 | 13 |
| Fentanyl | <3 | 4 | <3 | 13 | 3 | 17 | 7 | 21 | 13 | 49 |
| Buprenorphine | <3 | 8 | <3 | 9 | <3 | 11 | <3 | 11 | <3 | 10 |
| Hydrocodone | 0 | 5 | 0 | 4 | 0 | 6 | 0 | 0 | 0 | 0 |
| Pethidine | <3 | 5 | <3 | <3 | 0 | <3 | 0 | <3 | 0 | <3 |
| ***TOTAL*** | ***221*** | | ***230*** | | ***249*** | | ***219*** | | ***128*** | |

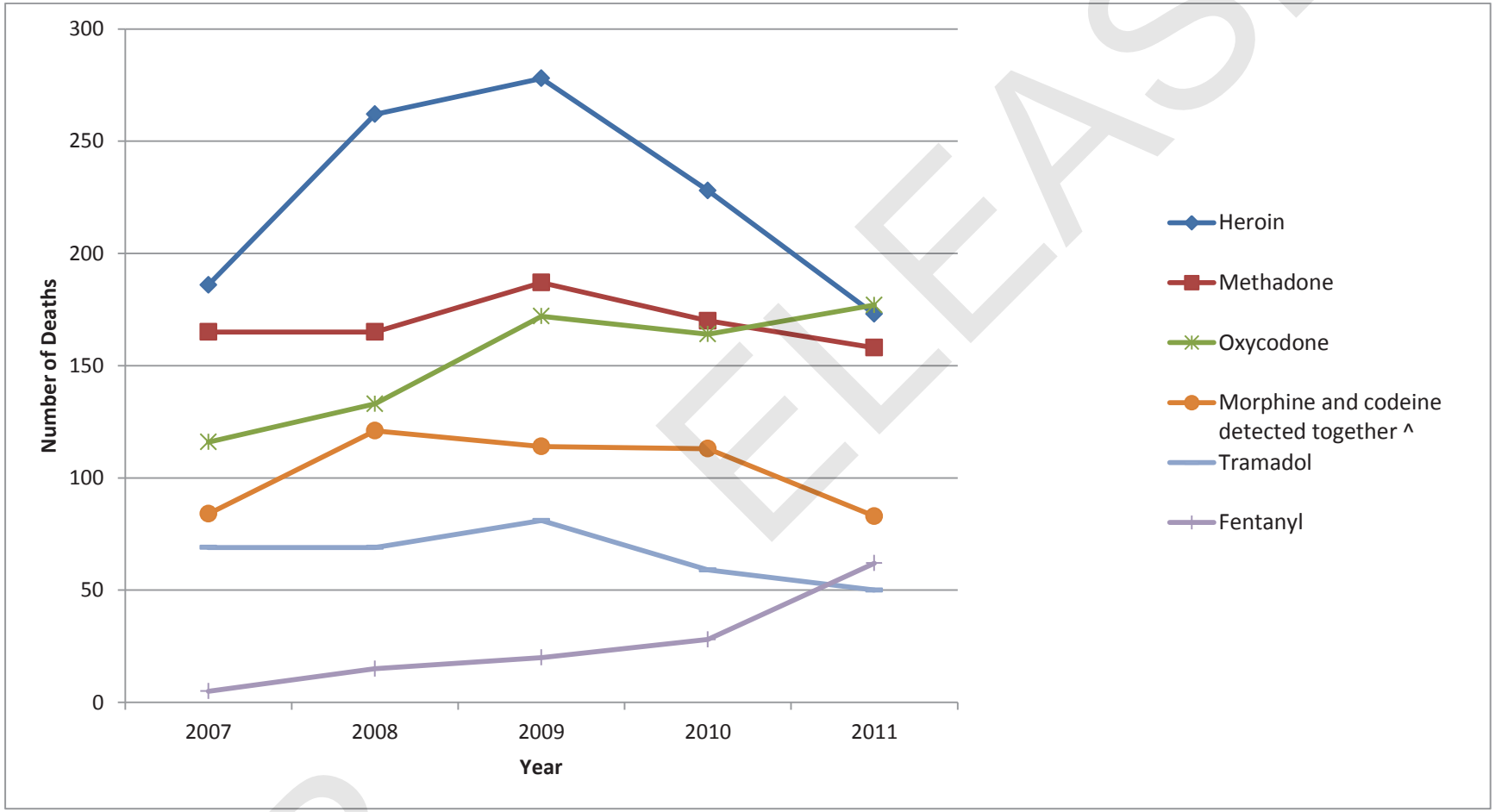
* – Not mutually exclusive for each opioid drug when multiple opioids were involved (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

^ – A proportion of cases (n=769) involved the possible use of a codeine combination product with paracetamol, ibuprofen, aspirin or doxylamine detected alongside the presence of codeine

# – "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

[7] The number of opioid related death in 2011 is likely to be an underestimation due to comparatively low case closure rates. Numbers are to be interpreted with caution. Please refer to the 'Limitations' section of this fact sheet for further information.

## Chart A: National opioid drug deaths 2007-2011[7], by year of death and selected opioid drug



## Table B: National *intentional self-harm* opioid drug deaths 2007-2011, by opioid drug (n=647)

| Opioid drug * | Opioid as sole opiate and sole drug | Opioid one of multiple drugs | Total |
|---|---|---|---|
| Codeine (without morphine detected) | 9 | 171 | 180 |
| Oxycodone | 22 | 158 | 180 |
| Morphine (without codeine detected) | 28 | 67 | 95 |
| Tramadol | 8 | 71 | 79 |
| Morphine and codeine detected together | 9 | 70 | 79 |
| (Dextro)propoxyphene | 11 | 43 | 54 |
| Methadone | 10 | 44 | 54 |
| Heroin | 19 | 33 | 52 |
| Other # | 6 | 15 | 21 |
| Fentanyl | 4 | 16 | 20 |
| Buprenorphine | 0 | 5 | 5 |
| Hydrocodone | 0 | <3 | <3 |
| Pethidine | 0 | <3 | <3 |
| ***TOTAL*** | ***126*** | [redacted] | |

* – Not mutually exclusive for each opioid drug when multiple opioids were involved (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

# – "Other" includes pholcodine, (dextro)methorphan, hydromorphone, dihydrocodeine, loperamide, oxymorphone, remifentanil or an opioid drug that was unspecified in the details of the case

## Table C: National *intentional self-harm* opioid drug deaths 2007-2011, by age and opioid drug* (n=647)

| Age of deceased | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | All opioid drugs |
|---|---|---|---|---|---|---|---|---|---|
| | (N=52) | (N=54) | (N=180) | (N=79) | (N=95) | (N=180) | (N=79) | (N=204) | (N=647) |
| 15-24 | 3.9% | 1.9% | 0.0% | 2.2% | 2.5% | 4.2% | 5.6% | 6.3% | 4.4% |
| 25-34 | 14.4% | 34.6% | 24.1% | 7.8% | 11.4% | 10.5% | 13.3% | 19.0% | 16.2% |
| 35-44 | 22.6% | 40.4% | 37.0% | 15.6% | 16.5% | 16.8% | 25.6% | 16.5% | 22.1% |
| 45-54 | 26.0% | 15.4% | 29.6% | 29.4% | 30.4% | 28.4% | 26.7% | 31.6% | 29.4% |
| 55-64 | 18.2% | 7.7% | 7.4% | 26.7% | 20.3% | 20.0% | 17.8% | 19.0% | 17.2% |
| 65+ | 14.8% | 0.0% | 1.9% | 18.3% | 17.7% | 20.0% | 11.1% | 7.6% | 10.8% |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

* – Not mutually exclusive for each opioid drug when multiple opioids were involved (e.g.: heroin may be combined with alcohol, benzodiazepines and other non-opioid drugs within the same individual case)

## Table D: National *intentional self-harm* opioid drug deaths 2007-2011, by gender and opioid drug (n=647)

| Gender of deceased | Heroin | Methadone | Oxycodone | Tramadol | Morphine (without codeine detected) | Codeine (without morphine detected) | Morphine and codeine detected together | Possible codeine combination product | Opioid drugs overall |
|---|---|---|---|---|---|---|---|---|---|
| | (N=52) | (N=54) | (N=180) | (N=79) | (N=95) | (N=180) | (N=79) | (N=204) | (N=647) |
| Male | 76.9% | 57.4% | 43.9% | 38.0% | 55.8% | 43.3% | 40.5% | 39.7% | 49.8% |
| Female | 23.1% | 42.6% | 56.1% | 62.0% | 44.2% | 56.7% | 59.5% | 60.3% | 50.2% |
| ***TOTAL*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** | ***100.0%*** |

# Appendix 2: Data Source and Method

## The NCIS

The National Coronial Information System (NCIS) is administered by the Victorian Department of Justice on behalf of the NCIS Board of Management.

The NCIS is funded by each State and Territory Justice / Attorney-General's Department, the New Zealand Ministry of Justice, and the following Australian federal agencies:

- Australian Department of Health and Ageing
- Australian Institute of Criminology
- Safe Work Australia
- Australian Competition and Consumer Commission
- Australian Department of Infrastructure and Transport

Data is provided by each of the Coronial Offices around Australia, the Australian Bureau of Statistics (ABS) and Safe Work Australia.

## Method

To identify opioid drug deaths on the NCIS, a search was undertaken of all closed cases where death or notification of death occurred between 1st January 2007 and 31st December 2011[8], where the object code was "Pharmaceutical Substances for Human Use" (PSHU).

Cases were manually reviewed for the confirmation of drug-related mortality[9], and were further identified as an opioid drug death when an opioid was referred to within a cause of death or a free-text object field, or when an object was coded within an opioid related category within PSHU (refer to **Error! Reference source not found.**).

Cases were only retained within the dataset when the opioid drug was considered to be a ***primary contributor to death***. This was determined when:

- Drug toxicity was noted within sections 1a through to 1d of the cause of death, or
- Aspiration of gastric contents was noted within the cause of death AND drug toxicity was noted anywhere in the cause of death, or

The detection or mention of paracetamol, ibuprofen, aspirin or doxylamine (within toxicology reports or Coronial documentation) alongside the presence of codeine was recorded as the possible involvement of a codeine combination product for each case.

[9] Cases were only considered to be drug-related when an object was coded as PSHU and there was also reference to a drug (other than alcohol or cannabis) within the medical cause of death

If the death was noted as being contributed to by a combination of multiple coded drugs (such as "mixed drug toxicity" or "multiple drug overdose"), the drugs that were part of the "multiple drug" combination were recorded (e.g.: heroin and alcohol toxicity).

The dataset was then manually reviewed to determine which opioid drugs were involved in each case. It must be noted that missing documentation may lead to an underrepresentation of heroin related deaths in the data set.

For the purposes of this analysis, each opioid was considered as a separate drug (e.g.: heroin and tramadol toxicity would be classed as a multiple drug fatality). An exception to this rule was the detection of ***both*** morphine and codeine (without any other opioid drug), in which heroin involvement remained unproven, due to complex intertwining metabolic and toxicological profiles pertaining to morphine, codeine and heroin[10].



[10] Konstantinova SV, Normann PT, Arnestad M, et al. Morphine to codeine concentration ratio in blood and urine as a marker of illicit heroin use in forensic autopsy samples. ***Forensic Sci Int*** 2012 Apr 10; 217(1-3): 216-21.

# Limitations

## Toxicological techniques

Rates and frequencies of these deaths may be influenced by whether a toxicological screen for specific opioid drugs was included in a standard screen, and whether toxicological techniques were sensitive enough to detect low levels of certain opioids (e.g.: fentanyl).

## Availability of case documentation

In some cases, reports associated with a death may not be available on the NCIS to confirm the details surrounding the fatality, and the level of detail contained in these reports can vary.

For more information about document attachment, please refer to the NCIS Website (http://www.ncis.org.au/data-collection-2/operational-statistics/).

## Open cases

The proportion of open cases on the NCIS may impact the dataset, especially for cases identified in more recent years. The percentage of closed cases for each relevant calendar year at the time of data extraction was as follows:

| Year | % closed |
|---|---|
| 2007 | 96% |
| 2008 | 96% |
| 2009 | 94% |
| 2010 | 93% |
| 2011 | 88% |

## Population growth and Reporting of "Frequencies only"

When comparing frequencies of certain types of fatalities (such as intentional self-harm deaths) between geographical locations (such as Jurisdictions or Local Government Areas), population numbers should be taken into consideration when drawing conclusions. An increase in case frequency might be impacted by an increase in population rather than an increase in incident. Please refer to the ABS website for population data.

http://www.abs.gov.au/websitedbs/D3310114.nsf/home/home?opendocument#from-banner=GT

2 October 2014

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
PO Box 48
BRISBANE QLD 4001
legislation@health.qld.gov.au

Dear Sir/Madam

QNADA makes the following submission to the consultation on *Medicines, Poisons and Therapeutic Goods Bill 2014*.

QNADA represents a dynamic and broad-reaching specialist network within the non-government alcohol and other drug (NGO AOD) sector across Queensland. We have 36 member organisations, representing the majority of NGO AOD providers all of whom have been consulted in regards to this submission.

QNADA members provide drug education and information, early intervention, outreach, detoxification, residential rehabilitation, psychosocial and medical treatment, relapse prevention, justice diversion, and social inclusion services.

Our submission will respond to questions of relevance to our members' activities from the consultation questions included in the background paper.

## Consultation Questions

### *Q2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?*

We believe that while the Bill represents an improvement on previous legislation, we are concerned about the potential implications of defining dependence.

The provision for a drug dependent person to be provided 'drug treatment' by someone who does not have approval to do so in the event of emergency is a welcome change to the new legislation. This change acknowledges that the provision of appropriate care should not be altered if the person has been deemed to be drug dependent.

QNADA is concerned that the inclusion of the definition of a 'drug dependent person' does not account for the complexity and multitude of different situations that could lead to an individual being assessed as having 'impaired control'. The inclusion of a definition in the Bill may further stigmatise those who have a dependence on substances and create a false delineation between those who have become dependent on a substance through 'therapeutic' prescription and those that have become dependent through other means, further isolating and potentially placing the drug dependent person at risk of harm.

### *Q11. Are the proposed licences, approvals and other authorisations appropriate?*

The removal of the 'operating approval' to establish a controlled administration facility for the primary purpose of the administration of controlled substances to drug dependent persons such as methadone is also welcome. This will allow for the provision of appropriate care

without unnecessary input from an at times uninformed public and supports the reduction of stigma towards people engaged in substitution programs.

### *Q13. In your view are the provisions in the draft Bill for criminal history checking and recall powers, appropriate?*

QNADA has concerns regarding the waiving of the protections under the Criminal Law (Rehabilitation of Offenders) Act 1986 for the assessment of suitability for a 'relevant authority'. There is no justification for treating those that are seeking an authority under the legislation to be treated differently to other citizens in the State who have moved on from a criminal history. This inclusion could serve to reinforce the stigmatisation of people who have recovered from their own dependence and its attendant harms by signalling to the public that those that wish to work with drug dependent persons need to be extra carefully screened than those working in any other industry requiring criminal history checks.

QNADA would welcome the opportunity to expand further on this submission. I can be contacted on (07) 3023 5050 or at [redacted] to arrange this and am able to provide further advice to your research team in support of our submission.

Yours sincerely

[redacted]

Rebecca MacBean

**Chief Executive Officer**

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Penny

Surname: Kenchington

Organisation and/or Professional position: Townsville Health and Hospital Service; Townsville Sexual Health service; Nurse Practitioner

Postcode: 4810

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: penny.kenchington@health.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Yes - In specific aeas of health (i.e Sexual health Programme) Nurses are currently authorised to supply, administer and pocess scheduled substances listed in a Drug Therapy Protocol. it is concenrning that the Hospital and Health Services may flounder without appropriate structures to give them guideance as to who is an eligible nurse with in a sexual health service and what boundaries of practice a nurse might practice within. When looking at the continuum of nurisng education from beginner to expert there is an enormous gap in 'eligibility'. Sexual Health Nurses in QLD where endorsed on their registration to be able to practice in a sexual health programme; with National registration this changed to being authorised to practice with the DTP in the Health (Drugs and Posions) Regulation 1996; now there will be an open and flexible legislation that is possibly open also to interpretation. It concenrns me that patient care and standards of practice will be compromised UNLESS there is guidance or guidelines written to assist the HHS in their credentialling of an eligible nurse in a sexual health programme.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

Section 37 (2) (b)…require an eligible person to comply with a stated code, guideline, protocol or standard.' This will lead to interpretation and variation of practice throughout the state. I cannot think of a control that will help with this.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

sexual health nurses (QLD) have developed competency standards to ensure the nurse is able to practice safely with the medicines used in the conditions that present in a sexual health service from a beginner to an advanced practitioner. A specific sexual health authorisation course was developed to educated beginning practitioners in this area of health to gain competencies to pocess, suppy and administer scheduled substances.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

I am concerned that there may be times when an unregistered 'health professional' may be unsafe and there will be no regisistering body to report to with regard to major errors in suppling or administering medicines. The risk management option by the HHS may be to restict all clinicans who are not prescribers (PPS elgible) in their practice even those with a registration and credentials/ authority to practice at an advanced level.

I believe this new legislation will require specialist sectors of health to provide guidance to the HHS as to who is an eligible person within a programme , ie examples of credentials required and what guidelines/standards are acceptable to effectively support the practitioner to deliver safe patient care , especially if there is no statewide Health Management Protocol or Drug Therapy Protocol to do this anymore.

The statewide senior sexual health nurses are continuing to insist on a statewide document that allows for consistant nursing practice in each sexual health service, however the Communicable Diseases Branch does not have the capacity to provide a strong goverance framework to support this process. This document will have to be authorised by each HHS, however each HHS may have no clue as to the business of their local speicalist services and what their advanced practice nurses are currently doing and what the HHS thinks they should be allowed to do - this will need guideance from somewhere!

I am hoping that the Regulatory Policy Unit might be able to help with the continuing development or goverenace around guidelines or standards that currently exist - but require regular updates

I would like to nominate myself for any further work around this issue and how we might be able to make each HHS understand who is eligible and what that practiitoner can or cannot do.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: [redacted] BEC Feed Solutions Pty Ltd

Postcode: 4300

Target group:

- ☒ Agriculture
- ☒ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☒ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Please note, detailed responses have been given for question 2 and 23, with some brief comments on several other questions. The response for question 23 would not adequately fit in this form and has been given in detail in the body of the email to which this form has been attached.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

There seems to be no reduction and most likely an increase in regulatory burden on industry.

Allowing a holder of an AgVet (APVMA) Good Manufacturing Practice licence to not need a manufacturing licence under the new Act certainly reduces regulatory burden. However, then requiring such a manufacturer to have a separate wholesaling licence under the Act, and to register with the Director General, increases the regulatory burden again. Could not the manufacturer's licence automatically invoke the rights and responsibilitities of a wholesaler's licence, regardless of which type of manufacturer's licence is held (State or Commonwealth)?

Anyway, the connection in the Bill between having an AgVet licence and not requiring a Queensland manufacturing licence is obscure. Although the Background paper says the AgVet licence will stand instead of a Queensland licence, Section 39 of the Bill only mentions the "Commonwealth schemes" in fine print as a note (not saying they are an alternative), and nothing in sections 99 to 101 says that the "Commonwealth scheme" can replace the need for a State manufacturer's licence. Furthermore, there is an implication that the AgVet licence might only apply to the manufacture of registered substances for which the licence has been granted, and not other non-registered yet still S4 stockfeeds and stockfeed components.

The requirement for a Scheduled Substance Management Plan, although it can be integrated with other management systems, is yet another increase in burden, especially where having an AgVet licence already invokes extensive controls on the use and management of substances.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

As mentioned in the more detailed answers to question 2 and 23, there are gaps in terms of (1) definition of means of replacing a Queensland manufacturer's licence with an AgVet licence, and (2) definition of how supplies of S4 medicated stockfeeds can be supplied to primary producers.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

This is a brief answer to question 6, which didn't have a form field set up in it. The range of terms such as authorisation, eligible persons, approvals, lawful direction, etc. is confusing. In particular, "lawful direction" could do with some amplification - lawful in accordance with this Act, or lawful in accordance with general legislation, or what; for example, lawful for a veterinary surgeon in relation to their responsibilities under veterinary legislation?

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Discussed in more detail in question 2, this will likely increase the number of licences required.

11. Are the proposed licences, approvals and other authorisations appropriate?

Referring to my detailed response to question 23, there is nothing to define the authorisation required by a primary producer to possess and administer S4 scheduled stockfeeds and stockfeed components. On a simple reading of it (not treated in detail as I have in my answer to question 23), it seems the primary producer has no explicit right to possess and administer S4 substances.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Explained in more detail in question 2, the Bill does not adequately recognise AgVet licences. There is no section 21(d) in the Bill.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

One year

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

We have a Quality Management System which is certified under several schemes including ISO9001, HACCP, FeedSafe, and FIAAA; and our GMP licence. These would be expected to cover the requirements of the scheduled substance management plan. There is simply an added administrative burden to identify the way in which the existing Quality Management System covers the new Plan's requirements.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

One year

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

There are several issues which one expects will be handled in Regulations rather than the Act itself, with respect to supply of S4 substances to primary producers. Whilst one might "expect" this, that doesn't guarantee that it has been thought about and will be included.

There seem to be too many loose ends and much obscurity associated with the supply of S4 substances to primary producers.

This comment was too detailed to fit in this space, especially as it relies on bolding and italics to try and make the point clearly, so I have attached it in the body of the email to which this submission is attached

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

## Julie Stokes

**From:** Legislation
**Sent:** Thursday, 2 October 2014 1:27 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Feedback on Medicines Poisons and Therapeutic Goods Bill 2014
**Attachments:** 2014-10-02 Medicines Poisons Therapeutic Goods Bill 2014 feedback.doc

Please see attached and below for feedback

Cheers,
Kelly

---

**From:** [redacted]
**Sent:** Thursday, 2 October 2014 10:59 AM
**To:** Legislation
**Cc:** [redacted]
**Subject:** Feedback on Medicines Poisons and Therapeutic Goods Bill 2014

G'day there,

Thank you very much for the opportunity to review and comment on the Medicines, Poisons and Therapeutic Goods Bill 2014.

BEC Feed Solutions manufactures stockfeed premixes and supplements, many of which are S4 scheduled. We have an AgVet (APVMA) GMP licence as we manufacture some veterinary chemical products (not all of which are S4), and we hold restricted drug licences under the current Queensland legislation [Health (Drugs and Poisons) Regulations 1996]. We will, of course, be intimately involved in and affected by changes that might be brought about by the proposed Act arising from the Medicines, Poisons and Therapeutic Goods Bill 2014.

I have attached a feedback form with comments on the Bill. I was able to get into that form most of the comments I wished to make. However, I could not get my detailed response to question 23 (issues raised with respect to regulations under the new Act) in the available field, so I have put it below in the body of this email. It is not a response just to question 23; that was just a convenient place to reference it to. More generally it highlights the lack of clarity within the Bill about how the supply of S4 substances to primary producers will be handled under the new legislation; they are a key part of the market for S4 medicated stock feeds and the Queensland economy.

If you want any further information about our concerns, please don't hesitate to call or email.

Thanks and regards,

[redacted]

[redacted], *BEC Feed Solutions Pty Ltd*

[redacted]

**Detailed comment on question 23 follows:**

There seem to be too many loose ends and much obscurity associated with the supply of S4 substances to primary producers.

At present, the restricted drug licence and/or administrative arrangements with the Health Department allow for manufacturers to supply S4 stockfeeds and stockfeed components direct to the primary producer on the authority of a veterinary surgeon's prescription (a "signed written order").

For example, a typical current licence (POIZ 10084, BEC Feed Solutions) states "*Where the stockfeed is a restricted drug it shall only be supplied on the signed written order of a veterinary surgeon, which contains the following particulars legibly written in ink: (i) the date it is written (ii) the name and address of the person to whom the stockfeed*

*is to be supplied (iii) the quantity of stockfeed to be supplied and the name and quantity of restricted drug in such stockfeed (iv) the period of treatment."*

What would replace these existing provisions in the new Act, or Regulations made under the Act? Let's look through the Medicines, Poisons and Therapeutic Goods Bill 2014.

Section 10 *"A **scheduled substance** is a substance prescribed by regulation …"*; *"…*[the] *regulation may prescribe a substance by reference to the Poisons Standard or another instrument …"*. Thus, scheduled substances include S4s and S7s.

Section 14 "*A person performs a **regulated activity** for a **scheduled substance** if the person does any of the following:*

*"(a) possesses the substance;*
*"(b) manufactures the substance;*
*"(c) supplies the substance;*
*"(d) administers the substance;*
*"(e) applies the substance;*
*"(f) gives a lawful direction to, authorises or asks another person to supply or administer the substance."*

Section 20 "*Meaning of **authority"***
*"A person has an **authority** to perform a regulated activity for a scheduled substance if the person –"*
*"(a) is an **eligible person** authorised by a regulation to perform the regulated activity for the substance "*

Section 36 *"Who is an **eligible person**"*
(1) (b) *"veterinary surgeons"*
(2) "***veterinary surgeon** means a person registered under the Veterinary Surgeons Act 1936"*

> In conjunction with Sections 14 and 20(a), one assumes that a veterinary surgeon will be authorised by a regulation to *"… give a lawful direction to … another person to … supply or administer the substance"*. After all, what is a veterinary prescription for if not to do that? One also assumes that the Mutual Recognition (Queensland) Act 1992 allows that the definition of veterinary surgeon for the purposes of the proposed Medicines, Poisons and Therapeutic Goods Act will include veterinary surgeons registered in other States and Territories of Australia.

Thus, a ***veterinary surgeon***, being an ***eligible person***, has the ***authority*** to perform the ***regulated activity***, for a ***scheduled substance***, of giving a ***lawful direction*** to a primary producer to ***administer the substance***. Furthermore, the ***veterinary surgeon***, being an ***eligible person***, has the ***authority*** to perform the ***regulated activity***, for a ***scheduled substance***, of giving a ***lawful direction*** to a manufacturer or wholesaler to ***supply the substance***.

For example, the scheduled substance could be an S4 medicated stock feed premix or an S4 medicated feed, being supplied to a primary producer who does not have a licence or approval other than the veterinary surgeon's "lawful direction" (a veterinary prescription).

What about the manufacturer/wholesaler? As far as supply is concerned, sections 40(c) and 41(b) limit the manufacturer and wholesaler respectively to:

*"supply the medicine or poison, primarily by wholesale, in the way stated in the licence to*
*"(i) a person who has an authority to possess, administer, supply or apply the medicine or poison; or*
*"(ii) a person who is a member of a class of persons stated in the licence;"*

However, it is pretty clear from the Bill that whilst the veterinary surgeon can give a lawful direction to supply or administer, that is not an "authority". So, can a veterinary surgeon really give a lawful direction to the manufacturer or wholesaler to supply the substance to a primary producer if the manufacturer or wholesaler is constrained by section 40(c) or section 40(d). OR, will the licence given to the manufacturer/wholesaler list primary producers in the "*class of persons stated in the licence*"?

Would a statement on the licence, such as that already quoted above ("*Where the stockfeed is a restricted drug it shall only be supplied on the signed written order of a veterinary surgeon, …")* be taken to be "*the way stated in the licence*", which would provide an alternative means of complying with sections 40(c) or 41(b)? Although, if the manufacturer held an AgVet GMP licence in lieu of a Queensland manufacturer's licence, such a condition would not be stated on the AgVet licence so could not be relied on to supply, and so this could only apply to 41(b) and not 40(c). And anyway, as mentioned in question 2 above, there is an implication that the AgVet licence might only apply to the manufacture of registered substances for which the licence has been granted, leaving the manufacturer to still require a Queensland manufacturer's licence for other non-registered, and yet still S4 stockfeeds and stockfeed components.
==========End comment==========


BEC is a leading supplier of animal nutrition to the stock feed industry

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Timothy

Surname: Logan

Organisation and/or Professional position: Queensland Branch President, Pharmacy Guild of Australia

Postcode: 4004

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☒ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☒ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

The Pharmacy Guild of Austrlia (Queensland Branch) [PGAQ] welcomes th opportunity to provide feedback on this draft of the Medicines, Poisons and Therapeutic Goods Bill (the Bill). The Bill is clearly designed as a framework Act, which largely leaves the technical details of most subject areas (other than the coercive powers of officers) left to subordinate legislation, and so our comments are made within those limits.

PGAQ submits that the Objects of the Act as detailed in the draft Bill are appropriate in that they identify that certain substances should be controlled; that certain competencies are necessary to safely deal with those substances; and that authorities, licences, approvals, standards, monitoring and enforcement will be necessary to achieve the safe outcomes that these controls are designed to deliver

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

PGAQ submits that safe use of scheduled medicine requires regulation, and that regulation requires investment by the state as well as stakeholders, including authorised persons and consumers. The PGAQ acknowledges that the Bill's recognition of compliance with other regulatory schemes, and development of and compliance with independantly assessed Quality Assurance systems concerning the handling of scheduled substances by authorised persons can reduce the regulatory burden on business without undermining public health and safety. PGAQ submits that the state needs to take this opportunity to achieve a degree of consistency with other jurisdictions regulation of medicines to allow for a more national approach (eg premises registration for pharmacy businesses to permit monitoring those premises for compliance to the new Act and regulations)

PGAQ has seen no information about where the current Pharmacy Business Ownership Act will fit into this legislative scheme

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

PGAQ submits that it is vital for the drafting of the legislation and subordinate regulation to be carried out in such away that the evolution of e-health initiatives in terms of communication and recording of information and orders for regulated medicines are not unintentionally prohibited.

Coupled with this is the importance of ensuring that consumer choice around access to prescribed medicines is not impeded by the potential for electronic messages to be channelled to a provider associated with the prescriber.

In a similar vein, PGAQ submits it is important to maintain the safety benefits and consumer protection of ensuring that the functions of prescribing and dispensing a scheduled medicine are kept separate to allow for independent review of the prescription, and ensuring competition by maintaining consumer choice in medicine providers.

We also submit that it is important for the State to be aware of the location of health resources and significant stockholdings of scheduled medicines, such as at hospitals, manufacturers, wholesalers and pharmacies, and have a capability of monitoring and enforcing compliance with the requirements of the Act and any subordinate regulations.

The PGAQ submits that there should be a requirement for any class of person who supplies, administers or applies an S2, S3, S4 or S8 medicine to keep records to generate an audit trail of medicine usage, and also to ensure medicines that enter the possession of an end user for later use in these categories are appropriately labelled

On:

(a) one construction of clauses 36 and 37; and

(b) the way the term ‘registered health practitioner’ is defined

it could be argued that all registered health practitioners constitute a class of person that can perform regulated activities and that regulated activities can only be assigned to (amongst others) ‘registered health practitioners’ and not to, for example ‘pharmacists’.

So this intention can be delivered, PGAQ seeks confirmation that, given the way the definition of registered health practitioner contained in the Dictionary to the Bill is used in paragraphs 36(1)(a) and 37(1)(b), sections 23 and 24 of the Statutory Instruments Act 1992 can be used to allow a subclass of registered health practitioners (pharmacists) to be identified in regulations made for the purposes of the Bill that deal with the traditional functions usually performed by pharmacists.

If this is not clear, relevant provisions contained in the Bill should be redrafted to remove any doubt that the outcomes contained in the Background Paper extracted above can be given effect.

PGAQ wishes to highlight the consumer safety risks inherent in permitting prescribers to increase the rate at which they may supply or dispense (under this Bills's definition of dispensing as entering a supply in a medical record), in which case there is no 3rd party oversight of the appropriateness and safety of the medicine, especially in light of what other medicines the patient may have used in the past, or currently uses, prescribed by other prescribers

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

The PGA submits that controls without monitoring, verification and enforcement will NOT achieve the objects of the Act in respect of the public safety accountability of authorised persons dealing with scheduled medicines. This has been demonstrated by the failure of the Pharmacy Business Ownership Act to require the state to verify statements of equity positions of persons operating Pharmacy Businesses, or that these Pharmacy Businesses have the requisite equipment and storage requirements for the safe handling and storage of scheduled medicines. The PGAQ submits that a 5-year review for a scheduled substance management plan is too long, and that 2-3 years is a more appropriate timeframe.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

PGAQ re-iterates that these comments are made within the limits of only having seen one part of the legislative scheme, and that the content of the Regulations is vital to assess the overall impact of the review.

The PGAQ is not clear that the effect of s28 (2) (b) authorises a teacher at a school, or an employee of a day-care centre administering a scheduled medcine to a minor after being requested to do so by the minor's legal guardian

s32 does not appear to reference the misuse of an electronic token or certificate to access an electronic prescription

s42 (2) (e) refers to 'a rural or isolated area ' but the dictionary has no definition of this, nor is there a schedules detailing towns in this category;

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

##*NOTE* This template has locked my ability to record my response to Question 6 in the space above due to locking of the document by the software in that space; andswers to both Question 6 and 7 will appear here, appropriately labelled##

##Question 6: PGAQ submits that the draft definition of supply is of such a broad nature that difficulties in interpretation of an activity as dispensing as opposed to another category of supply could occur without careful drafting of the subordinate regulations.

PGAQ also submits that the current exemptions to the definition of manufacturing that appear in s4 of the Health (Drugs & Poisons) Regulation 1996 should be utilised in either this Bill or the subordinate regulations##

##Question 7:

Quality Care Pharmacy Program;

Pharmaceutical Society of Australia's Professional Practice standards;

Pharmacy Board of Australias Codes and Guidelines

Australian General Practice Accreditation Limited##

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes, provided PGAQ's concerns about electronic tokens for access to electronic prescriptions are included in the scope of the Bill

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

From the point of view of a pharmacist owning and operating a pharmacy business, the narrowness of the definition of wholesaling needs to be addressed to permit efficiencies of sourcing scheduled medicines when quantity purchased influences landed price. We submit that the final draft of the bill be amended to permit a pharmacist who owns a pharmacy to deal with another pharmacist who owns a pharmacy in terms of purchasing scheduled medicines, where that is a minor component of their business activity (the primary focus being the practice of pharmacy at a pharmacy business).

Similarly, it is impractical and financially onerous for licenced wholesalers under this Act to deal with all medical practices and aged care facilities due to the small volume and irregular and unpredictable nature of their demand for scheduled medicines. We submit that the final draft of the Bill be amended to permit a pharmacist who owns a pharmacy business to deal with medical practitioners (and other authorised health practitioners, as regulated) and aged care facilities in terms of purchasing scheduled medicines for administration, application or supply as authorised by the Act and its subordinate regulations, where that is a secondary focus of their business (the primary focus being the practice of pharmacy at a pharmacy business)

PGAQ has no comment on the level of regulations applying to wholesalers and manufacturers (having dealth with the exemptions applicable to modern pharmacy practice we have mentioned in this submission), so have no comments on those licences

11. Are the proposed licences, approvals and other authorisations appropriate?

PGAQ re-iterates that, not having seen the full suite of legislation including subordinate regulations, our comments have that limitation.

We re-iterate our comments for Question 10, above

Additionally, it needs to be clear that repacking of medicines by an authorised dispenser, appropriately labelled, from the original manufacturers pack into smaller dispensed quantities is NOT manufacturing under the Act

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

PGAQ sees no issues to highlight for this question

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

PGAQ sees no issues to highlight for this question

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

PGAQ has little interaction with this part of the regulatory scheme, but its commercial experience suggests 6 months is a common transition period

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

PGAQ submits that the process of a pharmacist manufacturing scheduled medicines in compliance with a professional standard for individual patient use should not come under the registration provisions of the Therapeutic Goods Act

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

As long as the issue PGAQ has raised in Question 15, above, is addressed in the final draft of the Bill, no.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

As long as the issue PGAQ has raised in Question 15, above, is addressed in the final draft of the Bill, PGAQ has little interaction with this part of the regulatory scheme, but its commercial experience suggests 6 months is a common transition period

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

PGAQ has developed, in conjunction with all professional pharmacy representative and regulatory bodies, the Quality Care Pharmacy Program [QCPP] which sets standards against all aspect of operating a pharmacy business in a safe, lawful and financially viable and responsible way. Assessment occurs via independant assessors every 2 years, with a yearly self-assessment required for continued accreditation. The QCPP requires individual pharmacists working in the pharmacy business to be assessed against the Professional Practice Standards [PPS] - both the QCPP and PPS are recognised by the Pharmacy Board of Australia, and by the commonwealth Department of Health for various aspects of the Fifth Community Pharmacy Agreement, and the preceding Agreements since 2000. We submit that this accreditation scheme includes a scheduled substance management plan, and has been recognised as a quality standard as erquired for various sections of the Health (Drugs & Poisons) Regulation 1996. Accreditation schemes other than this as they apply to pharmacy businesses should be required to

- be assessed and approved as a Conformity Assessment Body accredited by either Joint Accreditation System of Australia and New Zealand (JAS-ANZ) or International Society for Quality in Healthcare (ISQua)
- only utilise assessors who have completed the training requirements of a recognised body for the accreditation of quality management system auditors, such as RABQSA
- provide equitable access and equal opportunity for all community pharmacies, to be assessed against the Standards regardless of their geographic location, such that they can provide accredited services to the communities they serve

PGAQ suggests that, in addition to pharmacy-oriented management plans, these concepts apply to other health professionals dealing with scheduled medcines as poart of their practice

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

PGAQ advises that the cost of a plan incorporating Pharmacy business development and maintenance of a Quality Assurance system that encompasses a scheduled substance management plan is typically in the range of $7500 per annum for an average pharmacy business (includes accreditation subscriptions, assessment fees, and labour in developing the plan). As this type of Quality Assurance is also required for certain services and activities carried out by s90-approved pharmacies under the National Health Act 1956, within the parameters of the 5th Community Pharmacy Agreement, these costs are already part of the operating expenses of the vast majority of pharmacy businesses

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

PGAQ submits that any authorised person dealing with any class of scheduled medicine should have a scheduled substance management plan within 90 days of this Act taking effect

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

PGAQ is agnostic about the nature of the relationship between the State and an auditor; PGAQ submits that all health practitioners dealing with scheduled medicines be visited by an auditor biannually, with more frequent visits if compliance is not demonstrated or achieved. PGAQ submits that failure to adequately monitor compliance with the requirements of this Bill and its subordinate regulations will allow for economically-inspired non-compliance to develop across a variety of professions by persons seeking to minimise operating costs without patient safety as a guiding principle

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

PGAQ submits that Quality Assurance accreditation should be considered by auditors as part of their scope, but that random visits by auditors are still necessary to detect compliance lapses to ensure safe use and access to medicines by the public

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

PGAQ submits that regulation should ensure that streamlining of regulation does not allow for a relaxing of standards of storage of scheduled medicines; advertising of scheduled medicines; labelling of supplied medicines; premises and equipment requirements for dispensers; qualifications of suppliers, administerers, appliers and dispensers. We submit that any regulation of dispensing checkers or pharmacy assistants makes clear that an authorised person such as a pharmacist is accountable for supervision of their protocols and performance

PGAQ also notes that paragraph 164(2)(f) allows the Chief Executive to make standards about 'requirements about other ways to perform regulated activities.' PGAQ submits that this paragraph is so vague as to be uncertain. Given that subclause 164(6) provides that the principal Act or regulation will prevail where there is inconsistency, it is difficult to ascertain what is the 'first way' a person is to perform regulated activity that can be avoided through following a standard made under paragraph 164(2)(f). PGAQ suggests redrafting so as to make what is intended clear.

PGAQ requests that the matters for which standards can be made (generally) and the matters contained in paragraphs 164(2)(a),(b) and (f) (particularly) should be assessed against the fundamental legal principles contained in section 4 of the Legislative Standards Act 1992, particularly paragraphs 4(5)(c), and in the case of paragraph 164(2)(f) of the Bill, that it satisfies paragraph 4(3)(k) of the Legislative Standards Act.

The Background Paper suggests that standards can be made with respect to 'prescribing dispensing and administering medicines.' It is difficult to see how subclause 164(2) of the Bill would permit standards being made in these areas. The Guild seeks advice on this point as to how a standard could be made with regards to these subject matters

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: Translational Research Institute (TRI)

Postcode: 4102

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☒ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes, they seem appropriate

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

This bills seems to reduce regulatory burden for stakeholders, while maintaining public health. I belive it is still lacking in provision for corporations / institutions with multiple entities, that may in fact increase the burden within these types of organisations. In the university and medical research fields, cost savings and other efficiencies have now been gained using a shared or cooperative approach, smaller research groups have all contributed to significant infrastructure projects and there are now a number of managed organisations where limited research funding can be combined and shared to enable access to better resources. Under this bill it seems the managing entity would become a supplier and each entity in the venture would have to hold their own relevant authority, this is an additional burden for essentially a single managed building. A single releant authority should be able to reflect all the parties using it at the premises.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Under the proposed authorisation of eligible persons / applicants, there is a concen that the requirement for criminal history checks are onerous and will lead to significant delays in processing approvals - this has been an issue with changes to other legislation, including the Radiation Safety Act. If a criminal history check is required for all approvals this may become unworkable. As an alternative, providing proof of identity (100 points - certified documents etc..) would cover the traceability aspect, this with an assurance on the application that the regulator must be notified if any of the listed offences have been committed.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

Disposal is always one of the biggest concerns for public safety. I assume this will be handled in the regulation / standards, so is too early to be able to comment on this.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Where will individuals who are not employed by an organisation who has a substance management plan fall (ie students doing research at a university)? Will they be covered like a 'employee' and be able to do a regulated activity if outlined in the organisations plan? It would be simplest for us if they were essentially treated like 'employees' (similar to how the WHS legislation covers them).

If people from one organisation (covered by a substances management plan) are working in a building owned and managed for them by a different organisation (covered by their own plan), which plan should those people work to? From a practical point of view, if those two organisations are able to come to an arrangement then people could potentially work from one or the other (or even parts of both). administering and having to maintain multiple plans in this cirumstance would be costly and confusing.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

The definitions in the bill are fairly clear. I belive there should be more definition of a supplier and an additional category for an agent. Where a managing entity is soley tasked to manage the purchase (on request only) of scheduled substances by another entity on their premises, as in the situtaion described in Q2, this is not exaclty what the bill is refering to as a supplier. And in this situation being defined as a supplier may be more onerous or a disadvantage. This may lead to having to decentralise, instead of centralise for efficiencies.

As for other standard and codes that apply to our inducsty to protect public health we are heavily regulated by the following:

Gene Technology Act (Ofiice of the gene technology regaultor)

Quarantine Act (Department of Agriculture)

Work Health and Safety Act (QLD)

AS/NZS 2243 Safety in laboratories

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

As long as supply from one authories person to another authorised person is not an offence

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Approvals are clearer in this bill, but in our case it would not reduce the number of approvals needed unless a true multiple entity approval and plan for a premises. Under section 81 it allows for issuing jointly to more than one person, this should be extended to more than one entity.

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes, appart from the need for criminal history checks for all applicants.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

No, I believe the criminal history checking will add unnessesary delays to applications. This could be managed by providing certified identification and an obligation in the Act that they must report any convictions.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

We would already have many of the required items and processes in place. Some of which would need to be more formalised in new policies and procedures. Similar systems are in place for Radiation management already.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

Main cost would be the time for people to do it. We would already have the requisite knowledge in house.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

12 months

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Possibly for situations where people are working with prohibited substances.

Outside of that then allowing organisations to self audit would reduce government time and costs.

External auditing while meeting timeframes has it's own problems if the auditors are not properly qualified, or if there is the additional burden of cost recovery for the audits.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Self auditigs and annaul reporting could help increase complience.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

These standards can be very useful provided they are not written in an overly prescriptive way. It has been more beneficial to us in the past if standards can give us practical guidance and put the onus on us figuring out specifics of how we will do that.

ie saying 's4 substances must be secured in such a way that the public cannot access them' and letting us figure out how to do that is much better than saying 's4 substances must be located in a lockbox which is secured to the wall'.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Matthew

Surname: Griffiths

Organisation and/or Professional position: Royal Brisbane and Women's Hospital, Directoir of Sciences Department ofNuclear Medicine (physics and radiochemistry)

Postcode: 4029

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☒ Hospital
- ☒ Industry - medicines
- ☐ Industry - poisons
- ☒ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: matthew.griffiths@health.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Could you please outline if this bill has any impact on the status of radio pharmaceuticals administered to patients under the direction of a radiologist or nuclear medicine physician under the radiation safety act? This includes both the manufacture and administration of radio pharmaceuticals.

Could you please outline if this bill has any impact on the practice of administration of non-radioactive materials by IV injection or orally to patients as part of a diagnostic imaging process approved by a nuclear medicine physician or radiologist? This includes non-pharmaceutically active materials required for nuclear medicine and contrast agents for diagnostic imaging.

Could you please clarify if a nuclear medicine scientists, as registered health practitioners, would be entitled under this bill to apply for permission to possess, administer etc, scheduled drugs that are currently only allowed to be prescribed/administered by medical practitioners or registered nurses.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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## Julie Stokes

**From:** Legislation
**Sent:** Thursday, 2 October 2014 4:03 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Medicines, Poisons and Therapeutic Goods Consultation Process Registration

Please see email below requesting inclusion in consultation

Cheers,
Kelly

---

**From:** Noel Gillard OAM [redacted]
**Sent:** Thursday, 2 October 2014 2:53 PM
**To:** Legislation
**Subject:** Medicines, Poisons and Therapeutic Goods Consultation Process Registration

St John Ambulance Australia Queensland requests registration for inclusion in relevant and ongoing consultation in the development of regulations consequent to the passage of the Medicines, Poisons and Therapeutic Goods Bill 2014 .

St John Ambulance is awarded current power in the existing Regulations and possesses Section 18 Licences in support of its current industrial health and community based Emergency Event Health and First Aid services provided throughout Queensland.

The St John Ambulance Australia Queensland contact is Noel Gillard at the contact points below.

Noel Gillard
General Manager - Community Services
St John Ambulance (Qld)

P: (07) 3253 0571 | F: (07) 3253 0599 | [redacted]
W: www.stjohnqld.com.au
225 St Pauls Terrace | PO Box 1645 | Fortitude Valley Qld 4006

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Lisa

Surname: Nissen

Organisation and/or Professional position: President - PSA Qld Branch

Postcode: 4102

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☒ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes, we believe so

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Yes, we believe so

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

We do not have any concerns so long as the subordinate regulations capture the following:

1. an ability whereever possible to maintain a separation between dispensing and prescribing

2. that there is a requirement for strict audit trails for any person who supplies, administers or applies an S2, S3, S4 or S8 substance

Subordinate regulations should also ensure that they are an enabler of e-health initiatives whilst balancing the need for privacy and security of the public and practitioners

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

The Act and subordinate regulations should ensure that there is a necessity to monitor practice and include enforcement measures to protect public safety.

We believe that a 5 year review for a scheduled substance management plan is too long as inappropriate practices can become embedded and difficult to reverse. We would welcome a 2 to 3 year review

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

This is a major change to the legislative framework and it will take the profession some time to digest and become accustomed to.

We would be keen to see what the timeline is for implementation and what the communication plan is to the profession. We would suggest that it is imperative to work with the profession through PGA, PSA and SHPA to ensure all parts of the profession, including pharmacy support staff are aware of changes.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Quality Care Pharmacy Program

PSA Professional Practice Standards

PSA Code of Ethics

Pharmacy Board of Australia's various codes and guidelines

Australian Standards for Safety and Quality in Health

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes, we believe so

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes, we believe so

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

We believe that the new legislation provides a more streamlined approach to licencing

11. Are the proposed licences, approvals and other authorisations appropriate?

There needs to be clarity around the standard practice in pharmacy of preparing Dose Administration Aids that enhance compliance. It should be clear that this is not considered "manufacturing".

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Yes

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Usually 6 months is appropriate.

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

We believe that extemporaneous dispensing for individual patient use should NOT be considered under the definition of "manufacturing".

It should be noted that this particular area of professional practice is currently under review by the Pharmacy Board of Australia

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No, as long as the issue in Q15 is addressed

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Usually 6 months is appropriate

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Both community and hospital pharmacy sectors have quality assurance and accreditation programs that adequately cover this issue. For example QCPP in community pharmacy.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

We have no comment as this is not our area of expertise

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

We would suggest 60 to 90 days.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Yes, we are comfortable with this approach

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Whilst current accreditation instruments deal with this adequately, we would support random audits as part of an evaluation process

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

It is important that the current standards in HDPR are maintained and potentially enhanced, particularly around supply, storage, advertising, dispensing, equipment and premises requirements.

We believe there is an opportunity to clearly define qualifications and responsibilites for pharmacy support staff.

We would encourage taking this opportunity to align our definitions with other jurisdictions for continuity of practice across the country

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

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METRO NORTH BRISBANE
Connecting health to meet local needs

# Medications Bill Feedback
# Additional Information

***Question 6***

The term chief executive is used extensively throughout the Bill and a definition would be helpful.

***Question 23***

The following is the proposed addition for medical assistants - Section 58 "C" of the Health and (Drugs and Poisons) Regulation 1996:

*Medical assistants*

*(1) To the extent necessary to practise medical assisting, a medical assistant is authorised to—*

*(a) possess a controlled drug at the place where the medical assisting practises medical assisting; or*

*(b) administer a controlled drug, other than an anaesthetic—*

*(i) on the written instruction of a dentist, doctor, nurse practitioner, physician's assistant or surgical podiatrist; and*

*(ii) under the supervision of a dentist, doctor or registered nurse; or*

*(c) administer a controlled drug to a person for whom it has been dispensed and under the supervision of a dentist, doctor or registered nurse.*

*(2) Subsection (1) does not apply if the registration of the medical assistant is subject to a condition that the medical assistant is not qualified to administer controlled drugs.*

*(3) Subsection (4) applies to a person (a trainee) who is undergoing a course of training, the successful completion of which will qualify the trainee to practise as an medical assistant.*

*(4) To the extent necessary to undergo the course of training, the trainee is authorised to—*

*(a) possess a controlled drug under the direction of a doctor or registered nurse at the place where the registered nurse practises nursing or the doctor practises medicine; or*

*(b) administer a controlled drug, other than an anaesthetic—*

*(i) on the written instruction of a dentist, doctor, nurse practitioner or physician's assistant; and*

*(ii) under the personal supervision of a dentist, doctor or registered nurse; or*

*(c) administer a controlled drug to a person for whom it has been dispensed and under the personal supervision of a dentist, doctor or registered nurse.*

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**Medicare Locals gratefully acknowledge the financial and other support from the Australian Government Department of Health**

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: Metro North Brisbane Medicare Local [redacted]

Postcode: 4030

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes, however these objectives can be further achieved appropriately utilising the skills of medical assistants, as set out in our responses to questions 5 and 23.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Yes, subject to our responses to questions 5 and 23.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

It is important to be aware that general practice has its own standards which address aspects of the scheduled substance management plan required under Part 6 Division 1 of the Bill. It would be viewed as unwelcome and superfluous red-tape if general practice were to be required to develop a scheduled substance management plan in addition to requirements to meet the current RACGP standards. (See also response to question 7)

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

N/A

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Section 5 of the Bill sets out the various ways the objects of the Act are to be achieved. Items (b), (c) and (d) can be further achieved by including 'Medical Assistants' in the definition of eligible persons in section 36, and allowing medical assistants to perform regulated activities (including to possess, supply and administer) for certain scheduled substances. Medical assistants have successfully performed regulated activities involving scheduled substances in other jurisdictions, including the United States of America, for a number of years. We note that other health professionals, including first aid providers, orthoptists and physician's assistants are considered 'eligible persons' in certain circumstances. These health professionals are required to complete study requirements and training, can apply to be registered and must undergo continuing education to maintain these skills.

Medical assistants in Australia are currently required to complete a Certificate IV in Medical Practice Assisting. Given the pressures and shortages facing the medical profession, appropriately utilising the skills of medical assistants would in our view help to further streamline the regulatory controls and create a more responsive and outcomes-focussed regulatory framework.

We propose that medical assistants, who have completed the requisite Certificate IV in Medical Practice Assisting (including medication specific competency electives) and undertake ongoing continuing education, be eligible to be a 'Medical Assistant'. A medical assistant would then be considered an eligible person who is able to perform certain regulated activities, subject to any restrictions or conditions that are considered reasonable. Medical Assistants who have not completed medication specific competency electives would have a specific notation on the public register of medical assistants stating that the person does not hold approved qualifications in medication administration.

In our view these regulated activities would be similar to the authorisations currently afforded to enrolled nurses under section 58A of the Health (Drugs and Poisons) Regulation 1996.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

General practice has its own standards developed by the Royal Australian College of General Practitioners. These are referred to as the "RACGP Standards for general practices 4th edition" and can be found here:
http://www.racgp.org.au/download/documents/Standards/standards4thedition.pdf .

Standard 3 relates to safety, quality improvement and education, including sections on clinical risk management systems, clinical governance, and qualifications of the clincial team. Standard 5.3 details criterion in relation to safe and quality use of medicines, vaccine potency, and healthcare associated infections.

General practices are accredited nationally through AGPAL (http://www.agpal.com.au/) and GPA (http://www.gpa.net.au/). Accreditation to the standards is for a three year period. The standrads are universally accepted, and whilst accreditation is not mandatory, approximately 70% of all Australian general practices are accredited to the standards.

In relation to immunisation, the accepted standard is "The Australian Immunisation Handbook 10th Edition" http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home . The handbook covers vaccination procedures and the administration of vaccines in Chapter 2.

In relation to medications, MIMS guides in both hard and electronic copy are available in general practice to support the safe administration of medications by providing up-to-date evidence based product information, identification, patient information, and interactions.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

N/A

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

N/A

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Yes, however this can be further improved. Please refer to our responses to questions 5 and 23.

11. Are the proposed licences, approvals and other authorisations appropriate?

As above

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

As above.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes. It should be noted that in some cases registered health practitioners have already undergone a criminal history check as a prequisite for registration with the relevant body. It should also be noted that for ongoing registration updated police checks are usually not required, and the practitioner signs the renewal form stating that there have been no changes since their last renewal.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

N/A

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

N/A

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

N/A

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

N/A

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Refer response to question 3.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

Depending on the level of detail required, the cost to general practice could be significant. However, following the RACGP standards is a suitable and no cost alternative for general practices.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

A transitional period of up to one year.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

N/A

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Entities and providers that meet the standards of existing auditing schemes, such as accreditation to the RACGP Standards, should be assumed to meet the requirements of the legislation.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

With the increase in chronic disease, an ageing population and recognised workforce shortages, primary care is facing real challenges to meet patient demand for access to services. Keeping patients well and out-of-hospital can only be achieved by providing patients access to the best care when they need it. Over the past 50 years, the role of the medical assistant has developed outside of Australia, and since 2007 the course has been offered in Australia as part of the National Health Training Package through the Certificate IV in Medical Practice Assisting. Medical assistants are formally trained to provide a flexible primary care workforce option to support administrative and clinical functions within a general practice: releasing nurses and doctors to undertake higher clinical duties appropriate to their training.

Currently, medical assistants are taught in the Cert IV course that they are not allowed to administer scheduled medications under the laws of some states and territories. They are trained and do administer Vitamin B12 injections, as this is not a scheduled medication.

As set out in our response to question 5, with appropriate formal training, clinical governance and supervision, medical assistants could undertake regulated activities similar to those found in Section 58A of the Health (Drugs and Poisons) Regulation 1996.

Surveys of general practice employers, medical assistants and their nursing and practice management colleagues have been conducted and show that there is strong support from the general practice sector for legislation to be changed to allow medical assistants to administer medications that are commonly found in general practice settings including, but not limited to:

-topical medications for wound care, such as medications applied to burns or impregnated within wound care products;

-inhaled medications including for nebulisation or emergency situations, eg oxygen, metered dosage aerosols such as ventolin or nitro-lingual spray;

-injected medications such as immunisations (including childhood, travel and flu vaccines);

-instilled medications such as eye drops;

-oral medications as prescribed by the doctor to treat presenting conditions.

Medical assistants work under appropriate clinical governance and supervision in ambulatory care environments and only carry out tasks as delegated by appropriately qualified supervisors. Additional units of competency could be added to the Cert IV in Medical Practice Assisting to cover the additional knowledge and skills necessary to administer medications in a supervised primary care environment.

Medical assistants who have gained the appropriate nationally-recognised qualification could then undertake regulated activities similar to those found in Section 58A of the Health (Drugs and Poisons) Regulation 1996.

Metro North Brisbane Medicare Local would be pleased to offer its Clinician's Advisory Group of 10 GPs to develop and provide industry feedback on proposed legislation and regulations in regards to medical assistants.

To that end we request that medical assistants be listed in the regulations as eligible persons in the class of health professional as outlined in s36(2) of the Bill, and that the regulations be developed to authorise medical asistant to perform regulated activity similar to those found in Section 58A of the Health (Drugs and Poisons) Regulation 1996.

The following is the proposed addition for medical assistants - Section 58 "C" of the Health and (Drugs and Poisons) Regulation 1996:

Medical assistants

(1) To the extent necessary to practise medical assisting, a medical assistant is authorised to—

(a) possess a controlled drug at the place where the medical assisting practises medical assisting; or

(b) administer a controlled drug, other than an anaesthetic—

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

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## Julie Stokes

**From:** Legislation
**Sent:** Friday, 3 October 2014 8:44 AM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Feedback Medicines, Poisons and Therapeutic Goods Bill 2014 - feedback

**From:** [redacted]
**Sent:** Thursday, 2 October 2014 10:25 PM
**To:** Legislation
**Subject:** Feedback Medicines, Poisons and Therapeutic Goods Bill 2014

To whom it may concern,

I am a clinical pharmacist practicing in a tertiary public hospital in Brisbane. I would like to provide feedback regarding the proposed legislation replacing the Health Drugs and Poisons Regulations.

In general I have concerns that the legislation is not specific in what is expected for many activities. I understand that the new legislation has been drafted in such a way to be less definitive and more flexible. While I agree certain flexibility would be useful to enable entities to write their own management plans for certain activities regarding scheduled drugs for activities that have low risk to the public.

There are some core regulated activities that I believe should be clearly defined in their requirements. In particular regarding the management of medicines. In the absence of specific requirements being detailed by legislation, the success of the new draft legislation will rely heavily on scheduled substance management plans being appropriate and I am unclear from the legislation on who will be assessing these.

For example under the current legislation I can clearly see that a prescription cannot be dispensed if it is more than 12 months old (section 193, 2f). Under the draft legislation it is not clear. If the scheduled substance management plan at my hospital stated 'Pharmacists may dispense any prescription irregardless of when it was originally written' than I could legally do so even though it would not be in the best interests of the public. Without descriptive legislation to guide entities in writing scheduled substance management plans there will likely be a large variation in how many aspects of managing medicines will occur (i.e. prescribing, administering, dispensing).

Requiring each entity to have a scheduled substance management plan seems to create significant paperwork. Previously entities only needed to ensure they met the requirements of the health drugs and poisons regulations which were very description.

The current legislation has many aspects that are out of date. For example, an entire appendix was dedicated to the storage of controlled drugs (schedule 8 medications) including such detail as the thickness of the steel plate. While sections of the current legislation could certainly use modernising and simplification there are some elements I feel should be kept. For example, clearly defining what should be on a prescription.

Many activities no longer appear to be required by legislation. For example under the current legislation I am required to keep a balance of schedule 8 medications and have a record of all dispensings in a physical book. This can be inspected by as required to ensure I am keeping appropriate records, that stock is clearly being monitored and that any discrepancies such as stock going missing are reported. Also amendments that were added to required extra details to be recorded when supplying psuedoephedrine containing products to avoid misuse are no longer required by legislation.

I have concerns that the proposed legislation is not clear in defining what regulated activities specific eligible persons can perform. For example prescribing a medication is a regulated activity and as a pharmacist who is a eligible person I could legally write a prescription as far as I can tell from the legislation. It would be clearer if the regulated activities each eligible person could perform was clearly stated.

My final concern is regarding the director general's ability to effectively suspend health practitioners under section part 5 of the draft legislation. This is a duplication of the Australian Health Practitioner Regulation Agency (APHRA) who already have the power to immediately suspend health practitioners if there is sufficient grounds. I am of the opinion that the members of APHRA are better qualified to make assessments of the appropriateness of a health professionals behaviour than the chief executive who may not have any actual tertiary training in health.

In summary while I support the modernisation of legislation I feel the current draft of the replacement legislation is not descriptive enough and would rely heavily on appropriate scheduled substance management plans. Significant variations in how medicines are managed throughout Queensland could occur as different organisations may have very different scheduled substance management plans.

Sincerely,

| | |
|---|---|
| Prepared by: Dr David Mills<br>Title: Principal Project Officer<br>Division/ Region: Corporate Services<br>Telephone: 3330 5940<br>Date Prepared: 2/10/14 | Approved by: Peter Griffin<br>Title: Assistant Director General<br>Business Unit: Corporate Services<br>Telephone: 3339 5800<br>Date Approved: |

Our Ref: CTS 23803/14
Your Ref: DG075004

Ian Maynard
Director-General
Department of Health
GPO Box 48
BRISBANE QLD 4001

Dear Mr Maynard

Thank you for your letter of 23 September 2014 concerning consultation on the draft Medicines, Poisons and Therapeutic Goods Bill.

The Department of National Parks, Recreation, Sport and Racing (NPRSR) notes this new legislation will remove potential areas of regulatory duplication, promote national consistency and streamline approval and permit requirements.

There are provisions in the new legislation that could impact a range of activities carried out by NPRSR, such as:

- the use of poisons by departmental staff for pest management in national parks; and
- policy development for the Queensland Academy of Sport.

In order to better clarify the implications of the new legislation for NPRSR operations, further consultation is requested with the following departmental officers:

- Tod Kelly, Manager, Policy and Legislation, Queensland Parks and Wildlife Service on telephone (07) 3199 7606 or via email todd.kelly@nprsr.qld.gov.au
- Paige Ridgewell and Mandy Downes, who share the role of Director, Policy, Research and Planning, Sport and Recreation Services on telephone (07) 3338 9212 or via email paige.ridgewell@nprsr.qld.gov.au and mandy.downes@nprsr.qld.gov.au.

Should your officers have any further enquiries, please have them contact Dr David Mills, Principal Project Officer, Governance and Strategy on telephone (07) 3330 5940 or via email david.mills@ehp.qld.gov.au.

Yours sincerely

John Glaister
**Director-General**

30 September 2014

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
PO BOX 48 BRISBANE QLD 4001

Email: legislation@health.qld.gov.au

To whom it may concern

RE: *Orthoptics Australia* response to draft Medicines, Poisons and Therapeutic Goods Bill 2014

Orthoptists employed in Public Hospitals and Private Clinics in Queensland are essential members of the eye care health teams working in eye clinics. Their current practices contribute to the efficient running of the clinics and the orthoptists knowledge ensures an optimal level of patient care. In addition, the Australian Orthoptic Board manages the registration and continuing professional development program. Currently, orthoptists registered with the Australian Orthoptic Board are endorsed to administer Schedule 4 drugs under a Drug Treatment Protocol (DTP) and have developed the required Hospital Management Plan (HMP).

Our understanding is that orthoptists are considered 'Eligible persons' under Part 3, Division 1 of the draft bill and the entity (e.g. Hospital and/or Private Clinic) develops the Scheduled Substance Management Plan. However, we are unclear as to the meaning and competencies of 'physician's assistants' (Division 1, Section 36(2)) and would like further clarification of this definition. We are concerned that physician's assistants have neither demonstrated training nor competencies, as required by the act.

The position of Orthoptics Australia is that we would prefer close consultation with orthoptists and effective monitoring of entities for compliance to keep our members and patients safe. Therefore, with regards to Part 6, Division 1, 97(b) our preference is for a shorter plan review of not more than 3 years as opposed to not more than 5 years. Shorter reviews would better capture the changing health environment.

Thank you for your consideration.

Regards

*Meri Vukicevic*

Dr Meri Vukicevic
President
Orthoptics Australia

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THE UNION FOR QNU NURSES AND MIDWIVES

QUEENSLAND NURSES' UNION

# Submission to Queensland Health

## *Draft Medicines, Poisons and Therapeutic Goods Bill 2014*

October, 2014

Queensland Nurses' Union
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E qnu@qnu.org.au
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## Introduction

The Queensland Nurses' Union (QNU) makes this submission to the Queensland Department of Health regarding the draft *Medicines, Poisons and Therapeutic Goods Bill 2014* (the draft Bill).

The QNU represents all categories of workers that make up the nursing workforce in Queensland including registered nurses, registered midwives, enrolled nurses and assistants in nursing who are employed in the public, private and not-for-profit health sectors including aged care.

Our more than 50,000 financial members work across a variety of settings from single person operations to large health and non-health institutions, and in a full range of classifications from entry level trainees to senior management. The vast majority of nurses in Queensland are members of the QNU and our membership continues to grow.
The QNU supports a clear and concise articulation of the regulatory requirements for nurses that reflect best practice in the possession, supply and administering of medicines.

## Current Regulation

The *Health (Drugs and Poisons) Regulation 1996* (Qld) ('the Regulation') contains sections that are confusing and exploited as a result of terminology that is not well defined. The Regulation also contains some errors of fact.

Sections 74, 183 and 270 of the Regulation are collectively known as the 'carer provisions' and have been a source of dispute and debate in aged care for many years. When Queensland's Chief Health Officer posted 'Circular 03/98' in 1998 stating that it was not appropriate for the carer provisions to be utilised in a 'nursing home', aged care employer representatives lobbied Queensland Health to develop guidelines for carers to be able to assist aged care recipients to take their medicines in all settings.

Queensland Health subsequently drafted some carer guidelines, which provided some parameters for carers to assist with medication in low care facilities (formerly known as hostels), however the draft guidelines clearly stated that carers were not to be involved in medicine management in high care facilities. Debate regarding the content of those guidelines continued over a ten year period. In an attempt to break the deadlock in 2008, the then Deputy Director General circulated the draft guidelines to all Directors of Nursing of Queensland Government aged care facilities. The unanimous decision of those Directors of Nursing was that the involvement of carers in assisting with or administering medicines would create a high risk of medicines error and subsequent harm to residents, even if those carers were trained and educated in medicines management. As a result, the Chief Health

Officer decided not to endorse any guidelines for carers to assist with medicines in aged care. Draft guidelines have not been considered by Queensland Department of Health since that time.

The absence of any official guidelines for the Regulation's carer provisions, combined with poor drafting of the Regulation, has led to industrial and professional disputes regarding whether carers are assisting with medicines (helping to take) which does not require endorsement, or are actually administering medicines (giving the dose, as defined in the Regulation) which requires endorsement. A recent survey of our members, sampling a wide range of aged care facilities, indicates that many facilities engage assistants in nursing and personal carers to administer medicines under the guise of assisting a person to take their medicine.

Clarity regarding the role of carers assisting with medicines in residential aged care facilities, that reflects best practice in the quality use of medicines, is sorely needed. Such clarity can be found in professional nursing standards and guidelines, which we will elaborate on in this submission.

With regard to the errors of fact in the current Regulation, we draw your attention to sections 58A(2) and 162(2) of the Regulation, which state that an enrolled nurse is not endorsed to administer a controlled or restricted drug if the enrolled nurse's registration is subject to a *condition* that they are not qualified to administer medicines. This is an error of fact because enrolled nurses who are not qualified to administer medicines have a *notation* on their registration, not a condition.

## Draft Bill

The QNU's primary concerns in relation to the draft Bill are regarding the provisions relevant to 'eligible persons', the provisions relevant to 'scheduled substance management plans' and those relevant to 'Standards'.

### Eligible Persons

The draft Bill proposes that particular classes of persons will be authorised to possess and administer medicines because of their profession or occupation. The QNU is concerned that this provision, when combined with a scheduled substance management plan, will authorise assistants in nursing and personal carers to administer medicines, particularly in residential aged care facilities.

The administering of medicines is a common but high risk healthcare activity and that risk is not ameliorated by the location of the care recipient. Aged care is now a very complex area

of healthcare with many aged care recipients presenting with multiple physical and mental illnesses and disease, in addition to their inherent frailty, disability and variable mental capacity due to ageing. As a result, the potential harm from a medication error in an aged care facility is no less than the risk of harm from a medication error in an acute hospital.

The QNU is confident that the Department of Health would not permit assistants in nursing in the Royal Brisbane and Women's Hospital, or the Princess Alexandra Hospital, or the Prince Charles Hospital, for example, to administer medicines to patients. Similarly, we submit that assistants in nursing (however titled) should not be permitted to administer medicines to aged care recipients, except in compliance with professional nursing standards and guidelines.

We expect that many aged care employers will argue that their carers are trained and deemed competent in medicines management. However, the training provided to carers is not consistent across the sector, with some employers requiring carers assisting with medicines to complete an accredited unit of study, whereas some employers will provide carers with only a two hour in-service session and then deem them competent to administer medicines. However, even the accredited units of study for 'assisting clients with medication', such as those contained in Certificate III and IV in Aged Care courses, stipulate that the carer will provide residents only with physical assistance and support in self-administering medicines. The accredited unit in no way attempts or purports to prepare carers to administer medicines. The provision of assistance with medicines to residents who self-administer will be discussed in the section on Standards.

The QNU submits that, given the equitable nature of the risk in administering medicines, the minimum requirements for inclusion in the class of eligible persons to administer medicines should be consistent across all institutions, whether an acute care hospital, a rural facility, an aged care facility, or a prison. This consistency should be articulated that in such institutions, eligible persons for the possession, supply and administering of medicines must be registered health practitioners.

The provisions of section 36(1)(d)(iii) of the Bill which prescribe that a person may be classed as an eligible person because they are required to perform regulated activities due to their occupation creates an inappropriately wide interpretation that could enable persons with little or no training to possess, supply and administer medicines. Such a provision will permit persons without the appropriate knowledge and skill to engage in regulated activities, thereby creating a high risk of medication error and a high risk of harm to the public. Unregulated carers can be made aware of the correct procedures for assisting a self-administering client to take their medicine, however they do not have the requisite education and knowledge to make clinical judgments about when the medicine is required, or should not be administered, or any adverse effects that may be present. The QNU

submits that assistants in nursing (however titled) should not be included in the class of eligible persons to possess, supply or administer medicines.

The involvement of assistants in nursing and personal carers in assisting with (not administering) medicines must only be under certain strict conditions or circumstances described in a scheduled substance management plan that is compliant with a relevant professional Standard. The relevant professional Standard will be discussed in this submission.

**Scheduled Substance Management Plan (SSMP)**

The requirement for an institution to have an SSMP is a positive step in the quality use of medicines, however there remains concerns regarding the SSMP being a process of self-regulation with no provision for the auditing of the entity's compliance with the SSMP requirements under the Act or the SSMP's compliance with recognised Standards.

Self-regulation has potential to create risks of harm to the public when applied to the quality use of medicines. Those entities whose processes are open to public scrutiny are likely to comply with all aspects of the SSMP and not require auditing, however those entities who evade public scrutiny through claims that such information is 'commercial in confidence' have high potential to be less than conscientious in ensuring their SSMP complies with all aspects of the legislation, given that it will not be open to audit or any scrutiny, unless a complainant alleges non-compliance and an action is taken by the regulating body in the court of appropriate jurisdiction.

The QNU has been leading the way in Queensland in encouraging healthcare and aged care providers to comply with recognised professional standards of practice. We frequently find that employers, even though they are aware of a particular standard, are reluctant, or refuse, to comply with those standards due to the additional costs involved. It follows that such employers would have difficulty in self-regulation for the quality use of medicines.

Further, given that many aged care providers are prepared to apply very liberal interpretations to the current Regulation in order to minimise recurrent labour costs, an expectation that such entities would have capacity to appropriately self-regulate with regard to the SSMP is ill-conceived.

The provisions within the Bill that prescribe what must be in an SSMP include the persons to whom the plan applies and the training and instruction provided to those persons. The QNU submits that, for the same reasons described in the section above regarding eligible persons – registered health practitioners - this Part of the Bill should prescribe that the SSMP

applies to eligible persons and that only eligible persons may possess, supply or administer scheduled medicines.

**Standards**

The possession, supply and administering of medicines is a regulated healthcare activity that should be compliant not just with legislation and regulation, but also with professional standards and guidelines developed for the relevant health profession.

The draft Bill prescribes that the Chief Executive has the power to make standards relevant to regulate activities. The QNU submits that the Chief Executive should refer to standards and guidelines that already exist in healthcare sectors and prescribe that those standards apply to regulated activities in Queensland.

With regard to aged care, such a professional standard exists for the management of medicines in aged care. This standard was jointly developed by two professional nursing associations, then known as the Royal College of Nursing Australia and the Australian Nursing Federation. The standard is titled: "Nursing Guidelines: Management of Medicines in Aged Care". The standard can be accessed at http://anmf.org.au/documents/reports/Management_of_Medicines_Guidelines_2013.pdf

This standard states that "*the role of assistants in nursing (however titled) in medicines use is that of assisting older people with self-administering their medicines from pre-packaged dose administration aids. They should not be directed by employers or facility staff to practice outside this role*."

Assistants in nursing (however titled) should only be permitted to assist those residents who have been assessed as having capacity to self-administer their medicines. To be consistent in the minimisation of the risk of harm to users of medicines, we submit that the Chief Executive should make the above standard a regulated standard when the Bill is passed and enacted.

With regard to the nursing and midwifery professions QNU draws attention to the specific requirements of the Nursing and Midwifery Board of Australia (NMBA). The NMBA in its role as regulator undertakes the key function of protecting the public "by making sure that only nurses and/or midwives who are suitably qualified to practise in a competent and ethical manner are registered" (NMBA, 2007). The Board's Codes and Guidelines stipulate that members of both professions must comply with registration and professional standards. The Codes of Professional Conduct (NMBA, 2008a; NMBA, 2008b) for nurses and midwives articulate that the professions must "practise in accordance with the standards of the profession and broader health system".

Relevant standards also exist in the private and public healthcare sectors. The current National Safety and Quality Health Service Standards (NSQSH) address medication safety and the QNU submits that these existing standards should apply to regulated activities. The benefits are twofold. The standards are subject of periodic review to ensure they reflect the best available evidence. Further, it would avoid duplication as currently in Queensland, both private and public sector hospitals and day procedure units are required to meet these standards.

In addition Queensland's Clinical Services Capability Framework contains a Module for Medication Services. This Module describes the minimum standards required of varying levels of medication service at public and private hospitals. The QNU submits that the Chief Executive should adopt both the national standards and this Module as a relevant Standard when the Bill is passed and enacted.

## Recommendations

The QNU recommends that the Bill prescribes the following:

1. That the minimum requirement for an eligible person in an institution such as a hospital, aged care facility or prison, is that the person must be a registered health practitioner;

2. Routine and regular auditing of Scheduled Substance Management Plans by the relevant authority;
.
3. Scheduled Substance Management Plans for an institution must state that only eligible persons (registered health practitioners) may conduct regulated activities;

4. The Chief Executive adopts the current National Safety and Quality Health Service Standards (NSQSH) as the overarching/foundation standard for medication safety;

5. The Chief Executive adopts the *Nursing Guidelines: Management of Medicines in Aged Care* as a prescribed Standard to be applied to regulated activities in Aged Care Facilities in Queensland;

6. The Chief Executive adopts the Medication Services Module of the Clinical Services Capability Framework as the prescribed Standard for medication services in public and private hospitals in Queensland.

## References

Nursing and Midwifery Board of Australia (2007) *A national framework for the development of decision-making tools for nursing and midwifery practice* retrieved from http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements.aspx

Nursing and Midwifery Board of Australia (2008a) *Code of Professional Conduct for Nurses* retrieved from *http://www.nursingmidwiferyboard.gov.au/Codes-Guidelines-Statements/Codes-Guidelines.aspx%23codesofprofessionalconduct*

Nursing and Midwifery Board of Australia (2008b) *Code of Professional Conduct for Midwives* retrieved from http://www.nursingmidwiferyboard.gov.au/documents/default.aspx?record=WD10%2F1355&dbid=AP&chksum=Mm624fvql2ZEKdEmT3l2ng%3D%3D

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Alun

Surname: Richards

Organisation and/or Professional position: Senior Medical Officer, Communicable Diseases Unit (CDU), Department of Health

Postcode: 4006

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: alun.richards@health.qld.gov.au and to anita.groos@health.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Ready access to medication and the ability of nurses and health workers to administer and supply S4 drugs in the sexual health treatment context is designed to encourage nurses and health workers to offer immediate treatment to patients with a positive test result for a sexually transmissible infection (STI) and to those who are symptomatic or a contact of a patient with a positive test result. This is particularly important in vulnerable population groups who may have infrequent contact with health services, are unlikely to return for follow up, and where the nurse or health worker may be the only point of contact with the health system. CDU welcomes the intent of the Bill to ensure nurses and health workers are able to continue to administer and supply medicines.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

CDU welcomes the intent to streamline different authorities (including for nurses and health workers) and to classify these by eligible persons with the use of supporting standards and guidelines. The proposed tabular format for an implementation support tool appears suitable to capture the medicines in scope and applicable standards to ensure good practice with medicines.

It is understood that in terms of administering and supplying treatment doses in the sexual health treatment context, the Bill will facilitate that a range range of standards or guidelines can be used (i.e. to apply for remote settings, general primary health care and GPs, and specialist or complex case management in sexual health services). It will be important to provide support to practitioners as they transition to the new regulatory framework.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

nil comment

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

It is not immediately clear how the use of standards or guidelines will address the current provisions under Health Management Protocol documents such as the Primary Clinical Care Manual which clearly specify when nurses and health workers must consult with a medical officer or nurse practitioner. It is assumed that the current locally endorsed Health Management Protocol system will meet the intent of scheduled substance management plans and/or standards required under the Bill, although it is advised that HHSs and other entities review the Protocols to ensure this is the case.

Because re-infection is common and untreated STIs have serious consequences, ensuring that sexual partners are treated at the same time as the person with a positive test result is important. Investigating options to support this through expedited partner therapy (providing the prescription or treatment dose to the patient with a positive test result to then give to their partner without the partner presenting for a consultation) has been identified as a priority in Queensland and it is important that the legislation enables this, from both a health care professional and patient/partner perspective (supply and possession).

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

nil comment

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

CDU welcomes the description of possession offences in section 24 (4) on page 20-21 as it should allow for expedited partner therapy in the sexual health setting. To facilitate expedited partner therapy, this and other sections of the new legislation should use terminology to allow for treatment doses to be given to or for the person and their partner. It is important that the health practitioner providing the medication to the patient for the partner is also covered by the legislation and it is suggested that this is also reflected in the supply side of the legislation.

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

nil comment

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

nil comment

11. Are the proposed licences, approvals and other authorisations appropriate?

It is not clear how the authorisation to be sought from a medical officer or nurse practitioner for some treatment regimens under current Health Management Protocols will be covered. It is important that the new system of standards and guidelines makes it as easy as possible, but without risk, for health professionals to offer immediate treatment for STIs if required.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

nil comment

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

nil comment

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

nil comment

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

nil comment

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

nil comment

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

nil comment

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

As stated above, it is assumed that the current locally endorsed Health Management Protocol system will meet the intent of the scheduled substance management plans although it is advised that HHSs and other entities review the Protocols to ensure this is the case. However, for some settings (e.g. remote or isolated practice, small clinic attached to an Aboriginal Medical Service) it may be difficult to develop a specific scheduled substance management plan. Will there be templates available to assist services develop these plans and/or how can smaller settings be incorporated or otherwise allowed for within the planning of a larger entity?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

nil comment

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

This is a matter for the relevant HHSs to determine.

For new treatment situations such as expedited partner therapy, it is likely that considerable consultation and possibly a trial and evaluation of new clinical practices would be required prior to finalising recommendations for standard implementation. This would potentially require one to two years to develop, implement and evaluate.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

nil comment

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

nil comment

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

A tabular format of regulated activity and applicable standards for eligible persons would be a clear way to present relevant information to guide the practicalities of day to day practice. To allow for the diversity of sexual health contexts (e.g. remote settings, GP practices, primary health care, and specialist clinics) it would be important that some sexual health content is captured in standards. This may take the form of a range of guidelines or other controls depending on the context or specific activity (e.g. expedited partner therapy).

I would be happy to provide further input to any process designed to develop standards for the sexual health area and to nominate key clinical opinion leaders for engagement in a process to establish relevant standards.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

## Julie Stokes

**From:** Legislation
**Sent:** Friday, 3 October 2014 12:41 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Medicines, Poisons and Therapeutic Goods Bill. Attn: Julie Stokes

---

**From:** Iain MacKenzie [mailto:Iain.MacKenzie@igem.qld.gov.au]
**Sent:** Friday, 3 October 2014 12:39 PM
**To:** Legislation
**Cc:** Fiona Lennon
**Subject:** Medicines, Poisons and Therapeutic Goods Bill. Attn: Julie Stokes

Good afternoon Julie,

I refer to a letter from your Director-General of 23 September regarding the above bill.

I can confirm that this office has reviewed the proposed legislation and has no further feedback to provide.

Kind regards,

**Iain S Mackenzie**
Inspector General Emergency Management
GPO Box 1425, Cluster 15.7, Brisbane, QLD 4001
Level 23, State Law Building, 50 Ann St, Brisbane Queensland 4000
**T**: 07 32251541 **M**: [redacted] **E**: Iain.Mackenzie@igem.qld.gov.au

Inspector General Emergency Management

Great state. Great opportunity.

Customers first Ideas into action Unleash potential Be courageous Empower people

Innovative Therapies

To:

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
PO BOX 48 BRISBANE QLD 4001

legislation@health.qld.gov.au

From:

[redacted]
Trading as Innovative Therapies
PO Box 835
Virginia BC, QLD 4014

and

Health World Limited
741 Nudgee Rd,
Northgate QLD 4013
[redacted]

Date: 3rd October 2014

741 Nudgee Road,
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PO Box 835,
Virginia BC QLD 4014
Phone: +61 7 3117 3390
Facsimile: +61 7 3117 3991

*Introduction*

Thank you for the opportunity to comment on this important regulatory change. Our comments in this consultation are made on behalf of [redacted] Innovative Therapies, and Health World Limited, a company that manufactures and supplies product to Innovative Therapies pursuant to a Supply Agreement.

Attached at Appendix 1 is a letter from [redacted] to the Queensland Department of Health of July 2014 outlining his concerns.

Our comments in this consultation relate to the section addressing the proposed adoption of the Therapeutic Goods Act and Regulations (**TGA**).

*Innovative Therapies business*

Innovative Therapies commenced business in 1999.

Its only business is the development and sale of natural medicines to health care practitioners in Queensland, including medical doctors and complementary medicine practitioners, for the management of long standing and complex medical conditions. In many instances these products are prescribed as the sole or main therapy for these patients, many of whom have not been able to achieve relief from other pharmaceutical therapies.

None of the products supplied by Innovative Therapies are able to be listed with the TGA because they contain ingredients that are not listable; however they are freely available for sale in most other countries around the world.

*Implications of the proposed adoption of TGA by the Queensland Government on Innovative Therapies*

If the TGA is adopted in Queensland and Innovative Therapies is not exempted, Mr Grant's business will be totally destroyed; he will not be permitted to sell any of his products, resulting in the loss of his livelihood and that of 10 Queensland-based employees.

*Implications for the health of Queensland consumers*

Such a change will also have a very significant impact on the health of Queensland citizens. Innovative Therapies only supplies to health care practitioners, who in turn prescribe these products to patients under their care. Many consumers take these products for the management of long standing and serious conditions (such as allergies, autoimmunity, mood disorders and depression) and will be seriously disadvantaged if they are no longer available.

Removal of these products from the market will likely encourage the purchase of similar products from overseas via the internet, without the safety of having a product made in a TGA GMP licensed facility. This would be a significant backwards step in health outcomes for a large number of Queensland consumers.

*Exemptions*

We are pleased to note the draft legislation contains a clause at paragraph 146 that provides for exemptions from the regulations for either a class of person or a product. We believe that this is an important feature of the draft legislation to ensure pre-existing legitimate businesses are protected.

We also note that the guidance document accompanying the draft legislation (at page 21) further clarifies that any product subject to such an exemption should be manufactured under TGA GMP. We strongly agree with this proposal and believe that this manufacturing standard is the best safeguard available to ensure product quality and consistency.

We note in the explanatory document that an exemption will be granted in cases where it can be demonstrated that the benefits are greater than the benefits provided by TGA regulation. We are concerned at the high level of uncertainty in this statement; it allows for a large degree of interpretation and does not provide any certainty on what test will be applied to satisfy the criteria of benefit.

For Innovative Therapies, there will be no benefit of TGA regulation, as it would lead to the loss of the entire business. We urge that the final regulations and guidance documents provide greater certainty around the way in which an exemption will be granted. By way of an example, we advocate that provided there are no consumer safety or product quality issues, an exemption will be granted if there would otherwise be a negative financial impact on an existing business as a result of the adoption of the TGA.

We also support the proposed exemption covering a person, rather than just a product or substance. One of the key features of nutritional science is the development of new ingredients, many of which are not allowed for use by the TGA. Although the TGA has provisions for the inclusion of new ingredients, the process is prohibitively expensive and time consuming. It can cost up to $100,000 for an application to the TGA to list a new ingredient for use, and may take up to 2 years to be approved or declined. The lack of any data protection or exclusivity arrangements within the TGA framework means that there is not sufficient financial incentive for companies to invest in applications for the inclusion of new ingredients. As a consequence, many ingredients that have been widely available in competent international jurisdictions for many years are not included on the TGA list because no one has made an application. By covering a person, the proposed exemption will allow for the continued development of new products, which is critical to the growth and success of a business such as Innovative Therapies.

*Transitional arrangements*

On the question of transitional arrangements, we believe that for those people and products that may not be covered by an exemption, a transitional period of 5 years is reasonable. Product development plans can take a number of years and the transitioning of existing product in the market place can also take a number of years. Whilst there may be a desire on the part of the government to introduce the changes

more quickly than this, we are not aware of any urgent health or safety issues that would require a shorter period, to the detriment of businesses that are forced to undergo such a transition.

*Product safety*

We believe appropriate safeguards for the public around the use of exempt product is an important issue.

There are two primary factors that contribute to product safety; the first is the quality system used in its manufacture, and the second is the safety and quality of the ingredients chosen to be included in the product.

As previously outlined, production under TGA GMP provides a high degree of certainty around product quality.

Where ingredients are being used that are not covered by the TGA list of approved substances, then other safeguards are required. These could include regulatory decisions made by competent international regulatory bodies such as Health Canada, the US Food and Drug Administration, and the European Food Safety Authority. Where ingredients are available for use under these regulatory jurisdictions, then the Queensland Government should be satisfied that the safety risk has been properly reviewed and assessed as minimal. The Government may also look to the history of use of products that are currently sold by sole trader businesses in Queensland, many of which have been on the market for well over a decade with very little evidence of safety issues. In the case of Innovative Therapies this is very clearly demonstrated through our comprehensive pharmacovigilance database.

*Legitimate use of ingredients*

We are aware some concern has been expressed that some ingredients, such as 5-HTP, have been used by illicit drug users to provide some benefit for the mood side-effects of illicit drug use.

However it should be noted, firstly, that the amount of 5-HTP in Innovative Therapies products is below the level in Schedule 2 of the Drugs Misuse Regulation 1987, and secondly that Innovative Therapies products are only available for purchase following a formal consultation with a health care practitioner.

An alternative source of 5-HTP is over the internet for personal use. It is much more likely that if an individual was planning to use an ingredient to minimise side effects of illicit drug use, they would purchase the product over the internet, rather than following a consultation with a health care practitioner for supply of a low and permitted dose of the ingredient. The internet source will be unaffected by the proposed adoption of the TGA by Queensland.

*Summary*

In summary, we are supportive of the proposed changes and the adoption of the TGA by Queensland, so long as the following criteria are met:

- An exemption is granted for existing sole trader businesses, provided;
  - ingredients used in exempted products are shown to be safe, either through a competent international regulatory approval or a history of safe use in Queensland, and
  - exempted products are manufactured in a TGA GMP licensed facility to ensure product quality, and
  - sole trader businesses can demonstrate a financial disadvantage from being regulated by the TGA.
- A 5-year transition period is provided for products that are not exempted, but which otherwise met the safety and quality conditions detailed in the above paragraph.

We thank you for the opportunity to make this submission and welcome any further discussion on this topic. Please direct any enquiries to Paul Mannion

We trust that you will consider the serious impact of this proposed change on businesses such as Innovative Therapies which have been operating legitimate businesses for many years, and the numerously affected consumers and employees.

Yours Faithfully

Trading as Innovative Therapies

Yours Faithfully
Health World Limited

Innovative Therapies

Appendix 1

The Queensland Department of Health

RE: Proposed changes to sole trader provisions and ratification of the Therapeutic Goods Act by Queensland

Dear Sir

I am writing in regard to proposed changes to the Health Act (1937), which if implemented as currently planned will have an extremely detrimental impact on my business and the health of thousands of our customers. I operate a Queensland sole trader entity, Innovative Therapies, which is a manufacturer and wholesaler of natural medicines. We attended a briefing held by the Department recently and were informed that a key part of the proposed change to the act would be the adoption of the Therapeutic Goods Act and Regulations for Queensland.

As you are aware, Queensland currently has not adopted the Therapeutic Goods Act and this allows for Sole Traders to sell a range of products that are not otherwise available in Australia. These include ingredients such as 5 hydroxy-tryptophan which are freely available for sale in most other countries around the world, but are not included on the TGA list of approved substances. Should Queensland adopt the Therapeutic Goods Act, this will effectively ban my company from selling products containing this and other ingredients that the TGA do not recognise. This will have a significant financial impact on my company of $2 million and will also mean the loss of 10 skilled manufacturing, warehouse, customer service and sales jobs based in Queensland.

We are also very concerned about the impact these proposed changes will have on the health and wellbeing of Queensland citizens. Our products are prescribed by health care practitioners including medical doctors and complementary medicine therapists for the management of long standing and complex conditions. In many cases these products are prescribed as the sole or main therapy for these patients, many of whom have not been able to achieve relief via other pharmaceutical therapies. These products are used to manage conditions including mood disorders, anxiety and allergic disorders. Should these products no longer be available then this is likely to lead to a dramatic worsening of these patients' conditions. It may also encourage patients to purchase products from overseas companies via the internet, the quality of which is variable and impossible to verify.

We are aware that a consultation is planned for this issue, however we urge you to include an exemption into the plans to allow companies that are currently working in this area to continue trading, regardless of the outcome of the consultation. We understand that there is at least one other company in our

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Innovative Therapies

industry that will be impacted by these changes, and we have included a copy of their concerns here for your reference as well.

Regards

INNOVATIVE THERAPIES

[redacted]



741 Nudgee Road,
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PO Box 835,
Virginia BC QLD 4014
Phone: +61 7 3117 3390
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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Cathryn

Surname: Baker

Organisation and/or Professional position: Executive Officer, Optometry Queensland/Northern Territory

Postcode: 4000

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

In general we support the proposed objectives as appropriate to promote and protect public health.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Optometry Queensland/NorthernTerritory is the peak jurisdictional body for optometrists in Queensland and the Northern Territory, representing the vast majority of registered optometrists practising in these jurisdictions. From the perspective of optometry and the practice of primary eye care, we believe the Bill strikes an appropriate balance. We note that the Bill provides for regulations which will have greater specifications relating to medicine use by specific health practitioners, and for the development of standards related to issues such as the storage and handling of medicines. The content of such regulations and standards may also impact on the balance between public safety and burden on health practitioners, and we would strongly encourage consultation reagrding the development of these also to ensure the balance is effectively achieved.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

With regard to the impact of the proposed legislation on optometry practice, we note no specific concerns.

The proposed legislation provides for regulations that will specify which medicines optometrists can prescibe to their patients. We believe it is important that, as is currently the case, regulations support optometrists who are endorsed to do so, to prescribe, as clinically appropriate, any medication listed on the national list of medicines published by the Optometry Board of Australia, which detail medicines which the registration board enables optometrists to prescribe. Linking regulations to the national list, as opposed to detailing listings within the regulations, ensures that optometrists in Queensland can continue to prescribe to meet their patient's clinical needs in accord with the full listing supported by the Optometry Board of Australia; it supports a more efficient process for accommodating any changes in the national list and helps support patient safety through national uniformity.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No specific controls we are aware of.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

We note no specific ommissions.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

This response relates to question 6, where the format did not enable us to insert a response. Whilst in general we believe the definitions of key terms are clear, we question the use of the term 'specialised program of health care' on p. 31 of the bill (Section 42.) We do not believe the meaning of this term is clear within the context and suggest it may require definition.

With regard to question 7, we note that the Optometry Board of Australia publishes registration standards, codes and guidelines directed at promoting public health and safety and which include elements of relevance to prescribing and administering medicines by optometrists. We believe that to the greatest extent possible legislation and regulations of the Queensland Government should align with the standards and guidance provided by the Optomety Board of Australia.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

We support the proposal to develop new regulation and standards where they align with established best practice, standards and guidelines from the Optometry Board of Australia and where they do not impose undue burden on practitioners. Ensuring that relevant stakeholders are made aware of such standards will be important to ensuring compliance with them. We question whether the bill should be amended to include some specification regarding the need to make any such standards widely available to those who may be impacted and to communicate to relevant stakeholders about the release of any new or revised standards.

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

## Julie Stokes

**From:** Lucy Fisher [redacted]
**Sent:** Friday, 3 October 2014 4:13 PM
**To:** Legislation
**Cc:** Medicine Poisons and Therapeutic goods Bill
**Subject:** Medicines Poisons and Therapeutics Bill

**Importance:** High

Private Hospitals Association PHAQ Queensland

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www.phaq.org

**Lucy C.A. Fisher**
**Executive Director**
[redacted]

To Whom it May Concern:

In response to the release of the *Medicines, Poisons and Therapeutics Bill*, the Private Hospitals Association of Queensland (PHAQ) would like to express its support for the intent of this Bill which is to rationalise the numerous prescriptive requirements currently governing the manufacture, storage, handling, administration and recording of drugs and poisons. In particular the introduction of a risk management approach via the concept of scheduled substance management plans is supported, and we endorse the stated concept that some entities may be exempt from such a requirement, where it can be demonstrated that their existing accreditation requirements would satisfy the new regulatory criteria. This is considered to be a sensible approach which will ensure compliance with minimum safe standards whilst minimising the potential for costly duplication of existing processes. Given that it is mandatory for hospitals to be accredited under the 10 National Safety and Quality Health Service Standards – one of which is Medication Safety, and that Queensland Private and Public Hospitals must also meet the requirements of the Clinical Services Capability Framework which includes a Medication module, we would anticipate that hospitals may well be considered suitable for exemption from relevant aspects of the substance management plan requirement under the proposed new legislative framework.

From a health care facility and health professional perspective however, much of the detail from a day to day practical perspective will be contained in the standards and regulations - yet to be released. It is these associated regulatory instruments which will be of considerable interest to our members and therefore at this stage in the process we would merely like to state our support for the key changes within the proposed new Bill as articulated on pages 7-8 of the *Background Paper - Consultation Draft of Medicines, Poisons and Therapeutics Goods Bill 2014 – September 2014.*

As the 'devil is in the detail', our organisation would welcome the opportunity to provide a substantive response once the Standards and Regulations are released for comment.

Kind regards

Lucy Fisher

Lucy Fisher
Executive Director
PHAQ
PO Box 370
KENMORE QLD 4069

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Mobile:
Email:
Web: www.phaq.org

Life Sciences Queensland

3rd October 2014

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
GPO Box 48
Brisbane QLD 4001

To whom it may concern,

**RE: Feedback to the new Medicines, Poisons and Therapeutics Goods Bill**

LSQ is a Queensland based industry lead not-for-profit organisation with some 130 Member entities (see www.lsq.com.au).

Feedback from a number of Members indicates that they are concerned at the possible outcomes that may result as an outcome of this current review.

Queensland currently enjoys the unique position that it has a Sole Trader Complementary Medicines arrangement available under the guidance of Queensland Health – and not the TGA.

Whilst the promise of reduction of red tape and better alignment of state and federal regulations is beneficial, feedback from our Members suggests that there is a responsible and acceptable set of arrangements that will afford all stakeholders with most of what they want, and that is meritorious of consideration.

It appears to be well accepted by Members, that under the proviso that manufacturing by Sole Trader Complementary Medicines can only be conducted in an appropriately licenced TGA facility – under the rules and regulations set by the TGA, then Queensland Health should continue to provide Queensland industry with a Sole Trader Complementary Medicines exemption.

Our Members believe that this arrangement should further be augmented with the new Queensland Health Medicines, Poisons & Therapeutic Goods Bill including a separate section for governance, which clearly identifies where the responsibility for Sole Trader Complementary Medicines sits within Queensland Health. It should also unambiguously articulate the level of authority they possess as well as any conditions and guidelines under which they must operate.

There is evidence that adoption of the Therapeutic Goods Act 1989 – without an exemption for sole traders, that a number of industry stakeholders would no longer remain in business – and whilst this is desirable in the instances where products are not manufactured under an appropriate manufacturing standard (and in a licenced TGA facility) there would be collateral loss of livelihood and jobs in the industry for those stakeholders who comply to appropriate quality frameworks, and loss of benefits to patients.

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Life Sciences Queensland

If there are particular products (that have clinical evidence of benefit) that are no longer able to be manufactured in Australia (Queensland), this will not stop patients from simply using the internet to order these products from overseas suppliers (and quite possibly from completely unsupervised manufacturing locations).

If it was determined that no exemptions would be available, Members indicate that they would need at least 36 months as an interim or transitional phase

Patient safety must be of primary concern in relation to this matter, and any products must be on the basis of evidence of benefit, however, changes that would only serve to create a different (and possibly higher) risk profile – that also damages industry and small business needs to be carefully considered

Thank you for the opportunity to provide comment

Yours sincerely,

[redacted]

**Mario Pennisi**
*Chief Executive Officer*
*Life Sciences Queensland Limited*



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## Julie Stokes

**From:** Legislation
**Sent:** Friday, 3 October 2014 4:59 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: medicines poisons and therapeutic goods bill 2014

-----Original Message-----
From: [redacted]
Sent: Friday, 3 October 2014 4:35 PM
To: Legislation
Cc: [redacted]
Subject: Fwd: medicines poisons and therapeutic goods bill 2014

>
> Good afternoon
> I would like to make some general comments to be considered when
> amending the current drugs and poisons regs.
> As a community pharmacy owner, aged care service provider and accredited RMMR pharmacist we provide services into a dozen RACF and disability services in rural Queensland.
> Currently compliance to PBS Nurses ACT 5CPA and Drugs and Poisons regs occupies 30-50% of the time of our aged care team.
> This is unsustainable for a small business and limits the scope of our practise to supply concerns. Improvements to eHealth and technology efficiencies should mean data transfer and record keeping should services to grow and focus on clinical service delivery and improved patient outcomes.

> To do this we need simplified compliance. improvements could be made
> to ensure;

> 1. Pharmacies can legally dispense from a medication summary (for an acute or chronic supply ) for a DAA patient whether they are in RACF hostels or the community. Removing the need for paper prescriptions to fill ongoing orders for chronically ill residents would enable health providers to focus more on care not supply.

> 2. Community Pharmacies should be able to provide traditional and future normal business to the community and related service providers eg RACFs without the burden of manufacturing and wholesaling licenses. I acknowledge standards need to be enforced but the burden of compliance is crippling small business and is anticompetitive. large operators benefit.

> Review of our Drugs and Poisons regulations at this time creates the opportunity to craft a document that leads internationally and meets the unique challenges of Australia.

> Thank you for this opportunity to contribute.

> Yours Sincerely
>
> [redacted]
> [redacted] | Medication Review Pharmacist [redacted]
>
> Coral Coast Pharmacies, West Bundaberg Pharmacy
> p: 07 4151 0755 | f: 07 4152 9999
> a: Bourbong Medical Centre

> 3/290 Bourbong Street , Bundaberg 4670
> e:
> w: www.coralcoastpharmacies.com.au
> fb: www.facebook.com/coralcoastpharmacies
>
>

| Medication Review Pharmacist

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fb: www.facebook.com/coralcoastpharmacies

The Royal Australian & New Zealand College of Psychiatrists
Queensland Branch

3 October 2014

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
GPO Box 48
BRISBANE QLD 4001

By email to legislation@health.qld.gov.au

To whom it may concern

**Re: Feedback on the proposed *Medicines, Poisons and Therapeutic Goods Bill 2014* (Qld)**

The Queensland Branch of the Royal Australian and New Zealand College of Psychiatrists (the College) appreciates the opportunity to comment on the draft of the proposed new *Medicines, Poisons and Therapeutic Goods Bill 2014* (Qld).

The College welcomes efforts to streamline and modernise the legislative framework governing medicines and poisons in Queensland. The proposed Bill appears to provide a clearer and more logical framework for those dealing with medicines and poisons to work within.

However, it is difficult for the College to provide specific feedback without access to the accompanying regulations which will set out the actual 'regulated activities' and conditions applicable to doctors (and other classes of eligible persons). The appropriateness of the new framework will hinge on the appropriateness of the regulations and the College would strongly recommend consultation on the draft regulations prior to their finalisation.

A matter of concern in relation to the draft Bill is the apparent removal of restrictions around the drug clozapine. Currently, under section 188 of the Health (Drugs and Poisons) Regulation 1996 (Qld), the dispensing, prescribing, sale or use of clozapine for human therapeutic use is restricted to psychiatrists, supervised psychiatry registrars and others holding a specific approval. These restrictions do not appear in the proposed Bill. Clozapine carries a risk of serious side-effects, including agranulocytosis, seizures, and myocarditis and requires careful, regular, expert monitoring. The College strongly recommends that the current restrictions around clozapine be continued either in the Bill or in the accompanying regulations.



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The Royal Australian & New Zealand College of Psychiatrists

Similarly, it appears that restrictions around stimulants are not maintained in the draft Bill. Currently, section 78 of the Health (Drugs and Poisons) Regulation 1996 (Qld) restricts who can dispense, obtain, prescribe, sell or use amphetamine, dexamphetamine, lisdexamfetamine, methylamphetamine and methylphenidate. These restrictions do not appear in the draft Bill. These stimulant drugs can be habit-forming and may have serious side-effects, including serious cardiovascular side-effects. It is important that only appropriately qualified and authorised people are able to deal with these drugs. The College strongly recommends that the current restrictions around stimulants by continued either in the Bill or in the accompanying regulations.

If you require any further information about this matter, please do not hesitate to contact Ms Jessica Collins, Policy Officer, on telephone (07) 3852 2977 or via email

Thank you again for consulting the College on these important reforms.

Yours sincerely

A/Prof Dan Siskind
**Chair**

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or [redacted] MD Nutritionals

Professional position

Postcode: 4216

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☒ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

If exemptions were not available to my Sole Trader health products I would face a significant regulatory burden.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

If the TGA regulatory framework was applied to my products I would face significant financial costs.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

No

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

No

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Compliance costs are currently manageable.

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Yes

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

N/A

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

If the Queensland government was to enact legislation to adopt the TGA as a law of Queensland I recommend the products currently supplied as Sole Trader products be given special consideration to be deemed exempt.

I recommend the following governance arrangements to protect public health and safety.

- Implement the term Sole Trader Complementary Medicines to denote products available to be sold in Queensland as sole trader products.
- Sole Trader Complementary Medicines are considered low-risk based on the history of use and the likelihood the ingredients contained within these products are not harmful to public health and safety.
- Sole Trader Complementary Medicines are supplied to healthcare professionals and labelled for 'practitioner dispensing only'.
- The proposed Medicines, Poisons and Therapeutic Goods Bill 2014 clearly defines Sole Trader Complementary Medicines. The Bill should clearly communicate these products are authorised to be supplied within Queensland and have been granted special exemption from the TGA as a law in Queensland. This special exemption was granted by the Queensland Health Department.
- Sole Trader Complementary Medicines are manufactured in a TGA licensed facility. These products are manufactured according to Good Manufacturing Practice (GMP). This will ensure quality is maintained at all stages of production from manufacture through to supply to the consumer.
- Sole Trader Complementary Medicines are labelled and packaged to a standard similar to the current TGA framework.
- Queensland based businesses who supply Sole Trader Complementary Medicines are granted a wholesale licence and have the necessary competencies to hold this licence.
- Marketing and advertising of Sole Trader Complementary Medicines is conducted in a manner that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer.
- Marketing and advertising of Sole Trader Complementary Medicines to healthcare professionals is conducted in a manner that promotes the quality use of the product, is socially responsible, does not promote use of the product to treat serious medical conditions, and does not mislead or deceive.

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

If the TGA was adopted as law in Queensland and exemptions were not available to my Sole Trader products my current business operations would become unsustainable.

I currently sell seven Sole Trader products and they derive a very substantial portion of my business income. The product list includes: Chromium Plus, Estro-Sense, FemBalance, GABA Mood Assist, Glutathione Cell Support, Indolplex and Niacinol Forte.

As a sole trader business who trades in Queensland the closure of my business would incur significant personal financial loss, cause financial and emotional stress to my employees, and would impact various stakeholders as my day to day operations contribute to the wider Queensland economy.

If the TGA regulatory framework was applied to my products I would face a significant regulatory burden. Many of the ingredients used in my products are not currently approved ingredients permitted for use in TGA approved complementary medicines. For my products to be entered in the Australian Register of Therapeutic Goods (ARTG) I would be required to seek evaluation for the use of new substances. Each new ingredient would require an application which would be an enormous undertaking. It would not be financially viable.

If the TGA regulatory framework was applied to my products it would not severely affect my day to day business practices. I currently supply my Sole Trader products in accordance with TGA guidelines.

I supply complementary health products that I believe contribute to the health of the Queensland community. If I was no longer able to supply my products it would cause distress to many of the customers who can gain health benefits from taking my products. My customers may turn to the internet to purchase health products that they believe are similar. Products available on international websites are not regulated by the TGA. If care is not taken, consumers may inadvertently break the law, waste their money or risk their health.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

If exemptions were not available to my Sole Trader products my organisation would face a significant regulatory burden. A transition arrangement would therefore not be a consideration as I would cease supplying my Queensland Sole Trader products

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

N/A

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

N/A

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

N/A

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

I believe monitoriing should be done however I am not sure it should be handed to third parties

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

None that I am aware of

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: _____

Surname: _____

Organisation and/or Professional position: Torres and Cape Hospital and Health Service

Postcode: 4870

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☒ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: _____

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

There are some concerns regarding the level of transfer of the specifics of regulation from being the regulator's responsibility to become the responsibility of industry, government agencies and the community.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Yes. It is not clear in the information provided what the extent of activites allowed will be, so it is difficult to comment. It seems that the sub-legislation (regulations) will describe the specifics e.g. 37 (1) and (2) are very vague and reliant on the content of the regulation

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

While beign an admirable goal, the adopting of an "…more responsive and outcomes-focussed regulatory framework", may not be appropriate in relation to such an imporant matter. It is effectively greatly transferring responsibility for the quality, and particularly the personal and public safety aspects of regulation from the regulator to become the responsibility of industry, government and the community on an individual basis.

There needs to be some inclusion or stipulation of the content and standards of education and specific competencies to become an "eligible person" and to undertake certain "regulated activities".

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

None immediately evident in the proposed legislative framework, but the content of the sub-legislation (regulations) will be vital to the appropriate safeguards and appropriate regulation.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

No

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Little knowledge in this field, so difficult to provide informed comment

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Little knowledge in this field, so difficult to provide informed comment

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

It appears as though this is a possibility, although compliance with the conditions will still create cost for implementation.

11. Are the proposed licences, approvals and other authorisations appropriate?

It would appear so within this bill, although some vital details will need to be considered in the regulations

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Little knowledge in this field so difficult to provide informed comment

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Little knowledge in this field so difficult to provide informed comment

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Little knowledge in this field so difficult to provide informed comment

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Little knowledge in this field so difficult to provide informed comment

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

Little knowledge in this field so difficult to provide informed comment

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Little knowledge in this field so difficult to provide informed comment

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

The documents are:

High risk medications register

Regulated schedule 4 register

A S8 register

Electronic list of medicines (ELMS)

A scheduled substance plan would be a more detailed and comprehensive document.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

Develop  a plan for each facility = 4 days per facility X  30 facilities = 120 working days = 6 working months =  approximately $42K

Implement a plan for each facility = 3 days per facility x 30 facilities = 90 working days  = 4.5 working months = approximately $32K

Total to initiate= $74K

However to only consider development and initiation misses the necessity to maintain the plans as compliant = 4 days per facility per year = 120 working days = 6 working months = approximately $42K per year.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Work load = 120 days +  90 Days = 9 months, among other tasks = 12 month deadline.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Yes. At the discretion of the DG applicable to the circumstances.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Little knowledge in this field so difficult to provide informed comment

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

We fail to see how the current system of Drug Therapy Protocols and Health Management Protocols could be "…cumbersome and lacking in transparency". The conditions under this system are entirely explicit and therefore about as clear (transparent) as they can possibly be. What these features provide is a system which encourages standardisation of evidence based, best practice approaches to medication use, administration and supply which are key ingredients for efficacy in health care as well as individual patient safety and therefore public safety. Abandoning this part of the current regulatory environment will inevitiably lead to - if not actually encourage - a move away from consistency and standardisation of best practice approaches to potentially a different approach in every facility or HHS in the State. This will not only increase variation, but will increase the necessity for disparate facility plans and constant staff orientation and training on this very topic. The move to a non-standardised approach under the motivation of becoming "outcome focussed" may reduce the regulartors administrative burden, but will almost certainly create more adverse patient events in relation to treatments provided under inconsistent conditions across the state.

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Russell

Surname: Bowles

Organisation and/or Professional position: Commissioner Queensland Ambulance Service (QAS)

Postcode: 4001

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☒ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: Commissioner.QAS@ ambulance.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Yes

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

No. The Bill provides an excellent conceptual framework for the Control and Management of Drugs in Queensland

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No. Because of QAS specific Codes of Practice (CoP) and Credentialling

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Comprehensive detail to be dealt with in the Regulations

Answer to Item 6: Definition of Regulated and unregulated practitioners.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Internal Code of Practice and Drug Management Policy and Procedures

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Yes - Absolutely

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Unregulated practitioners included in the regulations.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

N/A to QAS

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Not, in terms of activity relating to QAS

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No. Will make things easier

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

N/A to QAS

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

QAS has Drug Management CoP and Procedures and the proposed Framework provides QAS the opportunity to use innovative methods to control and manage drugs. Other than the prescriptive current legislation requirements that were never a good fit with the QAS out of hospital Environment eg Electronic Drug Registers. Dictated by the practice environment has required QAS to implement high level of drug security. .

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

No additional costs

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Already in place - to be refined.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Yes, particularly where there is no other internal audit / quality assurance function used. Broad powers to audit.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

This point in time the QAS supports the current approach.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

Yet to view Regulations and Standards

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# CMA Submission to Queensland Department of Health Consultation draft Medicines, Poison, and Therapeutic Goods

To:
Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
PO BOX 48 BRISBANE QLD 4001

legislation@health.qld.gov.au

From:
Complementary Medicines Australia
PO Box 450
MAWSON ACT 2607

3 October2014

Complementary Medicines Australia (CMA), formally the Complementary Healthcare Council of Australia, welcomes the opportunity to provide a response to the Queensland Department of Health on its consultation draft of the Medicines, Poisons and Therapeutic Goods Bill, dated September 2014.

The CMA represents all stakeholder groups in the complementary medicines industry. Our members include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi level marketers and consumers.

The consultation paper proposes a Bill for an Act to streamline the regulation of medicines and poisons, to apply the Therapeutic Goods Act 1989 (Cwlth) in Queensland, to repeal the *Health Act 1937* and to make consequential amendments to other legislation stated in Schedule 1.

CMA notes the objectives of Bill are to:

- **identify substances that, if not used appropriately, may harm the health or safety of persons;**
- **ensure persons who use the substances have the necessary competencies to deal with the substances safely, and**
- **to ensure that substances are used safely and effectively.**

CMA notes the objectives of the Act are to be achieved mainly by:

- **restricting the use of substances prescribed as scheduled substances.**
- **authorising classes of persons to use scheduled substances in controlled ways for legitimate purposes, including therapeutic, educational, industrial and agricultural purposes.**
- **providing for a licensing and approvals scheme to authorise other suitable persons to use scheduled substances.**
- **requiring persons authorised to use scheduled substances to have competencies and be accountable for the safe and effective use of the substances.**
- **requiring particular things to be done to ensure the safety and quality of scheduled substances at all stages of use from manufacture to supply to the consumer, including, for example, developing and adhering to a scheduled substance management plan; and**
- **providing for compliance with this Act to be monitored and enforced; and**
- **applying the Therapeutic Goods Act, and instruments made under that Act, as laws of this State (Queensland).**

Another aim of the Bill is to minimise compliance costs for industry by:

- **streamlining regulation; and**
- **to the extent possible, adopting an approach to the regulation that is consistent with the Commonwealth and other States.**

Through the Bill it is envisaged that adoption of the TGA as a law of Queensland will ensure that there is a 'level playing field' for all market participants and that areas of regulatory

duplication will be eliminated. However, there is the possibility that a number of businesses who currently manufacture therapeutic goods (that are not a scheduled medicine or poison) may have an additional obligation to have their products registered or listed and to hold a manufacturing licence. Consequently, the Bill includes a regulation making head of power that will enable a class of person or a type of therapeutic good to be exempt from the requirements of Commonwealth Act under clause 146.

It is envisaged that such an exemption would be conditional; that is the relevant goods would be produced in a manner that is consistent with the quality system requirements of the Code of Good Manufacturing Practice. The CMA supports this principle concept.

However, it if further anticipated this head of power will only be used if it becomes evident that benefits of adopting the TGA is not outweighed by the increased regulatory burden for particular businesses operating in Queensland. To this point the CMA welcomes the inclusion of this clause that provides for an exemption to the regulations to be made for either a class of person or product. However, in this time of Government de-regulation, the CMA recommends that exemptions be clarified, and be provided for those classes of complementary medicine products that have been traded under the sole trader legislation to consumers to date and that are manufactured under a TGA GMP approved facility.

Examples of the occupations, professions or positions proposed to be classified as 'eligible persons' under clause 36 include:
• health practitioners (including registered and non-registered health professionals).

CMA fully supports the objectives of the Bill around appropriate safeguards for the public, particularly around the use of exempt product, and concur that primary factors in establishing this is an appropriate quality system used in the manufacture of such goods and safety and quality of the ingredients chosen. In undertaking this consideration it should be noted what regulatory decisions have been made by other International regulatory authorises such as Health Canada and those countries belonging to the International Regulators Consortium[1].

The growing amount of information now available to consumers via the Internet, and the emerging use of the Internet by consumers as a 'self-help' tool to purchase medicines, including complementary medicines, will mean that if exemptions are not provided under this reform proposal, purchase of medicines will increase via the internet without the safeguard of a consultation with a healthcare practitioner or quality manufacturing process.

For an example of the deregulatory measures CMA are proposing to Government and the current regulatory barriers faced by the CM industry, please refer to the CMA Deregulation Agenda "light touch, right touch regulation for complementary medicines", at Appendix 1.

[1] http://www.tga.gov.au/about/international-irc.htm

LET'S CUT THE RED TAPE

# LIGHT TOUCH RIGHT TOUCH
## FOR COMPLEMENTARY MEDICINES

Reforming regulation of the complementary medicines industry

cma
Complementary Medicines Australia

# Light Touch, Right Touch Regulation for Complementary Medicines

## Deregulation Today for an Innovative Tomorrow

## September 2014

## Executive Summary

There is a real and immediate role for complementary medicines in contributing to consumer health through primary and secondary prevention of illness, creating healthy communities and businesses, and by encouraging and empowering all Australians to take better care of their health. Well-informed Australian consumers are keen to access innovative new products, even if this means ordering these products on-line from international sources. For the complementary medicines industry, as for other Australian industries, putting the right regulatory environment in place will nurture, promote and enable competitiveness and innovation.

Industry's top three deregulatory agenda recommendations are outlined below.

### 1) Deregulation of Ingredient Approvals

Many ingredients commonly used in overseas jurisdictions are unavailable in Australia due to a mandated costly and needless duplication of assessment. This is the primary factor inhibiting the growth of the Australian complementary medicines industry. Where ingredients have been approved as safe by competent overseas regulators, these decisions should allow for a pathway to automatic or expedited adoption.

- ***Estimated Value = $ 10 million per annum***

### 2) Deregulation of Marketing Approvals

Currently, advertising of complementary medicines is regulated via a complex and inefficient process. Approval for advertising is delegated by the TGA to two bodies which often requires advertisers to seek two sets of approvals across a media campaign. The system is already limited as only a sub-set of advertising media are included; most notably the rapidly growing area of internet advertising is not covered. Advertisements for low risk complementary medicines should not require pre-approval as they must comply with best practice under the Australian Consumer Law, similarly to foods and beverages that can also make health claims but don't require advertising pre-approval.

- ***Estimated Value = $ 25 million per annum***

### 3) Deregulation of Manufacturing Complexity

The current regulatory requirements for the Australian manufacture of complementary medicines are complex and extensive. A common issue raised is the lack of a level playing field with respect to approval and audit of overseas manufacturing facilities. Whilst Industry recommends that the current level of standards is maintained for global competitive advantage, GMP should be regulated by the TGA but using third party conformity assessment to allow for the most efficient and least costly accreditation framework.

- ***Estimated Value = $ 35 million per annum***

***TOTAL DEREGULATION VALUE $ 70 million per annum (available for investment in growth)***

## Contents



## Introduction

The purpose of this document is to outline the top three priority recommendations by industry for improving the regulatory environment for Australian complementary medicine businesses. Industry is proud of the high standard and quality of Australian complementary medicines. We believe the recommendations outlined below do not detract from the high quality standard, and do not signify a request for 'no regulation', whilst achieving the goal of supporting growth and reducing the regulatory burden on industry.

Complementary medicines have been widely embraced by the Australian community, with two out of every three Australians regularly using a natural healthcare product. Research shows that industry revenue, which now stands at $3.5 billion, is expected to grow to $4.6 billion in 2017-2018, and the industry expects to increase the number employees to 45,000 over the same period.[1] Australia's complementary medicines exports were worth over $200million in 2013.[2]

The sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports. However, there is still an enormous untapped potential for complementary medicines to contribute to the Australian economy in terms of both cost savings to the health system and fiscal contribution – the complementary medicines industry is one industry that, in a supportive environment, has the ability to grow exponentially and support local manufacturing, as well as providing a significant contribution to our exports.

## Background

Australia's Therapeutic Goods Administration (TGA) is responsible for regulating therapeutic goods, including medicines, medical devices, blood products, and complementary medicines which includes vitamins, minerals and supplements. The Australian complementary medicines industry is commonly regarded as one of the most strictly regulated in the world.

[1] NICM, http://www.nicm.edu.au/health_information/information_for_consumers/understanding_cm
[2] Austrade and ITS Global estimates of exports of both final products (destined for retail markets) and inputs (destined for manufacture) based on HS tariff codes 2936, 300450 and 2106).

The complementary medicines industry supports regulation of complementary healthcare products that is appropriate and commensurate with the low level of risk these products represent. The recent environment of escalating red tape has led to a stifling of product innovation, lower productivity, less job creation and minimised incentive for industry investment. The most frequently raised concern is the high price of operating in Australia (factors include small domestic market, long process time and duplication and complexity of regulations); an impost keenly felt when such regulation creates a disadvantage for local operators to compete globally.

In addition, the last few years have been a time of regulatory challenge to our industry as the TGA has embarked upon wide-ranging reforms as outlined in the document *TGA reforms: a blueprint for TGA's future*. Industry recognises that significant work has been undertaken to date on the reforms but believes that a number of the changes have increased the regulatory burden without a corresponding improvement in protection of consumer safety or access to improved or innovative health products.

Whilst it is perhaps understandable that the TGA has attempted to align the regulatory requirements across the range of therapeutic goods – prescription medicines, medical devices and complementary medicines - in practice this has meant that complementary medicines have increasingly been expected to meet regulatory standards more suited to high-risk prescription medications. Some reforms, such as the proposed labelling and packaging reforms and eliminating the free text field of the Electronic Listing Facility (ELF) when applying for a product listing, require amendments to the *Therapeutic Goods Act 1989*, and are not supported by industry in their current form.

Industry and the Australian community expect the TGA to act swiftly and decisively in the face of an existing or potential health and safety issue. It currently appears that the TGA is excessively focused on detecting advertising breaches associated with low risk medicines, which is removing limited resources from where they should be directed – the swift action upon serious quality issues. CMA would like to see the TGA acting, first and foremost, as a standard setting body in terms of advertising requirements and auditing of GMP, which would allow the streamlining of limited resources.

## 1. Deregulation of Ingredient Approvals

- ***Estimated Value= $ 10 million per annum***

**Issue**

The primary factor inhibiting the growth of the Australian complementary medicines industry is considered by industry to be the lack of availability of many dietary supplement ingredients that are commonly used in overseas jurisdictions. Unless an ingredient is included on the list of available substances, an application is required for evaluation of the substance for its inclusion. This process includes a quality and safety dataset and is a significant regulatory hurdle that can take approximately 1-2 years for the application to be evaluated - a significant investment of time and money.

**Proposed Deregulatory Change**

- Where ingredients commonly used in complementary medicines have been approved as safe by competent overseas regulators, these decisions should allow for a streamlined pathway to automatic or expedited adoption.

**Background**

Reflective of the work the TGA undertakes in information sharing with certain international counterparts, the evaluation process for substances that fit this category should be streamlined.

An expedited process has occurred recently with the TGA conducting an evaluation of a species of Garcinia for use in listed medicines based on information from international regulatory counterparts in Canada. Ingredients that are available in markets with comparable regulatory standards – for example Canada, Switzerland and Singapore – should be automatically accepted for use here in Australia.

Dependent on the progression of the NZ Natural Health and Supplementary Products Bill and the level of code of GMP principles that are adopted, an opportunity with New Zealand exists to consider the list of permitted ingredients previously put forward in ANZTPA phase one.

An existing model similar to the proposed expedited application process is the Patent Prosecution Highway (PPH), which speeds up the examination process for patent applications filed in participating intellectual property offices across a number of countries. PPH leverages fast-track examination procedures to allow applicants to reach final disposition of a patent application more quickly and efficiently than standard examination processing.

***Innovation in ingredients (e.g Australian Bush medicines)***

For novel ingredients, and submissions that contain unique data, a data protection mechanism such as that afforded under food and cosmetic regulatory frameworks should be established to provide an incentive for companies to invest in a regulatory application.

The applicant is required to submit a detailed dossier on the ingredient, but there is no data protection or exclusivity available on the material when a substance is approved for use in listed medicines, significantly reducing the incentive for companies to pursue applications.

Please see Appendix one, which provides additional detail with regard to a potential method to achieve a level of protection for applicants with innovative ingredients.

## 2. Deregulation of Marketing Approvals

- ***Estimated Value $ 25 million per annum***

### *2.1 Advertising reforms*

**Issue**

Advertising of complementary medicines is regulated via a complex and inefficient process. The current dated pre-approval system only covers a subset of advertising media and was never designed to take internet advertising into account (it's inclusion now is prohibitive). The system has a number of weaknesses, including the requirement for advertisers to often seek approvals from two separate delegates for a multi-media campaign, and a complaints system that is confusing, lacks certainty and is highly inefficient.

**Proposed Deregulatory Change**

- Maintain the current advertising regulatory standards (such as compliance with the *Therapeutic Goods Advertising Code*) but remove onerous regulatory burden through abolishing the current pre-approvals and complaints system. The marketing and advertising of listed medicines should comply with best practice under Australian Consumer Law and the responsibility of compliance should belong to the individual advertiser.

**Background**

Approval for advertising is delegated by the TGA to two bodies (Complementary Healthcare Council of Australia and Australian Self Medication Industry) which often requires advertisers wishing to advertise in broadcast and print media to seek two sets of 4-8 approvals via two separate delegates for the same advertisement.

Advertising complaints are heard by separate bodies, which make rulings that are often inconsistent with the approval provided for the advertisements previously. In effect, this means that an advertiser has to go through a preapproval process to ensure compliance, but then has no certainty that their advertisement will not be the subject of complaint and subsequent sanctions from the Complaints Resolution Panel and TGA.

Criticism has often been levelled at the Complaints Resolution Panel due to its lack of transparency and timeliness, limited penalties and lack of appeals process. Both consumers and industry want advertising that provides accurate and adequate information about complementary medicines whilst preventing misleading claims.

Advertisements for low risk complementary medicines should not require pre-approval, but rather comply with best practice under the deterrent of appropriate sanctions and penalties under Australian Consumer Law. Reputable industry members believe that non-compliant companies should face the legal and punitive consequences available to the ACCC which are significant compared to the current consequences of non-compliance.

### 2.2 Access to higher level claims (in the context of consumer self-management)

**Issue**

A new food standard to regulate nutrition content claims and health claims on food labels and in advertisements became law on 18 January 2013 – *Standard 1.2.7 Nutrition, Health and Related Claims*. Under this standard, foods are able to make stronger health claims (such as lowering high cholesterol), while having both lower manufacturing and evidence requirements, than complementary medicines listed on the Australian Register of Therapeutic Goods.

**Proposed Deregulatory Change**

- A modified/improved registration pathway that provides the ability to make higher level claims for complementary medicines with evidence substantiation but not necessitate duplicated/redundant safety and toxicology data requirements.

**Background**

At this stage, the pathway for a complementary medicine to be able to make stronger health claims is via the registration process; a process that requires a very substantial data package, similar to that required for the registration of a new pharmaceutical drug. Registration also requires safety and toxicology data, despite where the compound may have already been approved for use in listed complementary medicines sold on the Australian market (and therefore already deemed safe to be sold to consumers). This is a major regulatory hurdle and impediment to companies investing in clinical trials to validate their products, as the safety and toxicology package required could be considered as too big an investment relative to the potential returns.

CMA would like to see a modified/improved registration pathway that requires substantiation of evidence without the prohibitive additional cost of redundant product safety and toxicology testing. Where a company seeks to achieve registration for a compound which is currently listable, it should only have to provide evidence of efficacy (clinical trials) related to the higher therapeutic indications being made, not full safety or toxicology data. This evidence would then be assessed by the TGA for the use of higher level marketing claims commensurate with the evidence provided. Any company that wanted to use those claims must also go through the same regulatory submission process.

### 2.3 Evidence requirements for advertising claims on listed medicines

**Issue**

The recently updated guidelines for the evidence required to substantiate indications for use in listed medicines has increased the regulatory burden for sponsors. Compliance with evidence substantiation has significantly increased industry costs, slowing innovation and efficiency.

**Proposed Deregulatory Change**

- The evidence required and the claims that are available must allow for a level playing field with food regulations.

**Background**

The evidence base required for making indications/claims on natural medicines needs to be commensurate with the low risk associated with these products. The updated guidelines create a significant regulatory impost which will not stop companies determined to break the rules, but have created a very substantial burden for reputable companies that aim to be compliant with the rules.

As an example, the current evidence requirements, especially for weight loss, biomarker claims and other scientific indications are disproportionately excessive to the claims that are available. It is important that the evidence required and the claims that are available allow for a level playing field with food regulations. Under standard *1.2.7 Nutrition, Health and Related Claims* foods are able to make stronger health claims (such as lowering high cholesterol), while having both lower manufacturing and evidence requirements, than complementary medicines listed on the Australian Register of Therapeutic Goods.

## 3. Deregulation of Manufacturing Complexity

- ***Estimated Value $ 35 million per annum***

### Issue

With globalisation and increased commercial and economic pressures across national boundaries, the Australian complementary medicine manufacturing sector is under pressure to remain competitive and relevant. Whilst Australian manufacturers cannot be immune from global pressures, it is in the interests of all stakeholders, including the Australian Government, to ensure that local industry is supported.

Regulatory requirements for the Australian manufacture of complementary medicines are complex and extensive. The automatic adoption of the Pharmaceutical Inspection and Co-operation Scheme (PIC/S), followed by the drafting of exemption documents for complementary medicines manufacturers, creates an excessive regulatory burden upon industry.

### Proposed Deregulatory Change

- CMA recommends that complementary medicine specific guidelines should be designed and agreed in conjunction with industry. These guidelines would be based on the existing version of PIC/S and exemptions.
- Whilst Industry recommends that the current level of standards is maintained for global competitive advantage, GMP should be regulated by the TGA but using third party conformity assessment to allow for the most efficient and least costly accreditation framework.

### Background

The TGA implemented the 2009 PIC/S Code of GMP in July 2010. The relevant exemption documents for manufacture of complementary medicines have been completed, with the exception of the release for supply guideline which is currently being finalised, four years on. Whilst industry agrees that compliance with the principles of the PIC/s guide and codes of GMP and/or a quality system is required, the automatic adoption of PIC/s, followed by the drafting of subsequent exemptions, creates excessive impost upon industry.

A common issue raised is the lack of a level playing field with respect to approval and audit of overseas manufacturing facilities. It seems that even with TGA manufacturing exemption documents the requirements within Australia (such as stability, QBI, validation and product quality reviews) are too high. Audit frequencies are high and there are inconsistencies between auditors and their interpretation of the requirements and the documentation of key decisions, particularly when discretions are exercised.[3]

[3] ANAO audit on the administration of the Code of GMP

Given the low risk nature of these products, specific guidelines should permit allowances for reduced pre-market stability and validation testing, for ongoing stability testing for complementary medicine products, and grouping of like products for pre-market stability and validation testing.

As a more streamlined standard setting body, the focus of the TGA would be upon management of the licensing and audit of GMP status of supply chain participants such as manufacturers. This may be best achieved by third party conformity assessment rather than the current model, whereby the TGA, with limited resources, has staff travelling both nationally and internationally to perform audits. This leads to uncommercial fees and timeframes for licencing and audits.

## Conclusion

The peak body for the complementary medinces industry, Complementary Medicines Australia (CMA), acknowledges the Government's commitment to a reduction in the regulatory burden on industry, and the key deliverables for the TGA of reducing red tape and participating in international harmonisation to streamline regulatory requirements.

The Australian complementary medicine industry is commonly regarded as one of the highest quality, yet most heavily regulated in the world, and, in recent years, has been subjected to regulatory burdens more appropriate to high-risk pharmaceutical products. Our industry has the potential to significantly increase highly skilled and innovation rich local manufacturing, as well as providing a significant contribution to our exports. However, in order to fulfil this potential, a number of regulations and restrictions that currently stifle innovation need to be removed.

Removal of over-regulation will help the Australian complementary medicines industry to gain its position as an innovative and competitive market that is able to meet growing consumer demands.

## Appendix One

**Example method for achieving a level of protection for applicants with innovative ingredients**

When a sponsor applies to the TGA for evaluation of a new complementary medicine substance a compositional guideline is generated, which defines the substance that has been evaluated and approved for use in Australia.

The compositional guideline, being generated from a paid application should, once approved, be published on the TGA website as a final compositional guideline. Public consultation on the draft version, as is current practice, would no longer occur. This proposal does not, strictly speaking, change transparency of either the process or information, with Complementary Medicines Australia supporting that all compositional guidelines be published to enable industry to refer to the approved specifications as necessary. However this process could build in a window of exclusive use, prior to compositional guideline publication, which would be an incentive for industry to apply for the listing of a new substance.

Should another company wish to amend the final compositional guideline they can still do so by applying to the TGA. The amendment would need to provide justification and would be evaluated by the TGA. This process would incur a specified evaluation fee. If the amendment is considered to be appropriate, the final compositional guideline would be updated to reflect the change and re-published on the TGA website.

This process and the publication of compositional guidelines on the TGA website would not prevent another sponsor from submitting a closely related yet distinct substance with its own specific compositional guideline for separate assessment. A compositional guideline for a pre-existing complementary medicine substance would not be affected by this proposal.

***Complementary Medicines Australia***

Complementary Medicines Australia is the leading expert association exclusively committed to a vital and sustainable complementary medicines industry. We believe in a holistic healthcare model based on promoting long-term wellness of
the community.

We are unique in representing all stakeholder groups in the complementary medicines industry. Our members include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi-level marketers and consumers.

CMA is the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

## Julie Stokes

**From:** Legislation
**Sent:** Tuesday, 7 October 2014 9:09 AM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: Comments on MPTG Bill

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**From:** Clayton Doye
**Sent:** Friday, 3 October 2014 5:17 PM
**To:** Legislation
**Subject:** Comments on MPTG Bill

To whom it may concern.

My apologies for these appearing rushed. Please find below my comments in relation to the Medicines Poisons & Therapeutics Goods Bill.

1. The role of TGA and how associated legislation effect this bill is not very clear. Supporting information would of been helpful.
2. How will items currently listed in appendix C of the Standards be captured? At present they are captured as being a regulated poison.
3. The definition of manufacturing includes “repackaging”. Does the placing the products from three packets into one packet constitute repackaging. This is normally done by pharmacists to save room in drug safes.
4. 32 (1) What is a document “purporting” to be a script. Either is it is a script or it is fake.
5. 32 (1) (b) need to include signature.
6. 32 (6) Need to include the use of stickers or such as altering the prescription.
7. 42 Will general approval/s be specific to a premise or can one approval cover several premises (Tourist companies with boats etc)?
8. 49 How do interstate doctors effect drug treatment approvals? Will they need to have a management plan.
9. 83 (1) (b)14 day seems a bit short to issue a renewal, especially if the renewal goes Brisbane for mapling then sent to the regions.
10. 111 What happens if only one small quantity of a substance is identified? Also is there risks associated with the mixing (breathing in powders etc)
11. 123 Please remove the 21 day minimum time frame for compliance notice. It is contradictory to allow an offence to continue for 21 days and then remove authorities or prosecute if they do it again.
12. 168 There appear to be no structural or hygiene provisions
13. Hard to comment on the functionality of some aspects of the Bill without knowing what levels delegations will go to? For example what level will be delegated to issue and remove authorities.
14. Will any sections be listed in SPER Regs for PINable offences?
15. Will management plans need to be certified or approved before being used?

Please note that these are only my thoughts not TPHS (Cairns). Unfortunately we got swamped with G20 stuff (just wait until it hits Bris), then being school holidays, people on leave. This made it hard to get a coordinated response.

Happy to discuss

Cheers Stan

*Clayton Doye*
Acting Team Leader
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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: [redacted] Pharmacy Services, EPIC Pharmacy Group

Postcode: 4122

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☒ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☒ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Whilst it is accepted that the proposed legislation removes much of the prescriptive elements of the existing Health (Drugs & Poisons) Regulations 1996, It is difficult to answer this question without the details of the Standards and Regulations which apply to the scheduled substance management plan (SSMP), which effectively will replace the prescriptive elements of existing legislation.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

There is significant innovation in the healthcare sector which promotes efficiency and patient safety but not clearly provided for/authorised in the existing precriptive regulations, eg electronic medicines management systems with digital signatures, robotic dispensing which allows safe ("chaotic") storage of controlled drugs (as is in operation overseas), and other emerging technologies such as electronic controlled drug registers, which enables more efficient record keeping and balance checks, direct tamper-proof electronic records of stock movement (eg dispensary to wards), and enhanced data analysis capabilities to detect potential trends of diversion. Indeed such innovation and efficiency is a necessity to curb healthcare costs in an environment of increasing expectations of standards for patient safety, such as those outlined in the National Safety and Quality Healthcare Standards (NSQHSS). There should be no concerns with the new legislation, providing the Standards and Regulations pertaining to the scheduled substance management plan allow for all such innovations.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

Nothing perceived within our scope of practice.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Q.5 REPONSE: Nothing perceived within our scope of practice.

Q.6 RESPONSE: We note a few areas for clarification:

Definition of “Manufacturing” (Clause 16): there are a number of standard Pharmacy activities in relation to extemporaneous compounding that may be construed by this definition to be “Manufacturing”. Significant work is underway by the TGA and Pharmacy Board of Australia regarding the regulation of compounding, and may serve to enhance clarity regarding this definition. Furthermore in the examples listed as exemptions from manufacture under clause 16(3), limiting the injection examples to 2 medicines does not take into account current routine clinical care such as ambulatory cancer chemotherapy or palliative care where 3 or more medicines may be mixed in the same infusion by pharmacists or nurses, respectively.

Definition of “Supply”: Disposal of substance as waste is outlined as not being related to supply under clause 17(2)(c) but does not appear to be referenced as a regulated activitiy anywhere else in the draft bill. How is disposal of scheduled substances to be regulated to protect the public?

The term “wholesale” itself has not been defined in the draft bill, whereas the TGA Code for Good Wholeslaing Practice (listed as conditional to wholesaling license under curent legislation) has a broader definition than that of common dictoniaries:e.g. The Oxford dictoniary defines wholesale as “The business of selling of goods in large quantities and at low prices, typically to be sold on by retailers at a profit.” Whereas under the TGA Code, "Wholesaling" and "supply by wholesale" means:

a. supply of medicines for the purposes of resale or resupply; or

b. the supply of medicines for use in connection with a trade, business, profession or industry.

Whilst this may seem a reasonable definition, the broad terms used in the TGA Code capture some routine supply scenarios for Pharmacies that are met by similar standards required for Pharmacists to supply scheduled medicines to individual patients by over the counter (OTC) sales or when dispensed on prescription:

• Pharmacists providing contracted imprest services (or limited non-patient specific supplies of scheduled medicines) to hospitals, residential care facilities, prisons, other health services, or other authorised Registered Health Practitioners for professional use (e.g. GP Clinics, Medical Specialist’s suites). These supplies may be either from an onsite dispensary or an offsite Community Pharmacy.

• The provision of a limited range of Pharmacy-owned items onsite in a secured location at client facilities which enables after hours prescribing and administration of treatments without unnecessary delays and costs which would occur if every item had to be supplied on a named-patient basis by the Pharmacy.

• Emergency supplies of a single or small amount of a scheduled medicine to another Pharmacy for the purpose of meeting a therapeutic need for a patient before the patient’s Pharmacy can obtain supply from a wholesaler, or in the event of a medicine shortage. (Sending the patient to another Pharmacy fragments what may otherwise be an accurate and complete dispensing history and is therefore not best practice from a Quality Use of Medicines Perspective. Moreover, in some scenarios e.g. hospital pharmacies, such action may be inappropriate.)

We discuss this issue further in reponse to Questions 10 & 11 below.

** SEE Q.7 RESPONSE FOR REMAINDER OF OUR RESPONSE TO Q.6 **

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Q.6 REPONSE (CONT'D):

Drug Treatment Approval (Therapeutic) (Clause 43(2): this would appear to be the appropriate approval for Pharmacies however it lacks “supply” of medicines as an authorised regulated activity, which is in contrast to a Drug Treatment Approval (Dependency) in Clause 43(1), and approval that may be granted for example to a Pharmacy providing staged supplies to drug dependent patients (eg methadone clinics). The activitiy “give a treatment dose of the medicine” described in Clause 43(2)(c) and the definition for “treatment dose” do not adequately describe the practice of Pharmacists in supplying ongoing quantities of medicines to patients.

Definition of "eligible persons" (clause 36): we request inclusion of “Pharmacy support staff” as a very common example of the "health professionals" classification (clause 36(2)). A broad term such as this would not limit the scope of practice to existing roles such as Pharmacy Assistants and Dispensary Technicians, but allow for future expansion of their roles and scopes of practice (such as is seen internationally) which is necessary to ensure the Pharmacy workforce can continue to deliver high quality healthcare despite escalating costs for provision of such services.

Q.7 RESPONSE:

The National Safety and Quality Health Service Standards (and ACHS EQUIP National Standards), National Competency Standards Framework for Pharmacists in Australia, Society of Hospital Pharmacists of Australia Practice Standards, Pharmacy Board of Australia Codes and Guidelines (and similar Codes and Guidelines by the respecitve Boards of other Registered Healthcare Practitioners that deal with scheduled medicines), Pharmaceutical Society of Australia Professional Practice Standards, Pharmacy Guild of Australia Quality Care Pharmacy Program, Clinical Oncological Society of Australia's Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy, Australian/New Zealand Standards and ISO Standards in relation to aseptic compounding of hazardous and non-hazardous Pharmaceuticals.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

It is unclear whether Pharmacies (including onsite Hospital Dispensaries that are operated by contracted Pharmacists) will be approved under a "Drug Treatment Approval" (Clause 43), or whether they will be required to apply for multiple approvals (e.g. wholesale licenses, manufacturing licenses) to perform a range of regulated activities in relation to the possession and supply of scheduled medicines which essentially carry similar requirements, e.g. supply to individual patients on prescription or as OTC sales or supply of non-patient specific medicines to another treatment facility, health service or pharmacy for the purpose of meeting the therapeutic needs of patients in their care. As discussed in response to Q.6 above, there are a number of routine supply scenarios that Pharmacies can perform which carry very similar requirements as those for the supply of scheduled medicines to individual patient on prescription or as OTC sales, but are deemed as "wholesaling" and thus carry additional compliance costs, not only in terms of license fees, but also potentially capital investment and operating costs depending on how regulations are interpreted by different individuals acting on behalf of regulators, e.g. mandating a separate drug storage area to the dispensary for wholesaled medications (often a duplication of the medications held in the dispensary). The requirements to be met under the TGA's Code of Good Wholesaling Practice largely reflect the similar requirements for dispensaries under the Health Regulations 1996 (Drugs & Poisons and Dispensary Regulations) in relation to the storage and supply of scheduled medicines to individual patients. In some respects Pharmacies exceed these requirements with Pharmacy staff requiring certain qualifications to perform certain tasks in relation to scheduled medicines, whereas wholesaling code stipulates "responsible adult". Other accreditation schemes such as the Pharmacy Guild of Australia's Quality Care Pharmacy Program (QCPP) for Community Pharmacies and the National Safety and Quality Health Service Standards for Hospital Pharmacies (including contracted hospital Pharmacy services) further ensure compliance with similar requirements as those in the TGA Code. Furthermore there are other aspects to wholesaling licensing and practice (e.g. samples and wholesale representatives) that are not relevant to standard Pharmacy practice. So it would seem further consideration should be given to the role of Pharmacies and how they are to be approved under the new Act without requiring multiple licenses and other potential compliance costs for services which essentially have overlapping requirements. When considering imprest services in particular, the imprest supply activity per se is only one element of a comprehensive imprest management service. Imprest management services encompasses a range of ongoing activities to ensure safe medication practices and protect patients from harm (and indeed healthcare workers – often deemed the "second victim" in serious adverse patient outcomes). Such activities are discussed in a number of Standards outlined in response to Q.7 and include (but are not limited to) review of appropriate stock levels and medication to match casemix, safe storage practices such as standardisation and labelling of imprest layout, with additional measures high risk medicines and look-alike sound-alike medicines. Our experience in other jurisdictions is that when imprest supply by a pharmacy is considered wholesaling, the regulatory compliance requirements (stocking and picking the imprest orders directly from a discrete wholesaling area within the pharmacy which often duplicates the stock holdings of the dispensary) are resource intensive, negatively impacting on the available resources delivering the other important safety elements of the imprest management service. In the supply model described below, such an imposition is an unnecessary duplication of the activities already performed by a licensed wholesaler from whom and imprest supply may be sourced. Moreover, in small hospitals, there is simply not room for a dispensary to be able to have duplication of medicines storage for dispensing and wholesaling supply. An example of an innovative imprest supply model as part of a contracted Pharmacy service to an institution providing patient care consists of placing imprest/ward stock orders directly with major licensed wholesalers on behalf of entities (using scanners & electronic data interface), accepting discrete shipments from the wholesaler which are then taken to each clinical area for receipting, unpacking and restocking. Only emergency supplies of urgently required imprest medicines are supplied directly from dispensary stock to the client facilities/services.

11. Are the proposed licences, approvals and other authorisations appropriate?

We have addressed much of this in response to Q.10 but will reiterate that further consideration needs to be given to the role of Pharmacies and whether the existing draft bill adequately describes their services and provides for their approvals. An option would be for there to be a Pharmacy license/approval which encompasses the range of routine supply activities described above.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Assuming this actually refers to Section 21(b) (rather than 21(d)), then this is adequate.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

No comment

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

No

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

N/A

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

It is anticipated that some but not all elements of scheduled substance management plan (SSMP) would be covered by existing Medicines Management and/or Medication Safety policies/procedures that hospitals have developed to meet the requirements of accreditation standards, particularly the NSQHSS. In our case (as a contracted Pharmacy service prvoider), such policies and procedures have been prepared collaboratively, taking into account the multidsciplinary nature of the medicines management pathway with acute health care.

However, this question is challenging to answer accurately without having access to the relevant standards and regulations which must be met by the SSMP. Further clarity is required regarding the SSMP requirements for contracted Pharmacy services to entities operating hospitals and residential aged care facilities, where such pharmacy services are provided by a community pharmacy (onsite or offsite) or an onsite hospital dispensary operated by a contracted pharmacy service provider, eg the Pharmacy operator may have their own SSMP for internal activities (procurement, storage, supply), but also be required to integrate within a broader hospital-wide SSMP given the medincines management pathway is multidisciplinary in nature.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

Again, difficult to answer without full details of requirements of SSMP.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Using the National Safety and Quality Health Services Standards as a surrogate indication, 6-12 months would be a reasonable timeframe, with the longer timeframe required for larger more complex health services, particularly if multiple organisations are required to comply with the one common SSMP.

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

Under the current National Safety and Quality Health Service Standards Accreditation Framework, surveyors are frequently Health Professionals currently working in the healthcare industry, and are required to declare any conflicts of interest.
http://www.achs.org.au/media/23727/Surveyor%20commitments.pdf

It should be a similar requirement of any third party auditors.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

No

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

We welcome such standards and regulations as essential to guide the creation of SSMP's that allow of innovation and efficient delivery of patient care which protects the public and the staff providing such services.

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Penny

Surname: Hutchinson

Organisation and/or Professional position: Darling Downs Public Health Unit

Postcode: 4350

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: EH_DarlingDowns@health.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

More information is required to determine whether any subordinate legislation will adversely burden industry, government or the community. The Bill does not burden industry, government or the community in its current form.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

More information is required about the controls which will apply to certain classes of persons listed under section 36 of the Bill. It is also unclear what the impacts this Bill will have on non-registered health practitioners such as hospital and/or community pharmaceutical assistants, persons involved in the carrying out of immunisation programs e.g. local government Enviornmental Health Officer's (EHO) or other persons who perform regular functions in the supply of sheduled substances such as carriers. It is understood that the combination of conditions of approval, licence or otherwise the adopted industry protocol/Scheduled Substance Management Plan will clarify these controls. It is therefore difficult to comment on the impact of these controls at present. There is a perceived risk that the Scheduled Substance Management Plan proposal may result in inconsistenscies across industry, state-wide, which may cause some difficulties for EHO's who monitor and enforce these provisions.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

The Bill does not appear to capture dosage or application rates concerning offences for administering drugs or poisons, or otherwise applying poisons, where there is labelled instructions. A potential risk would be where a person oversupplied the medicine to somebody under their care or an authority (for e.g. pest management technician) over-applied a poison; resulting in a health risk. While the Scheduled Substance Management Plan may capture over-dosage as a risk in an institutional setting, for e.g., the mentioned activities would not be required to prepare and work under a Scheduled Substance Management Plan. Provision for using the correct dosage and rate could be captured in the definition of authorised way.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

A provision equivilent to section 178 of the Health Act 1937 (Evidence) should be included.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

The key offences listed in the Bill are reasonable, however more information is needed to comment on the offences expected to be covered in the subordinate legislation.

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes.

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

The new legislation does reduce the number of licences a larger company (i.e. multiple locations) is required to possess, which may reduce cost to industry in that respect. Approvals under the Health (Drugs and Poisons) Regulation 1996 do not come with a fee. The proposed Bill may have increased compliance costs if approval fees are imposed in the subordinate legislation and approval holders/licensees move towards industry-based accreditation schemes. In that respect, more information is required.

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Section 20(f) of the Bill provides recognition for other licences/approvals under other State and Commonwealth legislation as an 'authority' and includes a list of examples. No issues are identified.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Criminal history checks should also include the company's director. It is unclear whether a change of the nominated person will trigger the need for a criminal history for the new nominated person.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

It is unclear what enforcement role the Hospital and Health Service Health EHO's will have.

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

It is not recommended and more information is required about risk categories and audit frequencies will be prescribed. Third party auditors may come with additional cost to industry. Furthermore, government agencies could be responsible for the licencing and monitoring of the activities of the third party auditors, which will come at a cost to those agencies.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

No.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

Online ordering of scheduled substances should be captured under the subordinate legislation. This should include electronic signatures and electronic purchase order requirements, which are becoming a standard in commercial transactions.

The requirements concerning the sale of medicated stock feed needs to be better clarified in the subordinate legislation. Currently, it is interpreted that a Veterinary Surgeon must supply the medicated stock feed to the animal's owner, which is not realistic. Manufacturers of medicated stock feed should be able to supply the substance to the animal's owner where a veterinary surgeon has provided written instruction to the manufacturer to do so.

The controls for community pharmaceutical assistants should be defined in the subordinate legislation, which has been overlooked in the current Regulation. In some respect, the roles and responsibilities of pharmacists have been devolved to qualified pharmaceutical assistants.

Industry representatives, including AgSafe and business, report that the storage of S7 poisons (S7 retail licence holders) has become inconsistent across the state. S7 storage requirements should be better defined to provide certainty for business. Storage of all scheduled poisons should be consistent at a national level.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name:

Surname:

Organisation and/or Professional position: Metro North Hospital and Health Service

Postcode: 4029

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☒ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: MD16-MetroNorthHHS@health.qld.gov.au

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

The Bill acheives a good degree of balance between the set objectives and the regulatory burden, however consideration should be made on increasing the detail on electronic medication management, i.e. the use of electronic signatures for prescriptions.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Nil identified

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

Nil identified

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

The legislation should be more 'visionary' and 'future-proof' i.e. focusing on multi-professional groups with increasing scope of practice.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

No

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Yes

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Not available

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

Not applicable

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Not applicable

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Not applicble to Metro North Hospital and Health Service

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Metro North Hospital and Health Service have established facility-based management plans, however these will eventually transition to a standardised plan that can be utilised by any facility in Metro North.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

No identified cost burden

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

Not applicable

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

External auditors must have a wealth of experience in public hospital pharmacies and knowledge of current hospital business models.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

The use of case study scenarios and practice application would provide great value.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

Nil

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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Queensland Government

Department of
**Housing and Public Works**

Our Ref: HPW02539/14
Your Ref: DG075004

Ms Julie Stokes
Consultant Pharmacist
Medicines Regulation and Quality
Queensland Health
GPO Box 48
BRISBANE QLD 4001

Dear Ms Stokes

Thank you for Mr Ian Maynard's letter of 23 September 2014 to Mr Neil Castles, Director-General, Department of Housing and Public Works about the consultation period for the draft Medicines, Poisons and Therapeutic Goods Bill. Mr Castles has forwarded the correspondence to the Residential Services Unit, Department of Housing and Public Works for consideration and response.

Departmental staff from the Policy and Legislation Unit and the Residential Services Unit have reviewed the consultation draft. Based on the available information, it would appear that the proposed bill is unlikely to have a significant impact on the ability of providers to meet their medication management obligations in accordance with the *Residential Services (Accreditation) Act 2002* and its associated Regulation.

Thank you for the opportunity to consider the consultation draft. I can be contacted on telephone (07) 3008 5824 or by email at terry.green@hpw.qld.gov.au if you need any more information or input from the Department of Housing and Public Works.

Yours sincerely

[redacted]

Terry Green
**Acting Manager**
**Residential Services Unit**

**Level 4B 80 George Street**
**Brisbane Queensland**
GPO Box 690 Brisbane
Queensland 4001 Australia

**Telephone +617 3224 6525**
**Facsimile +617 3224 5616**
**Website www.hpw.qld.gov.au**

# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or [redacted] - Sigma Pharmaceuticals

Professional position

Postcode: 3178

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☒ Industry - medicines
- ☒ Industry - poisons
- ☒ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

Yes

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

There are no issues with the proposed measures.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

It is imperative that electronic systems (signatures, ordering, receipt, management of posions movement and control) are recognised as effective mecahnisms under the legislation

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Yes

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Yes

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

Yes

11. Are the proposed licences, approvals and other authorisations appropriate?

Yes

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Yes

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Yes

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

12 months

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Our company maintains a set of documents that address the relevant aspects of the code as is required. It would be very helpful if a template is provided (such as provided by other states) to guide the licence holder on the development of a scheduled substance management plan.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

There will be a cost associated with this and it depends on the level of detail (expertise) required to complete it.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

12 months

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

As a CSO approved distributor, consolidation of audits currently conducted by the CSO Agency (on behalf of the Commonwealth Department of Health) will be favourable.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

As above.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

# Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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# Consultation feedback template

September 2014

## *Medicines, Poisons and Therapeutic Goods Bill 2014*

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: Claire

Surname: Bolge

Organisation and/or Professional position: Australasian Podiatry Council - Communications & Policy Officer

Postcode: 3057

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☒ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☐ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

The Object of the Act appears to be suitable.

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

The Act, or subsequent regulations, need to be specific about how it will relate to legislation such as national law governing the National Registration and Accreditation Scheme for the registration of health professions.

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

The Act appears suitable subject to regulations making clear reference to the restrictions to be applied to specific professions such as podiatry. It is crucial that new regulations are consistent with the recommendations under the HPPP and enable practitioners to practice in accordance with endorsement available under national registration.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

We believe the controls proposed are appropriate.

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

Not that we can determine at this time. It is noted that some areas will require appropriate regulations to close some gaps such as scope of practice limits.

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Podiatrists, as registered health practitioners under NRAS, are regulated in the interests of protecting the public from harm.

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

The offences appear to appropriately cover the scope of harm.

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

The penalties appear to be consistent with penalties in other states.

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

11. Are the proposed licences, approvals and other authorisations appropriate?

Practitioners who are currently authorised to prescribe, such as podiatrists, should have specified drug treatment approval to ensure that their ability to authorise, supply and administer continues.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

Yes, to a point. The legislation does recognise registered health professionals, however it's uncertain how specifics will be applied such as the approved drugs list, as this will be dealt with under regulation.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

Criminal checks should not be required where the check is already mandated under other laws, such as the requirement that registered health practitioners maintain annual criminal checks.

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

We do not have a view on this point.

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

Not as far as we can determine.

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

No

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

Assuming the regulations provide for appropriate prescribing practice by podiatrists, the law appears appropriate.

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

Podiatrists are currently in the process of undergong practice accreditation, which would fulfil the requirements of a scheduled substance management plan, and which should be acceptable to meet specified standards, providing th accreditor is covered under ISQUA.

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

There is currently insufficient data available to assess the impact of implementing a management plan, however the majority of providers are unlikely to have the necessary experience in holding or administering scheduled substances as it is.

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

The government should work with accrediation agencies where possible to monitor and enforce these standards, rather than appointing auditors as a matter of course. Auditors, and the government, should be appointed in instances of detected failures.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

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ADOHTA
AUSTRALIAN DENTAL and ORAL HEALTH THERAPISTS' ASSOC Inc.
PO Box 405 NUNDAH Q 4012 0439 608 765

3 October 2014

**Consultation: Medicines, Poisons and Therapeutic Goods Bill 2014**

Protecting the community is an integral role for Government. ADOHTA supports the new Act continuing to ensure compliance among health care providers and practitioners. However, it is also necessary that the proposed regulations reflect the current scope of all members of the workforce. The education, training and scope of practitioners should be taken into consideration when determining who may supply and administer certain medicines and poisons.

The current *Health (Drugs and Poisons) Regulation 1996* outlines a prescriptive list of drugs which dental therapists, oral health therapists and dental hygienists may *administer* only. In contrast, dentists may *obtain*, *possess*, *administer* and/or *supply* a non-prescriptive restricted drug in the practice of dentistry.

Dental and oral health therapists and dental hygienists are highly-skilled autonomous members of the oral health team. Oral health practitioners practice in rural and remote parts of Queensland which do not have a permanent dentist. Current students of Central Queensland University's Bachelor of Oral Health program will graduate with an adult scope of practice.

The over-regulation of the dental and oral health therapy profession will continue to see an underutilisation of a large part of the dental workforce. The ability for therapists to work autonomously in structured professional relationships has been recognised by the Dental Board of Australia.

Structured professional relationships are the framework for referral to a dentist when the required care is *outside the scope of practice* of a dental hygienist or a dental or oral health therapist. Standards of education, training and competence should be taken into consideration when determining a standard or guideline for the regulated activity of the profession.

Ambiguities exist in the language of the proposed new guidelines. Offences in the new Act are related to practitioners who perform regulated activities with regulated substance *outside the scope of their profession*, however the enforcement is based upon the current, obsolete act, which does not consider the evolving scope of graduates.

The limitations on therapists to practice independently has huge impacts on efficiencies – particularly in rural and remote parts of the state which do not have a permanent dentist presence. The prescriptive nature of the Act inhibits therapists – who are educated and

trained to be competent members of the workforce – from practicing according to their level of capability.

This omission from the legislative framework will serve as a future regulatory burden. ADOHTA supports a new standard being established for dental and oral health therapists and dental hygienists. A new, non-prescriptive legislative format for oral health practitioners will allow therapists to provide services within their full education and training.

ADOHTA hopes to be afforded the future opportunity to take part in establishing a new standard of authorisation for dental and oral health therapists and dental hygienists.

Clair Parsons

Executive Officer

DG 075139.

ODG DATE RECEIVED 03 OCT 2014

Previous/related/similar to DG075004

INVITATION ☐

DG delegated to.....

Comments .....

.....

.....

Acknowledgement letter completed ☐

ACTION OFFICER HSCT

COPY PROVIDED TO .....

REPLY FOR DG'S SIGNATURE REQUIRED ☐

due (to DG Corro) ...../...../.....

briefing note also required ☐

ACTION DIRECT* ☑

direct action required by ...../...../.....

DG Corro to be advised of completion of action - ☐

Copy of response (letter or email) required ☐

NRR – (No response required - for information only) ☐

COMMENTS .....

.....

.....

*Nomination of an item as 'action direct' requires the actioning area to determine whether a response is required. The actioning area is also responsible for determining who the appropriate signatory of the response should be.

Queensland Government

Our ref: DG28736

Your ref: DG075004

Office of the
**Director-General**

Department of
**Transport and Main Roads**

Mr Ian Maynard
Director-General
Queensland Health
GPO Box 48
Brisbane Qld 4001

Dear Mr Maynard Ian

Thank you for your letter seeking feedback on the Medicines, Poisons and Therapeutic Goods Bill.

The majority of the Bill does not have any direct impacts on the Department of Transport and Main Roads. However, there is a minor consequential amendment proposed to the definition of "analyst" in the *Transport Operations (Road Use Management) Act 1995*.

Analysts are authorised to sign evidentiary certificates under the *Transport Operations (Road Use Management) Act 1995* to state the level of alcohol or the presence of drugs in a person's blood or saliva for the purpose of drink and drug driving legislation.

Queensland Health will need to ensure that, before the proposed legislation commences, analysts who conduct testing for drink and drug driving purposes are appointed as State analysts under the *Public Health Act 2005*, as those analysts are currently appointed under the *Health Act 1937*.

If you require any further information, we encourage you to contact Mr James Liddy, Principal Legislation Officer on 3066 2472 or by email at james.a.liddy@tmr.qld.gov.au. Mr Liddy will be pleased to assist.

Yours sincerely

Neil Scales
**Director-General**
**Department of Transport and Main Roads**

85 George Street Brisbane
GPO Box 1549 Brisbane
Queensland 4001 Australia

Telephone +61 7 3066 7316
Facsimile +61 7 3066 7122
Website www.tmr.qld.gov.au
ABN 39 407 690 291

DG 075155

ODG DATE RECEIVED 7 OCT 2014

Previous/related/similar to DG075004

INVITATION ☐

DG delegated to.....

Comments .....

.....

.....

Acknowledgement letter completed ☐

ACTION OFFICER HSCT

COPY PROVIDED TO .....

REPLY FOR DG'S SIGNATURE REQUIRED ☐

due (to DG Corro) ...../...../.....

briefing note also required ☐

ACTION DIRECT* ☐

direct action required by ...../...../.....

DG Corro to be advised of completion of action - ☐

Copy of response (letter or email) required ☐

NRR – (No response required - for information only) ☑

COMMENTS .....

.....

.....

*Nomination of an item as 'action direct' requires the actioning area to determine whether a response is required. The actioning area is also responsible for determining who the appropriate signatory of the response should be.

Queensland Government

Queensland Fire and Emergency Services

Office of the Commissioner

Our Ref: 07457-2014
Yr Ref: DG075004

30 September 2014

Mr Ian Maynard
Director-General
Department of Health
GPO Box 48
BRISBANE QLD 4001

Dear Mr Maynard

Thank you for your letter dated 23 September 2014 requesting feedback on the draft Medicines, Poisons and Therapeutic Goods Bill.

The Public Safety Business Agency (PSBA) is co-ordinating and will forward the response on behalf of Queensland Fire and Emergency Services.

Should you have any queries please contact Ms Samantha Laws, Director Policy, PSBA on telephone number (07) 3364 6507.

Yours sincerely

[redacted]

Lee A Johnson AFSM FIFireE
**Commissioner**

Emergency Services Complex
125 Kedron Park Road, Kedron
Queensland 4031

GPO Box 1425, Brisbane
Queensland 4001
Australia

**Telephone** 13 QGOV (13 74 68)
**Facsimile** (07) 3247 8110
**Website** www.qld.gov.au/emergency
**ABN** 19 823 962 345

DG 075156

ODG DATE RECEIVED 7 OCT 2014

Previous/related/similar to DG07504

INVITATION ☐

DG delegated to.....

Comments .....

.....

.....

Acknowledgement letter completed ☐

ACTION OFFICER CHSCT

COPY PROVIDED TO .....

REPLY FOR DG'S SIGNATURE REQUIRED ☐

due (to DG Corro) ...../...../.....

briefing note also required ☐

ACTION DIRECT* ☑

direct action required by ...../...../.....

DG Corro to be advised of completion of action - ☐

Copy of response (letter or email) required ☐

NRR – (No response required - for information only) ☐

COMMENTS .....

.....

.....

*Nomination of an item as 'action direct' requires the actioning area to determine whether a response is required. The actioning area is also responsible for determining who the appropriate signatory of the response should be.

Queensland Government

Department of
**Science, Information Technology, Innovation and the Arts**

Ref: 00231-2014 – 23950/14

Mr Ian Maynard
Director-General
Department of Health
GPO Box 48
BRISBANE QLD 4001

Dear Mr Maynard

Thank you for your letter of 23 September 2014 consulting the Department of Science, Information Technology, Innovation and the Arts on the draft Medicines, Poisons and Therapeutic Goods Bill 2014 (the Bill).

It is noted that the draft Bill aims to remove regulatory duplication and promote national consistency by applying the *Therapeutic Goods Act 1989* as a law of Queensland and by recognising manufacturing authorisations under the *Agricultural and Veterinary Chemicals Code Act 1994*.

The Department of Science, Information Technology, Innovation and the Arts has reviewed the information provided on the draft Bill and considers it a welcome development which will benefit Queensland's research and drug manufacturing sectors. In particular, our public research organisations and universities will be able to be covered under a single general approval, while drug manufacturers such as Patheon at the Translational Research Institute will only require national level approval.

Should you require any further information, you may contact Dr Christine Williams, Assistant Director-General, Department of Science, Information Technology, Innovation and the Arts by email at christine.williams@dsitia.qld.gov.au or on telephone 07 3170 5404.

Yours sincerely

[redacted]

Sue Rickerby
**Director-General**
1/10/14

Level 5 Executive Building
100 George Street Brisbane
GPO Box 5078 Brisbane
Queensland 4001 Australia

**Telephone +617 3215 3700**
**Website www.qld.gov.au**

Queensland Government

Enquiries to: Ms Julie Stokes
Consultant Pharmacist
Medicines Regulation and Quality
Telephone: 3328 9225
File Ref: DG075004

23 SEP 2014

Ms Sue Rickerby
Director-General
Department of Science, Information Technology, Innovation and the Arts
GPO Box 5078
BRISBANE QLD 4000

Dear Ms Rickerby Sue,

I am writing to formally advise you that a draft Medicines, Poisons and Therapeutic Goods Bill is open for public consultation prior to its introduction to the Legislative Assembly. The *Health Act 1937*, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 are being repealed and replaced with a new contemporary approach.

The Department of Health is requesting feedback from a wide range of stakeholders and I would like to invite feedback from your agency.

The consultation draft of the Bill and supporting documents are available at the Get Involved website at http://www.getinvolved.qld.gov.au/gi/consultation/2122/view.html. A copy can be provided on request by contacting the Department of Health via email legislation@health.qld.gov.au or telephone 3234 1793. I have enclosed a copy of the webpage for your information.

Please note that relevant officers in your Department may have already been alerted about the consultation on the draft Medicines Poisons and Therapeutic Goods Bill.

The closing date for feedback is 3 October 2014.

Thank you for your participation in modernising our legislation.

Yours sincerely

[redacted]

Ian Maynard
Director-General

Office
19th Floor
Queensland Health Building
147 - 163 Charlotte Street
BRISBANE QLD 4000

Postal
GPO Box 48
BRISBANE QLD 4001

Phone
3234 1553

Fax
3234 1482

DG 075162

ODG DATE RECEIVED 8 OCT 2014

Previous/related/similar to DG075004

**INVITATION** ☐

DG delegated to.....

Comments .....

.....

.....

Acknowledgement letter completed ☐

**ACTION OFFICER** NSCI

**COPY PROVIDED TO** .....

**REPLY FOR DG'S SIGNATURE REQUIRED** ☐

due (to DG Corro) ...../...../.....

briefing note also required ☐

**ACTION DIRECT*** ☑

direct action required by ...../...../.....

DG Corro to be advised of completion of action - ☐

Copy of response (letter or email) required ☐

**NRR** – (No response required - for information only) ☐

**COMMENTS** .....

.....

.....

*Nomination of an item as 'action direct' requires the actioning area to determine whether a response is required. The actioning area is also responsible for determining who the appropriate signatory of the response should be.

Queensland Government

Department of
Agriculture, Fisheries and Forestry

Reference: **22733/14**

03 OCT 2014

Mr Ian Maynard
Director-General
Queensland Health
GPO Box 48
BRISBANE QLD 4001

Dear ~~Mr Maynard~~ Ian

Thank you for your letter of 23 September 2014 concerning the opportunity to comment on the Medicines, Poisons and Therapeutic Goods Bill 2014.

I attach the Department of Agriculture, Fisheries and Forestry submission that supports the Bill but also provides some suggestions on alignment with the National Registration Scheme for Agricultural and Veterinary Chemicals to further support Queensland agriculture.

If your Office requires any further information, please contact Mr Dick Watts, Principal Scientific Advisor on telephone 07 3087 8095 or email richard.watts@daff.qld.gov.au.

Yours sincerely

[redacted]

**Jack Noye**
**Director-General**
**Department of Agriculture, Fisheries and Forestry**

Att

Floor 8
Primary Industries Building
80 Ann Street Brisbane
GPO Box 46 Brisbane
Queensland 4001 Australia
**Business Centre** 13 25 23
**Website** www.daff.qld.gov.au
**ABN** 66 934 348 189

Thank you for the opportunity to comment on the Medicines, Poisons and Therapeutic Goods Bill 2014.

Alignment of control of use of agvet chemicals with drugs and poisons controls

Controls on possession, supply and use on medicines and poisons capture a large range of industrial, therapeutic and agricultural and veterinary (agvet) chemicals. This submission relates solely to the uses of medicines and poisons in agriculture. It is important to note that some commodity chemicals that are generally regarded as industrial chemicals are approved as agvet chemicals.

As identified in the background documents, there are 'sister' systems whereby agvet chemicals are registered with supply controls administered nationally by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and use controls administered by states and territories. This system is intended to be complementary with the hazard control system whereby chemicals are scheduled nationally and the controls are through states and territories.

There has been a long standing overlap of the systems which has been confusing for suppliers and users of agvet chemicals. However, that overlap is not necessarily inappropriate because one is a risk assessed system and the other a hazard assessed system. The efforts of the Department of Health to align the systems are commendable but there are areas where further alignment would be beneficial.

It is very pleasing to have the 'Poisons Standard' adopted more directly as it enables better alignment with agvet chemicals where scheduling decisions are applied by the APVMA.

Veterinary chemicals, as defined by the Agvet Code, are typically, S5, S6, S4 or S8 but there are also examples where they are S7 and occasionally appendix J. Whether the scheduling of S7 and appendix J (Conditions for availability and use of Schedule 7 poisons) for veterinary chemicals is appropriate is questionable but these are matters for the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS). Whilst there remain S7 and appendix J veterinary chemicals, it is recommended that controls on S7s should apply to veterinary chemicals that are defined as medicines in the Bill.

In the Bill, there are general offences whereby a person must not possess, supply or administer (use) an S4 or S8 medicine or a prescribed S7 poison excepted where it is lawful. The Bill also describes the schemes of the TGA and Agvet thereby implying that those schemes may authorise use and supply.

Currently, the Drugs and Poisons Regulation only exempts use of regulated poisons when they are registered by the APVMA and used for their registered purpose for use as a pesticide. However, there are poisons that are agricultural chemicals (as defined by the Agvet Code) but are not pesticides (as defined by the Poisons Standard). There are also approval mechanisms within the Agvet scheme that are not covered by the term 'registration'. Whilst the Bill appears to do so, it is recommended that the Bill allow for all the

mechanisms by which agvet chemicals can be approved and avoid terms such as pesticides.

As described above there are veterinary chemicals that are S7 therefore are not currently exempted from the use controls in the current legislation because there are not 'pesticides'. It is also important to appreciate that veterinary chemicals can be authorised by a veterinary surgeon which is authorised by state control of use legislation rather than the Agvet Scheme (as defined in the Bill).

The reference to the Agvet Scheme within the Bill does not appear to be correct. The intergovernmental agreement that sets up the scheme (http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/domestic-policy/history-of-coag-reforms/iga-coag) indicates that the scheme is about registration and supply control conducted by the Australian Government and controls on the use of agvet chemicals by states and territories. The scheme is not just the *Agricultural and Veterinary Chemicals (Queensland) Act 1994 and the Agvet Code of Queensland under that Act.*

*Vertebrate pest poisons*

In the overview document, there is the intention to enable controls detailed in appendix J of the Poisons Standard. However, a reference cannot be found to appendix J in the Bill therefore it is unclear what the intention is for the adoption of appendix J conditions. There are a number of agvet chemicals in appendix J including fumigants and vertebrate pest toxicants such as strychnine that are condition 1, '*Not to be available except to authorised or licensed persons*'. Sodium fluoroacetate (1080) is condition 3, '*not to be used except by or in accordance with the directions of accredited government vermin control officers'.* Advice is sought of how appendix J conditions are intended to be implemented as potentially it may have an effect on accessibility to the chemicals by agriculture.

The National Registration Scheme for Agricultural and Veterinary chemicals also contains mechanism to require authorisation before supply and use of selected agvet chemicals called 'Restricted Chemical Products' (RCP). However, the list of agvet chemicals requiring authorisation in that scheme is different to those in appendix J. Whilst it may not be possible to completely align the lists because of differing regulatory focus, it is recommended that the Department of Health engage with the APVMA to achieve as much alignment of the control mechanisms as possible.

The information sheet for agricultural users is solely about agricultural chemicals users and does not provide guidance on veterinary chemical users. To facilitate the understanding of the new legislation for veterinary chemical users, the development of an information sheet would be advisable.

The information sheet for agricultural users describes the intentions for the controls on 1080 and strychnine. At Minister McVeigh's direction, the Department of Agriculture, Fisheries and Forestry (DAFF) has been working with the Department of Health to achieve greater access to 1080 for landholders. The new controls are expected to follow those agreed access arrangements.

However, it is desired that there is a consistent policy and regulatory approach to all appendix J poisons that includes vertebrate pest management chemicals that is consistent with their risks. At present, there are specific regulatory approval regimes for 1080, strychnine and cyanide.

One area of concern is the continuance of the current requirement that 1080 baits contain less than 0.03 % fluoroacetic acid. DAFF do not have the complete historical knowledge about why this control has been adopted. However, it is noted that there is no restriction in the 'sister system' under Agvet Code about bait concentrations. The APVMA could approve baits above this concentration so long as there was not a risk to public health, trade or the environment.

In particular, there a range of new technology developments whereby 1080, strychnine or cyanide could be placed in capsules that are ejected into the mouths of vertebrate pests. These new technologies could potentially be approved by the APVMA in the near future. These capsules are expected to be above 0.03% fluoroacetic acid because although the absolute amount of the poison is not expected to change over that used in baits, the total carrier in the capsule is quite small.

It is recommended that further consideration is given to what risk the bait concentration control is achieving. If the risk mitigation control is needed, are there better mechanisms to achieve that function that would not prevent the easy progression of vertebrate management technologies. For instance, the control could be expressed on an absolute amount of poison rather than a concentration.

It is further recommended that if concentrations controls on 1080 baits are continued that it be clarified whether it is a control on the concentration of fluoroacetic acid or its sodium salt. Noting that under the Poisons Standard, fluoroacetic acid includes its salts.

Use of poisons in domestic situations

The Poisons Standard states '*that products for domestic use must not include poisons listed in Schedule 7*'. However, The Department of Health is encouraged to consider their policy with regard to uses of S7 poisons in domestic situations on agricultural properties. Currently, some agricultural users of S7 poisons are spraying domestic fruit trees surrounding their residence because the agricultural chemical product is approved on that crop. Under the current legislation, these situations appear to be exempted from use control on S7s because it is registered for the purpose.

Licensing manufacturers

The Department of Health are to be commended for their efforts to simplify the licensing regimes for medicines and poisons. The recognition of GMP licensing under the Agvet Code assists in reducing regulatory burden. However, advice is sought on the application of proposed legislation when a specific product is approved under GMP licensing under the Agvet Code but other products produced by the manufacturer but are not part of that scheme. Would a medicine and poisons licence be required in that situation?

Under the Agvet code, a medicated stockfeed is not a veterinary chemical product if it is prepared according to the label instructions therefore is outside the Agvet Code GMP licensing scheme. The definition of manufacture in the Bill indicates that manufacturing is '*not mixing the scheduled substance with another substance*'. This describes feed mills that make medicated feeds. Is the policy intention that feed mills will not require manufacturer licensing?

Scheduled Substance Management Plan

The requirement for Scheduled Substance Management Plan for prescribed S7 poisons has been noted. Agriculture is a large user of S7 poisons so potentially this will be an area of increased regulatory burden on Queensland agriculture. As the list of prescribed S7s has not been disclosed, it is not possible to determine the level of impact this may have. DAFF look forward to further engagement on the list of prescribed S7s that will require management plans.

Queensland Government

Enquiries to: Ms Julie Stokes
Consultant Pharmacist
Medicines Regulation and Quality
Telephone: 3328 9225
File Ref: DG075004

23 SEP 2014

Mr Jack Noye
Director-General
Department of Agriculture, Fisheries and Forestry
GPO Box 46
BRISBANE QLD 4000

Dear Mr Noye Jack,

I am writing to formally advise you that a draft Medicines, Poisons and Therapeutic Goods Bill is open for public consultation prior to its introduction to the Legislative Assembly. The *Health Act 1937*, the Health Regulation 1996 and the Health (Drugs and Poisons) Regulation 1996 are being repealed and replaced with a new contemporary approach.

The Department of Health is requesting feedback from a wide range of stakeholders and I would like to invite feedback from your agency.

The consultation draft of the Bill and supporting documents are available at the Get Involved website at http://www.getinvolved.qld.gov.au/gi/consultation/2122/view.html. A copy can be provided on request by contacting the Department of Health via email legislation@health.qld.gov.au or telephone 3234 1793. I have enclosed a copy of the webpage for your information.

Please note that relevant officers in your Department may have already been alerted about the consultation on the draft Medicines Poisons and Therapeutic Goods Bill.

The closing date for feedback is 3 October 2014.

Thank you for your participation in modernising our legislation.

Yours sincerely

[redacted]

Ian Maynard
Director-General

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19th Floor
Queensland Health Building
147 - 163 Charlotte Street
BRISBANE QLD 4000

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BRISBANE QLD 4001

Phone
3234 1553

Fax
3234 1482

## Julie Stokes

**From:** Health Ombudsman <health.ombudsman@oho.qld.gov.au>
**Sent:** Friday, 10 October 2014 12:58 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** CORRECTION: OHO feedback: Medicines, Poisons and Therapeutic Goods Bill

Good afternoon Dr Stokes,

After receiving your email yesterday, I became a little concerned because your responses were to emails that were internal feedback, and not part of the official response. It was brought to my attention that when I sent in the official OHO response, I had inadvertently attached copies of our internal emails. I apologise for this error, and ask that you please disregard the internal emails that were accidently attached. I would be grateful if you would please note that the below text **only** comprises the response from OHO:

**Generally, the following is noted:**

- The draft Bill provides a broad framework for the regulation of medicines and poisons in Queensland, and will be a positive move in in substance abuse management.
- OHO considers the simplification of eligible persons authorisation, substance management plans and offence sections to be positive moves.
- The consistency with the Commonwealth and other jurisdictions is noted.
- Ensuring Australian Pesticides and Veterinary Medicines Authority and Therapeutic Goods Administration based legislation will impact upon all in Queensland and not just corporations is viewed positively.

**Specifically regarding the *Health Ombudsman Act 2013*, and the OHO, the following is noted:**

- The draft Bill's principles are consistent with the guiding paramount principle of the *Health Ombudsman Act 2013* – that the health and safety of the public are paramount.
- That clause 160 provides for the release of information to support investigations by the OHO in a way that is consistent with the OHO's current arrangements.
- That power provided by clause 161(1) to require information from the OHO is reasonable and appropriate, given that under 161(3), the OHO can refuse under equally reasonable and appropriate circumstances.
- That in deciding whether an applicant is suitable to hold drug treatment approval, regard will be given to any conditions or other limitations placed on a practitioner's registration under the Health Practitioner Regulation National Law (clause 49(2)(c) )
- That the way various classes of drugs/poisons will be regulated according to the draft Bill can apply equally to unregistered and registered health practitioners if they are authorised to deal with them in a particular way as "eligible persons".

Overall, the OHO supports the draft Bill noting that the limited timeframe provided for review has meant not as thorough consideration has been given to the draft Bill as would ordinarily be desirable, and has provided limited opportunity to test the draft Bill with scenarios. Further, the OHO would appreciate the opportunity to review any amendments to the draft Bill.

Should you have any queries regarding OHO's commentary on the draft Bill, or wish to request further feedback following any amendment to the draft Bill, please do not hesitate to contact Halie Geissmann, Executive Advisor, Office of the Health Ombudsman on telephone 3158 1006, or via email at health.ombudsman@oho.qld.gov.au.

Kind regards,

Halie Geissmann

**Office of the Health Ombudsman**

T: 133 OHO (133 646)
E: health.ombudsman@oho.qld.gov.au
W: www.oho.qld.gov.au
P: PO Box 13281, George Street Brisbane Qld 4003

Office of the HEALTH OMBUDSMAN
Listen. Respond. Resolve.

---

**From:** Health Ombudsman
**Sent:** Thursday, 9 October 2014 2:17 PM
**To:** Medicine Poisons and Therapeutic goods Bill
**Cc:** Lisa Pritchard; Sylvie Brdjanovic
**Subject:** OHO feedback: Medicines, Poisons and Therapeutic Goods Bill

Thank you Dr Stokes – We understand that it was simply a confusion. We appreciate the short extension we received.

Please see attached the official feedback from the Office of the Health Ombudsman sent yesterday afternoon.

If you have any further queries, please do not hesitate to contact me via this email address, or on telephone 3158 1006.

Kind regards,
Halie Geissmann
Executive Advisor

**Office of the Health Ombudsman**

T: 133 OHO (133 646)
E: health.ombudsman@oho.qld.gov.au
W: www.oho.qld.gov.au
P: PO Box 13281, George Street Brisbane Qld 4003

Office of the HEALTH OMBUDSMAN
Listen. Respond. Resolve.

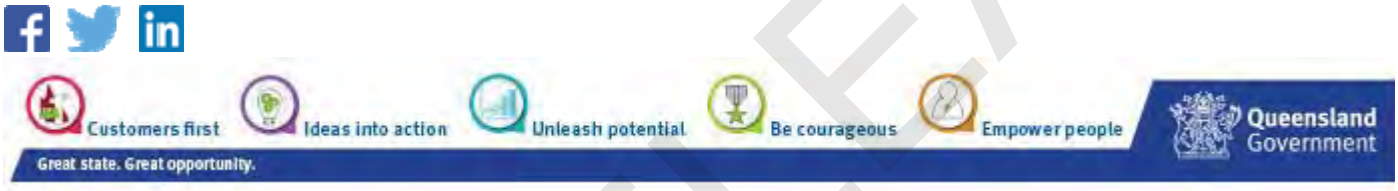
**From:** Medicine Poisons and Therapeutic goods Bill [mailto:mptg.bill@health.qld.gov.au]
**Sent:** Thursday, 9 October 2014 2:05 PM
**To:** Sylvie Brdjanovic; Lisa Pritchard; Halie Geissmann
**Subject:** RE: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill

Thank you all for this comment on the draft Bill particularly given the extremely short timeframes we were able to extend. Once again, my apologies for the late notice due to a mis-understanding in our office that there are two ombudsmen. We will make sure that there is sufficient opportunity to consult with the OHO as regulations and standards are developed.

Kind regards

Julie

**Dr Julie Stokes**
Consultant Pharmacist
Medicines Regulation & Quality | Chief Health Officer Branch | Health Services and Clinical Innovation Division
Department of Health | Queensland Government
Locked Bag 21 Fortitude Valley BC QLD 4006
t. 07 3328 9225
e. julie.stokes@health.qld.gov.au | www.health.qld.gov.au






**From:** Sylvie Brdjanovic [mailto:Sylvie.Brdjanovic@oho.qld.gov.au]
**Sent:** Friday, 3 October 2014 8:49 AM
**To:** Lisa Pritchard; Halie Geissmann
**Subject:** RE: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill

Sure happy to redirect callers to Halie.

While I agree that the timeframe did not allow the OHO to give due consideration to the matter and that this can be reflected in the feedback, I would suggest making two other points:

- That the principles of the Bill support the paramount guiding principle of the HO Act i.e. that the health and safety of the public are paramount
- That a preliminary review of the confidentiality provisions in the Bill indicate that the provisions for release of confidential information to OHO for HO investigations is useful and supports the current arrangements to protect the health and safety of the public as too is the provision in the Bill for the general release of confidential information as authorised by another law.

My final thoughts are that the Bill provides the broad framework for the regulation of medicines and poisons and while the principles in the Bill are reflected in national frameworks and contemporary clinical practice, the devil is always in the detail, hence the ability to review the regulations would be essential when providing feedback that is more than just agreement with the general principles of the Bill. I understand that the regulations will not be available soon so I'm not too sure what additional comment can be provided when the Bill is circulated under the ATI stage.

Sylvie

**Sylvie Brdjanovic**
Director, Triage and Assessment

T: (07) 3158 1081
M:

**From:** Lisa Pritchard
**Sent:** Friday, 3 October 2014 7:11 AM
**To:** Sylvie Brdjanovic; Halie Geissmann
**Subject:** Re: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill

Hi Halie
Can you let us know if you talk to MRQ pls?
Sylvie - if they contact you again can you put them onto Halie please? I agree with Halie's comments and plan.
Lisa

Sent from my HTC

**Lisa Pritchard**
Executive Director Assessment and Resolution

T: (07) 3158 1079
M:

----- Reply message -----
From: "Leon Atkinson-MacEwen" <Leon.Atkinson-MacEwen@oho.qld.gov.au>
To: "Lisa Pritchard" <Lisa.Pritchard@oho.qld.gov.au>
Cc: "Halie Geissmann" <Halie.Geissmann@oho.qld.gov.au>, "Leon Atkinson-MacEwen" <Leon.Atkinson-MacEwen@oho.qld.gov.au>
Subject: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill
Date: Thu, Oct 2, 2014 9:31 PM

If something can be done then that is great

L

Sent from my iPhone

**Leon Atkinson-MacEwen**
Health Ombudsman

T: (07) 3158 1005
M:

On 2 Oct 2014, at 7:25 pm, "Lisa Pritchard" <Lisa.Pritchard@oho.qld.gov.au> wrote:

> Brilliant, thanks Halie.

Sent from my HTC

**Lisa Pritchard**
Executive Director Assessment and Resolution

T: (07) 3158 1079
M: [redacted]

----- Reply message -----
From: "Halie Geissmann" <Halie.Geissmann@oho.qld.gov.au>
To: "Lisa Pritchard" <Lisa.Pritchard@oho.qld.gov.au>
Cc: "Leon Atkinson-MacEwen" <Leon.Atkinson-MacEwen@oho.qld.gov.au>
Subject: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill
Date: Thu, Oct 2, 2014 6:57 PM

Hi Lisa - I have had a look and briefly discussed it with Leon. I also spoke to the area that sent out the consultation. Given the size of the Bill Leon considered it was an inappropriate length of time to consult. I was awaiting a call from Bill from MRQ regarding whether it would be possible to submit our consultation later and for their cab sub to reflect this, and make amendments following first lodgement regarding our consultation. I did not hear back.

I can coordinate the response however, it would be more appropriate for the Bi to be properly considered rather than be reflected in the cab sub as 'consulted' and potentially have an issue come to light.

Leon, would you prefer Sylvie prepare something and submit?

Halie

**Halie Geissmann**
Executive Advisor

T: (07) 3158 1006
M: [redacted]

On 2 Oct 2014, at 6:46 pm, "Lisa Pritchard" <Lisa.Pritchard@oho.qld.gov.au> wrote:

> Hi Sylvie
> I hope you're feeling better?
> I forwarded the information to Halie to see if she could coordinate but I haven't had time to talk to her so I don't know how far she got. Robbie had a call from Bill so I told him the same thing.
>
> Halie - did you get chance to look at this??
>
> Thanks
> Lisa
>
> Sent from my HTC

**Lisa Pritchard**
Executive Director Assessment and Resolution

T: (07) 3158 1079
M: [redacted]

----- Reply message -----
From: "Sylvie Brdjanovic" <Sylvie.Brdjanovic@oho.qld.gov.au>
To: "Lisa Pritchard" <Lisa.Pritchard@oho.qld.gov.au>
Subject: For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill
Date: Thu, Oct 2, 2014 5:56 PM

Lisa
Will a response be prepared – I had missed a phone call from MRQ and I think they are following up. I can prepare an appropriate response, without completing their consultation form, that if Leon was happy with, we could send to MRQ tomorrow. I understand the Minister will be looking at the Bill and briefing notes on the weekend, hence the pressure from QH to seek responses asap.
Sylvie

**Sylvie Brdjanovic**
Director, Triage and Assessment

T: (07) 3158 1081
M: [redacted]

---

**From:** Lisa Pritchard
**Sent:** Thursday, 2 October 2014 10:14 AM
**To:** Halie Geissmann
**Cc:** Sylvie Brdjanovic
**Subject:** For Exec corro - new Medicines, Poisons and Therapeutic Goods Bill

Hi Halie
Is this something that could be coordinated by you as Exec corro please?
Thanks
Lisa

**Lisa Pritchard**
Executive Director Assessment and Resolution

T: (07) 3158 1079
M: [redacted]

---

**From:** Sylvie Brdjanovic
**Sent:** Wednesday, 1 October 2014 1:59 PM
**To:** Lisa Pritchard
**Subject:** FW: Attention Scott - new Medicines, Poisons and Therapeutic Goods Bill

Lisa

This has been provided to OHO by Queensland Health for comment by 3 October 2014. Should we circulate it?

**Sylvie Brdjanovic**
Director, Triage and Assessment

T: (07) 3158 1081
M: [redacted]

---

**From:** Medicine Poisons and Therapeutic goods Bill [mailto:mptg.bill@health.qld.gov.au ]
**Sent:** Wednesday, 1 October 2014 12:43 PM
**To:** Complaints
**Subject:** Attention Scott - new Medicines, Poisons and Therapeutic Goods Bill

Hi Scott,

Here is the email that should have been sent to the Health Ombudsman. The links to the Bill and the documents can be found via the Get involved website, but I have attached key documents here.

Apart from the features of the model (how to be authorised to do things with medicines and poisons and in what circumstances, standards and management plans) I would like to draw attention to sections 158-161 about confidentiality and information sharing, where we have tried to be clear about releasing of information to the health ombudsman.

Thank you for bringing this matter to the attention of Lisa and/or Sylvie.

Kind regards
Julie

**Dr Julie Stokes**
Consultant Pharmacist
Medicines Regulation & Quality | Chief Health Officer Branch | Health Services and Clinical Innovation Division
Department of Health | Queensland Government
Locked Bag 21 Fortitude Valley BC QLD 4006
t. 07 3328 9225
e.julie.stokes@health.qld.gov.au |www.health.qld.gov.au

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<image004.png>

## New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

The Department of Health has released a draft of the proposed new Medicines Poisons and Therapeutic Goods Bill intended to provide a modern framework to regulate how medicines and poisons are used in our community.

You are receiving this email as a stakeholder in the regulation of medicines and poisons.

As you or members of your organisation deal with medicines or poisons that are currently regulated under the Health (Drugs and Poisons) Regulation 1996, we would like to know how the proposed new Act may affect you or members of your organisation.

The draft of the Bill and consultation questions can be found at:

- Get Involved

  or

- a copy can be provided on request by contacting the Department of Health via email atlegislation@health.qld.gov.au or by phone on 07 3234 1793

**How to provide feedback**

The consultation questions ask for feedback about some specific aspects of the proposed regulatory scheme as well as the Bill itself. You can respond to the consultation questions by:

- using the online survey atGet Involved
- downloading the consultation feedback template form, and emailing the completed form to the Department of Health atlegislation@health.qld.gov.au

  or

- posting the completed consultation feedback form to:

  Medicines, Poisons and Therapeutic Goods Consultation Process
  Regulatory Policy Unit
  Department of Health
  PO BOX 48 BRISBANE QLD 4001

Feedback may also be provided by way of a written submission, if preferred.

Please forward this email to colleagues or members of your organisation who may wish to be informed of the proposed change and to provide feedback.

Thank you for your participation in modernising our legislation.

**********

services, loss of information, harm or is infected with a virus, other malicious computer programme or code that may occur as a consequence of receiving this email.

Unless stated otherwise, this email represents only the views of the sender and not the views of the Queensland Government.

**********

## Julie Stokes

**From:** Julie Stokes
**Sent:** Friday, 10 October 2014 8:56 AM
**To:** Medicine Poisons and Therapeutic goods Bill
**Subject:** FW: LGAQ comments draft Medicines and Drugs legislation

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**From:** Sophie Dwyer
**Sent:** Thursday, 9 October 2014 5:33 PM
**To:** Logan Timms; Julie Stokes
**Cc:** Dorean Erhart; Greg Hoffman; Stephan Bohnen; Luke Hannan; Beth Norman
**Subject:** RE: LGAQ comments draft Medicines and Drugs legislation

Many thanks Logan. That is most helpful.
regards

Sophie Dwyer PSM
Executive Director, Health Protection
Chief Health Officer Branch

Ph: 07 33289266
Mob: [redacted]

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**From:** Logan Timms [redacted]
**Sent:** Thursday, 9 October 2014 3:05 PM
**To:** Sophie Dwyer; Julie Stokes
**Cc:** Dorean Erhart; Greg Hoffman; Stephan Bohnen; Luke Hannan; Beth Norman
**Subject:** LGAQ comments draft Medicines and Drugs legislation

Hi Sophie and Julie,

Thank you for the extension to submit comments. We have looked through the draft legislation and accompanying documentation. We can see no major issues with the policy rationale underpinning the proposed changes. The requirement to move away from individual approvals to organisational approvals for poisons is a genuine example of local government empowerment and provides greater service delivery management options. Indeed, moving away from a 'one size fit all' approach reflects the practicalities of Queensland including its local governments and their differences in terms of geography, revenue and general resources.

The LGAQ continues to support the Government's red-tape reduction initiatives, where appropriate, and considers that the major risk with the ongoing development of this particular Bill is the *inadvertent* imposition of extra red-tape. For example, Queensland councils have an enviable track record of ensuring the use and storage of animal welfare and management substances are subject to robust Workplace Health and Safety protocols and that training and standard operating procedures are in place to manage operational processes in relation to these substances. It would be a shame to have to double up on the work already undertaken on this matter. LGAQ recommends that a number of grandfathering/deeming/savings provisions be included to ensure that either **1)**existing plans specifically dealing with baits, tranquiliser or euthanasia drugs or howsoever referenced are deemed to comply with the Act until reviewed and/or **2)** that a reasonable transition period be provided to establish the relevant management plans prior to any auditing by Queensland Government officials. It would also be helpful to provide some guidance on minimum requirements regulators would be looking for in relevant management plans. LGAQ has raised a number of specific issues in the attached table.

LGAQ also recommends that consultation on the development of the supporting regulation and standards be undertaken in a similar way to the proposed primary legislation. LGAQ has access to some very experienced and technically proficient local government officers who are keen to offer their invaluable assistance particularly in the development of standards.

Thank you again for the opportunity to comment.

Kindest Regards
Logan

Logan Timms
Team Leader – Advocacy
Strategic Policy and Intergovernmental Relations
LOCAL GOVERNMENT ASSOCIATION OF QUEENSLAND
**D** 07 3000 2238 Local Government House PO Box 2230
**F** 07 3252 4473 25 Evelyn Street Fortitude Valley BC Qld 4006
**M** [redacted] Newstead Qld 4006 **W** www.lgaq.asn.au

**Consultation Draft of the Medicines, Poisons and Therapeutic Goods Bill 2014**

**2 October 2014**

Thank you for the opportunity to provide comments on the Draft Bill. Officer-Level comments from Strategic Policy, Department of Justice and Attorney-General are outlined below. The Court Policy and Legal Unit has also been consulted by Strategic Policy in preparing these comments.

Please note that these comments have not received any endorsement or approval at Ministerial or Director-General level.

## Offence provisions

***DJAG Contact officer**:* *Julie Rylko, A/Principal Legal Officer*
*34041456*
*julie.rylko@justice.qld.gov.au*

### *Proposal*

The Draft Bill contains various offence provisions.

The "key offences" are contained in Part 2 of the Bill and are intended to replace over 50 separate offences under the existing legislation.

While the offences apply to all persons, it is proposed that the offence provisions recognise that the legislation enables certain persons to perform a regulated activity for a scheduled substance (i.e. medicines, poisons and prohibited substances). In addition, the provisions clarify that certain officers involved in the administration of the legislation and other relevant Acts will not be caught by the offences while carrying out their statutory duties.

Each of the "key offences" (i.e. those general offences in subdivision 1, Division 3, Part 2) also include a 'reasonable excuse' provision (for example to cover a person responding to a medical emergency).

### *DJAG's comments*

- The proposed maximum penalties for offences in the Draft Bill appear to be reasonable however further information is requested about how they compare with the current penalties and as well as relevant comparable provisions across the Queensland statute book and inter-state provisions?
- DJAG queries whether an element of knowledge should be included in the offence in section 32(1) of the Draft Bill if it is not intended to capture persons who do not or could not reasonably know that the prescription is given to them by a doctor who does not have authorisation?
- Similarly, DJAG queries whether the offence in section 32(4) should include an element of knowledge to ensure that it does not capture a person who uses a

prescription which they do not know has an alteration etc which is made by a person who did not write the prescription (for example a receptionist at a doctors surgery who writes on the prescription given to them by a doctor for collection by a patient).

- With respect to the offence in section 32(3), the reference to "otherwise write on a prescription" may cover a broad range of conduct and therefore capture, for example, a patient who makes a notation on the prescription (for example, to remind them of the doctor's instructions). Can Queensland Health advise whether the offence is intended to capture such conduct and if not whether the offence should be amended to excuse or exempt such conduct?
- Section 141 provides that a proceeding for an offence under the Act is to be taken in a summary way. These provisions (along with some provisions in the Bill for appeal against internal review of an original decision to seize or forfeit a thing) will affect the Queensland Magistrates Courts. Can Queensland Health please confirm that this impact is likely to be minimal and is not significantly different from the current position?

**Criminal history checks**

***DJAG Contact officer**:* *Julie Rylko, A/Principal Legal Officer*
*34041456*
*julie.rylko@justice.qld.gov.au*

***Proposal***

The Draft Bill contains provisions in Division 8, part 4 for criminal history checks in relation to licenses and approvals.

***DJAG's comments***

- The proposed provisions abrogate various rights under the *Criminal Law (Rehabilitation of Offender) Act 1986* by inclusion of charges (not just convictions) and displacing rehabilitation provisions. It is noted that these provisions are departures from the current legislation. No reason or justification has been provided for these extensions. Also, this raises an FLP issue which will need to be sufficiently justified in the Explanatory Notes for the Bill as well as in the submission to Cabinet seeking Authority to Introduce the Bill.

**Application of Therapeutic Goods laws**

***DJAG Contact officer**:* *Julie Rylko, A/Principal Legal Officer*
*34041456*
*julie.rylko@justice.qld.gov.au*

***Proposal***

The Draft Bill includes provisions in Part 10 to apply the TGA as a law of Queensland. In particular, Part 10 contains Division 5 which relates for offences. The object of this division is to provide that an offence against the applied provisions is to be treated as if it were an offence against a law of the Commonwealth and that associated Commonwealth laws apply to offences (including for example, laws of the Commonwealth relating to sentencing and punishment and release of persons convicted of offences).

***DJAG's comments***

- The need for section 157 (No double jeopardy for offences against applied provisions) is unclear given the rule against double punishment is already legislatively enshrined in Queensland in section 16 of the Criminal Code and also section 45 and associated definitions (particularly of a "law" in schedule 1 which includes a law in force in the State as part of the law of the State) of the *Acts Interpretation Act 1954*.

**Consequential amendments**

***DJAG Contact officer**:* *Julie Rylko, A/Principal Legal Officer*
*34041456*
*julie.rylko@justice.qld.gov.au*

***Proposal***

The Draft Bill repeals the *Health Act 1937*.

***DJAG's comments***

- Consequential amendments are also likely to be required to the *Drugs Misuse Act 1986* and *Drugs Misuse Regulation 1987* (in particular references to the Health Act will need to be replaced). These should be discussed further with the drafter and DJAG would welcome the opportunity to review the inclusion of consequential amendments in these areas prior to introduction of the Bill.

**Part 8: Review and appeals**

***DJAG Contact officer**:* *Nicole Drew, Legal Officer*
*32390754*
*nicole.drew@justice.qld.gov.au*

***Proposal***

Part 8 of the Draft Bill relates to the appeal and review provisions.

***DJAG's comments***

- It appears to be largely consistent (with one exception) with DJAG's soon to be released revised Administrative Review Policy (ARP). The currently published 2008 version can be found at http://www.justice.qld.gov.au/corporate/accessing-departmental-information/publishing-scheme/our-policies.

- In particular, the following is noted:

  - Section 126 mandates internal review before an application to external review may be lodged. This is consistent with the ARP.
  - Section 129(2)(b) requires that internal review is not dealt with by the original decision maker or a person in a less senior office than the original decision maker. The ARP has always stated (and it is intended that it will continue to state) that the internal review decision maker is to be "a more senior person

within the same department". So technically the Bill is inconsistent with the ARP on this point – although it is noted that other legislation requires the same thing (i.e. that the internal review decision maker is at least the same level as the initial decision maker).

- Section 131 provides external review rights are vested with QCAT - consistent with the ARP.

**QCAT-related issues**

***DJAG Contact officer:*** *Sarah D'Andilly, Legal Officer*
*38980178*
*Sarah.DAndilly@justice.qld.gov.au*

*MOU with QCAT required*

The Bill confers additional original (stay) and review jurisdiction on QCAT. QCAT requires the Department of Health to enter an MOU with QCAT to cover the costs of the new jurisdiction. The Department of Health can contact QCAT direct regarding the MoU through Louise Logan, the Principal Registrar of QCAT, on louise.logan@justice.qld.gov.au or on 07 3406 7759.

*Transitional Provisions*

The Bill notes 'savings and transitional provisions to be included based on requirements arising from consultations and further development of the Bill.' DJAG considers transitional provisions are necessary for review rights. The easiest way to deal with transitional review rights, in DJAG's view, would be to provide that review rights arising from applications/approvals under the Health (Drugs and Poisons) Regulation 1996 should continue under that Regulation. QCAT agrees with this position.

*Consequential Amendment to the QCAT Regulation*

A consequential amendment will be required to the QCAT Regulation to list the new legislation as an enabling Act.

*Clarification necessary regarding QCAT Review pursuant to sections 91 and 122*

Sections 91 and 122 refer to a "QCAT Information Notice". If it is proposed that an applicant can apply to QCAT for an external review of decisions under sections 91 and 122 (that is, without first going through the internal review process), then this needs to be made clear.

*Statutory Review of QCAT*

As part of the statutory review of QCAT pursuant to section 240 of the QCAT Act, DJAG has been considering provisions of QCAT enabling Acts, with a view to rationalising and streamlining provisions. In this vein, DJAG at officer level is considering including general provisions in the QCAT Act, akin to section 128(4)-(5) of the Bill. This position has not yet been finalised and won't be finalised until some time in 2015, but it is prudent to advise the Department of Health now of this possible eventuality.

Given the Bill's impact upon QCAT, DJAG asks that it continue to be consulted on the Bill and proposed Medicines Poisons and Therapeutic Goods Regulation (which DJAG has not yet seen).

**Confidentiality provisions**

***DJAG Contact officer:*** *Alexis Hailstones, Principal Legal Officer*
*30065996*
*Alexis.Hailstonesy@justice.qld.gov.au*

Section 159 creates an offence for disclosure of 'confidential information' by a relevant person. 'Confidential information' is defined in section 158 to include 'information about a person's health or affairs' that has become known by a person undertaking functions under the Act. It is noted that (unlike the definition of confidential information in section 139 of the *Hospital and Health Boards Act 2011*) this does not extend to information which would reveal a person's identity.

It is appropriate that a duty of confidentiality applies to a person who obtains confidential information in such circumstances. However the legislation recognises that there are cases where it is appropriate to disclose information.

Section 160 permits release of relevant confidential information for investigations conducted by the Coroner and the Health Ombudsman. Is it necessary to provide for disclosure to the Police for the purposes of investigations?

Section 161 allows the chief executive to ask a public sector unit to provide information, including confidential information, if necessary to perform the chief executive's functions and prevent an imminent risk of harm to the life health or safety of a person or animal. This appears to be a reasonable provision.

Under section 145 of the Bill, the Therapeutic Goods laws (ie the *Therapeutic Goods Act (Cth)* as modified by the Bill) will apply as laws of Queensland. However, there are a number of Commonwealth oversight laws (the *Administrative Appeals Tribunal Act 1975*, the *Freedom of Information Act 1982,* the *Ombudsman Act 1976* and the *Privacy Act 1998*) which, under section 152 of the Bill, will apply to matters arising under the applied provisions. Section 152(2) provides that State oversight laws will not apply in such cases. This may have resource implications for Queensland Health, as State employees will need knowledge of Commonwealth administrative laws and their application, and will need to make decisions as to which matters, decisions and documents fall under which regime. While there are similarities between Commonwealth and State 'administrative provisions', there are also significant differences.

Consultation with the Office of the Information Commissioner may also be of assistance in relation to aspects of this Bill.

**General**

DJAG asks that it be further consulted on the Bill and proposed Medicines Poisons and Therapeutic Goods Regulation in a timely manner before Cabinet consideration. In addition DJAG would appreciate the opportunity to consider how its feedback is reflected in any Cabinet submission prior to the submission being formally lodged.

# Consultation feedback template

September 2014

## Medicines, Poisons and Therapeutic Goods Bill 2014

The *Medicines, Poisons and Therapeutic Goods Bill* and further information about the Bill is available at Get involved. The closing date for consultation is **3 October 2014.**

## Personal details:

Given name: [redacted]

Surname: [redacted]

Organisation and/or Professional position: Fernvale Produce and Hardware

Postcode: 4306

Target group:

- ☐ Agriculture
- ☐ Animal welfare
- ☐ Correctional facility
- ☐ Education or childcare service
- ☐ Health care professional
- ☐ Hospital
- ☐ Industry - medicines
- ☐ Industry - poisons
- ☐ Industry - therapeutic goods
- ☐ Local government
- ☐ Nursing home
- ☐ Other government agency
- ☒ Retailer

Your response will be considered as part of the decision making process. Once a decision is made, you will be notified of the outcome by email.

☒ Yes, keep me informed by email: [redacted]

## General questions

1. Are the proposed objectives of the new legislation (the Object of the Act and how those objects will be achieved) appropriate to promote and protect public health?

Yes

2. Does the Bill achieve an appropriate balance between its public health objectives and the regulatory burden imposed on the industry, government or the community?

No

3. Do you have any concerns about the proposed legislation, particularly in relation to the impact of these controls on industry, e.g. efficiencies and innovation? Controls include authorisation of who can access medicines and poisons under what circumstances, obligations for record keeping and reporting, and offences and penalties.

Yes, As an a rural retailer, the new bill does not appear to be significantly different to the current situation. Currently Rural retailers must be AgSafe Accreddited (Federal Government supported industry self regulation program) which coveres all aspects of storage, use and sale of pesticides, poisons and animal health scheduled products. The QLD poisions licensing system is a complete duplication of this existing Federal system, incurring additional direct cost on rural retailers and the QLD Government to administer and send inspectors.

4. Are there any additional controls that need to be provided for in the legislation to protect public health and safety?

No

5. Are there any omissions or gaps in the proposed legislative framework? If so, what are they and how should they be addressed?

No

6. Are the definitions for the key terms throughout the Bill clear, in particular, definitions of eligible persons, manufacturing, wholesaling and other definitions?

7. Are you aware of any other standards or codes that apply to your industry and relevant to public safety and protecting the public from harm?

Yes

## Offences and penalties

8. Do the key offences cover the scope of harms that need to be addressed in order to protect public health and safety?

Yes.

Agsafe

Level 4 AMP Building

1 Hobart Place

Canberra City ACT 2601

GPO Box 816

Canberra City ACT 2601

Phone 02 6230 4799

Fax 02 6230 6710

info@agsafe.com.au

9. Are the proposed penalties for the offences under the Bill reasonable? If not, what would you recommend be changed and why?

Seems overely complicated

## Licences, approvals and other authorisations

10. In your view, does the new legislation reduce the number of licences, approvals and other instruments required under the legislation and establish a framework that will reduce compliance costs?

No. Nothing has changed, there is still unneccesary duplication with the Federal Agsafe accreditation system, which is supported by the Federal Government.

11. Are the proposed licences, approvals and other authorisations appropriate?

No. It is duplicative in the Rural Retail industry and merely imposes and unneccessary cost on business and the QLD Governement to administer.

12. Does the proposed Bill adequately recognise licences or other approvals that may be granted to perform a regulated activity under another Act or law of the Commonwealth (e.g. see the examples listed in section 21(d))?

No. This new Bill needs to brought into line with the Federal Government agreement with Agsafe to regulate the use, storage and sale of agricultural chemicals, animal health products etc.

13. In your view are the provisions in the draft Bill for criminal history checking and recall powers appropriate?

14. For the medicines and poisons manufacturers who would be licensed under the new legislation (e.g. medicated stock feed manufacturers and S7 poisons manufacturers), what transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the new legislation?

## Therapeutic Goods Act 1989 (Commonwealth)

15. Are there other persons or entities or situations that should be exempt from the proposal to adopt the Therapeutic Goods Act 1989 (Commonwealth) as a law of Queensland. If so, what are they and what evidence is available to ensure there is appropriate governance arrangements to protect public health and safety?

16. Do you feel you may be adversely affected by the adoption of the Therapeutic Goods Act 1989 (Commonwealth) as a law in Queensland; if so in what ways?

17. What transition arrangements (e.g. period of time), would you consider reasonable to make any changes necessary to be compliant with the Therapeutic Goods Act 1989 (Commonwealth)?

## Scheduled substance management plans

18. The Bill proposes that certain entities and eligible persons in charge of an institution such as a hospital or community-based pharmacy have a scheduled substance management plan to describe how the entity's processes and facilities meet the standards and other controls. To what extent do you already have documents that fulfil the requirements of a scheduled substance management plan (e.g. quality assurance plan, accreditation documents)?

19. What do you anticipate the cost will be to your business of developing and implementing a scheduled substance management plan?

20. What period of time would you consider as reasonable to develop and implement a scheduled substance management plan as part of the transition arrangements for the new legislation?

## Monitoring and enforcement

21. Should the Director General of the Department of Health be able to appoint third party auditors to monitor and promote compliance with the medicines, poisons and therapeutic goods legislation? In what situations and with what limits?

The current system seem very wasteful in this respoect when applied to Rural Retailers. Every year for the past 10 years the Department of Health has sent 2 people in a Government car to our premises to inspect the storage and sale of three S7 products. Even today they struggle to comprehend that we retain the records of who purchases the products on our Point of Sale system, not in a poisons book.

The management of inspection needs to be totally overhauled to a complaint based and/or self inspection system that is proportionate to the risk and volume of product being sold (retail situations) by each outlet, see how the department of mines regulates small volume sellers of ammunition. Currently this is most cerntainly not the case with the result being that there are unneccessary costs on the business and the QLD Governement.

22. In your view, are there other ways that exist to make better use of legislation and existing auditing schemes?

Yes. Have an online Local, State and Federal Government business licensing portal. Business can self select the licenses and permits that they require, pay and state in a statuatory declaration that they are complient. The respective regulatory departments can offer a free advisry service to assist businesses that are not sure of their licensing requirements to become complient, rather than the stick/inspector approach that we have currently. Non-complient businesses would be penalised as they are currently.

A system like this would drive our juristictional duplication, increase tranparency and reduce cost to business and the government.

## Standards and regulations

23. The Bill allows for the establishment of standards and the making of regulation on matters such as storage, handling, manufacturing and eligible persons. You are also welcome to provide your views on matters relevant to the new regulation.

## Written submission

**Email:**

legislation@health.qld.gov.au

**Post:**

Medicines, Poisons and Therapeutic Goods Consultation Process

Regulatory Policy Unit

Department of Health

PO BOX 48 BRISBANE QLD 4001

Submissions will not be made publicly available. However, submissions may be subject to disclosure under the *Right to Information Act 2009*, and access applications for submissions will be determined in accordance with that Act.

The Queensland Government is bound by the *Information Privacy Act 2009*.

The information you provide on this form will only be used for the purpose of informing the State Government's final position on Medicines, Poisons and Therapeutic Goods Bill.

We will not share your name or contact details with anyone without your consent. This consultation is a public process and any comments you provide may be published and/or online and may be transmitted outside of Australia. You may wish to bear this in mind when providing your comments.

You are not obliged to provide comments and if you do so it is under the condition that you agree that your comments may be published including on the internet. We will not publish your name or contact details.
Your comments may be moderated according to our acceptable use policy.

Read our privacy statement for details.

## Julie Stokes

**From:** Julie Stokes
**Sent:** Wednesday, 10 September 2014 10:11 AM
**To:** BROOKS, Vanessa; MAKEJEV, Luke; SHEPPARD, Shirley
**Subject:** RE: New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

Hi Vanessa,
Re electronic scripting etc. The Bill mentions this explicitly as an area for which standards will be set. We may need to develop them, or hopefully, there will be nationally consistent standards around e-medication management that can be adopted.

Much of the day-to-day specifics will be in regulation and standards – there will be consultation in development of these.

Thank you for distributing the email.

Kind regards

Julie

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**From:** BROOKS, Vanessa [mailto:Vanessa.Brooks@dcs.qld.gov.au]
**Sent:** Wednesday, 10 September 2014 9:49 AM
**To:** MAKEJEV, Luke; SHEPPARD, Shirley
**Cc:** Julie Stokes
**Subject:** FW: New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

Hi all,

Julie has asked me to forward this email to give you the opportunity to provide input.

Most of my feedback was around electronic scripting capability including electronic signatures and issues around standing orders etc.

Hopefully you will cover anything I have missed for our environment.

Hope you're both well,
Vanessa.

**Vanessa Brooks**
Nurse Unit Manager
Brisbane Women's Correctional Centre
& Helana Jones Correctional Centre
Prison Health Services: Offender Health
Mental Health & Specialised Services
West Moreton Hospital and Health Service

T: **3271 8960** | F: **3271 8974**
E: **vanessa.brooks@dcs.qld.gov.au**
E: **vanessa.brooks@health.qld.gov.au**
Locked Bag 2500
Sumner Park Q 4074
AUSTRALIA

*Your partner in healthcare excellence*
**www.health.qld.gov.au/westmoreton**

**From:** Medicine Poisons and Therapeutic goods Bill [mailto:Medicine-Poisons-and-Therapeutic-goods-Bill@health.qld.gov.au]
**Sent:** Monday, 8 September 2014 5:17 PM
**To:** BROOKS, Vanessa
**Subject:** New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

Dear Vanessa,

I have already sent the email below to you but I am hoping that you would please send it on to the appropriate persons a for Arthur Gorrie and Gatton Prisons as these have private services that would be covered by the new Bill.

Kind regards

Julie Stokes

**Dr Julie Stokes**
Consultant Pharmacist
Medicines Regulation & Quality | Chief Health Officer Branch | Health Services and Clinical Innovation Division
Department of Health | Queensland Government
Locked Bag 21 Fortitude Valley BC QLD 4006
t. 07 3328 9225
e. julie.stokes@health.qld.gov.au | www.health.qld.gov.au

## New Medicines, Poisons and Therapeutic Goods Bill public consultation open from 4 September to 3 October 2014

The Department of Health has released a draft of the proposed new Medicines Poisons and Therapeutic Goods Bill intended to provide a modern framework to regulate how medicines and poisons are used in our community.

You are receiving this email as a stakeholder in the regulation of medicines and poisons.

As you or members of your organisation deal with medicines or poisons that are currently regulated under the Health (Drugs and Poisons) Regulation 1996, we would like to know how the proposed new Act may affect you or members of your organisation.

The draft of the Bill and consultation questions can be found at:

- Get Involved
  or
- a copy can be provided on request by contacting the Department of Health via email at legislation@health.qld.gov.au or by phone on 07 3234 1793

**How to provide feedback**
The consultation questions ask for feedback about some specific aspects of the proposed regulatory scheme as well as the Bill itself. You can respond to the consultation questions by:

- using the online survey at Get Involved
- downloading the consultation feedback template form, and emailing the completed form to the Department of Health at legislation@health.qld.gov.au
  or
- posting the completed consultation feedback form to:

Medicines, Poisons and Therapeutic Goods Consultation Process
Regulatory Policy Unit
Department of Health
GPO BOX 48 BRISBANE QLD 4001

Feedback may also be provided by way of a written submission, if preferred.

Please forward this email to colleagues or members of your organisation who may wish to be informed of the proposed change and to provide feedback.

Thank you for your participation in modernising our legislation.

**Medicines, Poisons and Therapeutic Goods Bill 2014**
Department of Health | Queensland Government
GPO Box 48
BRISBANE QLD 4001
t. 07 3234 1793
e.mptg.bill@health.qld.gov.au | www.health.qld.gov.au

All reasonable precautions will be taken to respect the privacy of individuals in accordance with the Information Privacy Act 2009 (Qld).

s.47(3)(b)

| Details | Respondent type | question1 | question2 | question3 | question4 |
|---|---|---|---|---|---|
| [redacted] SWNRM | Land management organisation | yes, the objectives are appropriate to promote and protect the public health | the regulatory burden imposed upon the community and industry is necessary for the industry to have access to 1080 poison for pest control on a landscape scale.The proposed bill achieves an appropriate balance between community safety and the need to have access to these poisons for landscape management when dealing with pests such as wild dogs | I have no concerns re the proposed legislation in that it supports on ground efforts currently being undertaken by land managers for feral pest mitigation. The proposed bill should strive to ensure that regional land managers have easy and less onerous access to 1080 for wild dog baiting regimes and as a part of whole of property management plans. | The inclusion of sign age and neighbour awareness has already be highlighted in the proposed bill and these are appropriate safety mechanisms |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University | NR<br>NR= No response | NR | The General Approval needs to be explained more around what it covers with specific examples for the university environment. For example, will compounding products for testing etc. be covered by the general approval envisaged for the university to have i.e. can manufacturing for research purposes be covered under general approval? | NR |
| Agriculture - No contact details | Agriculture | Yes agree. | Yes agree. | Our focus is on feed manufacturers' holding wholesale licences for S4 veterinary chemical products. The proposed legislation should more clearly identify this area - refer to 16 (3) where the examples should include "mixing a scheduled substance into stock feed for animal feeding".<br>We would like to see more clearly that addition of S4 medicines in stock feed does not mean the feed mill is a manufacturer of scheduled substances.<br>We believe that feed mills with wholesale licences under section 20 will have staff that will have authority to add S4 medicines to feed. Our interpretation is that these staff will not be an "eligible person" but will still have authority. If this is not the case the proposed legislation would be significantly more restrictive that existing legislation and prevent the livestock industries from accessing S4 medicines through feed supply. | None |

| Details | Respondent type | question1 | question2 | question3 | question4 |
|---|---|---|---|---|---|
| Andrew Jones Mackay PHU | Public Health Unit | NR | Probably not.  Reason being most of the specific details will be in the Regulation and Standards which are yet to be released. | Specific details are lacking which hopefully will be suitably addressed in the Regulation and Standards. | NR |
| B2BWorld Pty Ltd | Seller of complementary medicines | I do not believe so. There is a clear disconnect between high-level Canberra based health knowledge, and on-the-ground face-to-face real-life health management knowledge which State Governments are best at assessing.<br><br>A clear example is the failure of the TGA to update the List of Substances that may be used in Listed Medicines on the Australian Register of Therapeutic Goods, ARTG, in Australia since 2007.<br><br>At the same time there has been an explosion in the use of complimentary medicines worldwide because of the universally known health benefits from using such substances, many of which are not included on the approved list e.g. 5-hydroxytryptophon, which the human body itself produces and is therefore inherently safe when taken at the appropriate dosage and in accordance with practitioner instructions.<br><br>The effect of the legislation is to criminalise the behaviour of people who responsibly help others improve their health with products such as 5-hydroxytryptophan simply because the TGA are out of touch with normal practice permitting the supply of 5- | No. At a time of deregulation, it seems strange that these moves a afoot. If the bill's purpose was to improve public health, it would be better served by directing additional resources to those at the coalface endeavouring to keep people healthy, rather than building a new army or bureaucrats to fix a system that isn't broken and works well. Using the magic word "contemporary" to justify such changes is intellectual laziness. ISIS is contemporary also, but it is not good. | Clearly these changes will impose additional costs on an industry that is already struggling from competition from operations such as Chemist Warehouse and iherb.com<br><br>It will do nothing to improve public health and will only drive more passionate and effective healthcare people out of business.<br><br>Innovation will be stifled, even more than it is already. Increased regulation is the enemy of innovation.<br><br>Once again, it is quite staggering, that the government wants to ramp up the penalty, investigative, enforcement and prosecution regime applicable to people whose motivation is to keep people healthy, turning the people who want to help others get and stay healthy into potential criminals. | The question assumes the legislation is appropriate. As I do not agree it should be enacted, the question is redundant. |
| Agriculture - No contact details | Agriculture | Yes | In the interest of public safety I believe there should be a higher state of regulatory burden imposed on industry and much more consultation with sellers. | No | Unsure |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| | Allied health peak body | NR | NR | NR | This Bill forms part of the framework of legislation and practice that ensures patient safety. It will also expressly allow for innovation of the health model. This innovation will include independent prescribing for suitably qualified health workers.<br><br>Patient safety would be enhanced should this Bill provide for independent prescribing by suitably qualified health practitioners. The APA submits that independent prescribing by physiotherapists would protect public health and safety by reducing treatment delays and improving specificity and responsiveness of prescribing. |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner | yes, I agree | NR | In regards to Manufacture (section 16 & 25 of the Bill), it states that Manufacture is deemed to include<br>(d) assembles, labels, packages or repackages;<br>â€¢this can become an issue in rural/remote areas where a Registered Nurse or Indigenous Health Worker may need to supply a smaller amount of the medicine than the package available (e.g. break down a packet of 100 paracetamol, or e.g. trimethoprim).<br><br>In the current Regulations, there is provision to cover this in section 4(4) where it states<br>"Also, a registered nurse or indigenous health worker does not manufacture a controlled or restricted drug or a poison only by packing it or repacking it under a certified written policy, about packing or repacking controlled or restricted drugs or poisons, published by the department" Recommend a similar clause is included in section 16 (3) of the Bill<br><br>In section 36 of the Bill, (discussing who an eligible person is defined as) it includes an eligible person as being-<br>(1) (c) persons undergoing training for registration as registered health practitioners or veterinary surgeons;<br>It is important to note that registered nurses and Indigenous health workers may be undergoing training for endorsement or authorisation (e.g. scheduled medicines endorsement for rural and isolated practice, and authorisation for immunisation and sexual health for RNs). There needs to be provision for these as well (as per the current Regulations). (So these trainees can still administer medicines as part of their training, e.g. section 70A, 179AA, 265AA of the Regulations)<br><br>Section 26 â€¢Offence to supply (which the definition under section 17, includes â€œ(d) give the substance to a person to use, whether for free or in exchange for | NR |
| [redacted] | Pharmacist | Yes | Yes | No | No |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health | Yes | Yes | No significant concerns | No |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| Paul Lovelock<br>University of Queensland | University | I'm not an expert on public health policy, but the draft seems reasonably suitable to protect the unauthorised use of scheduled substances. | With the caveat listed above, the draft seems reasonably balanced. | Cost recovery is a concern for the research community - generally researchers act on behalf of the community and would prefer to allocate their limited funds to research materials. Unclear about costs at this stage, but we would submit a request for adding the option of a fee waiver when issuing approvals for genuine research or teaching purposes. | With little expertise in public health policy, this would seem to be a reasonably comprehensive document |
| Ruth Hay, Queensland Health | Queensland Health | It is important that legislative control of scheduled substances is contemporary and keeps abreast of current practice to ensure individual practitioners are not inadvertently in breach of legislation as models of care change.<br>The "outcomes" based approach to the proposed Act compared to the current very prescriptive legislation may present additional risks as there is potential for varying levels of interpretation of what is intended | The ability to manage scheduled substances in a way that complies with an intended outcome is a significant shift. Differing intepretation is likely to present a new risk to the public as well as the introduction of some potential "loose" terms such as "reasonable grounds" - in whose view are things deemed to be reasonable or not? and how much variation of this will there be? There is a risk of accommodating the lowest common denominator that will not enhance public health and safety | Clause 21 outline that an offence will occur if a person does not perform a regulated activity in the "authorised" way. The clause goes on to outline how this may translate and states that a person would comply if "is given lawful direction to perform the activity for the substance by a person who is authorised, or purports to be authorised,to give the direction". Does this open the door for situations where the cleaner is given lawful direction to supply or administer medicines within a hospital? The inclusion of "lawful" direction may not allow this as the cleaner would not be an eligible person but perhaps "lawful" may be interpreted as something quite different eg does not put the person at risk from a OHS perspective? | The proposed Act will be supported by some regulations as well as practice standards. These may well provide futher detail and therefore greater understanding on how public health and safety is intended to be addressed by this legislation. Without this next level of detail it is difficult to determine what additional controls may not have been addressed. |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| Chris Raftery Qhealth | Nurse Practitioner | yes, in streamlining current convoluted system into consistent and efficient legislation | yes on preliminary overview of chnages | thinking smarter not harder, involving technology in solution and streamlining duplication, I can only see positives in this | on face value balance is present between public safety and health professional control |
| [redacted] McDonald Holdings | Land management organisation | Yes, we believe they are | Yes, it does and allows landholders to have more input to landscape management | No, we do not have any concerns | no |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service | Objectives and how they will be achieved are comprehensive and thorough. However, the Act refers to 'scheduled substances' only, when in fact there are many examples of scheduled substances not being scheduled by virtue of pack size alone, rather than the substance itself.<br>For example, Ibuprofen 200mg in packs of less than 25 are unscheduled, but the substance itself is just as concerning as a person can purchase multiple packs and do damage.<br>I would like to see a way that the Act is applied to substances, not just schedules.<br>Refer also to S11 - definition of Medicines.<br>Not just S2 etc; but needs a statement about multi-listed products with the the most restrictive schedule applying. | Significantly frees up the regulatory burden. Until the Regulation is written its unclear if that balance with public health objectives is met. | I find this difficult to comment on, as presumably the details will be in the Regulation. | That will depend on the Regulations |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| [redacted]. Health Professional, sole trader | Naturopath | yes | yes | no | no |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | The objectives include identifying substances that may harm the health or safety of persons or animals and to ensure that persons who use these substances are competent to do so. One major issue for the veterinary profession is anti microbial resistance and in the hands of unqualified persons, may lead to health and safety issues but also to trade issues which could affect Queensland's economy. | The illegal use and misuse of restricted and controlled drugs is already a major problem with many aspects of veterinary science including the racing industry. Any further relaxation of access is likely to exacerbate the problem. On page 8 of the overview document, there is reference to examples of occupations, professions or positions to be classified as 'eligible ' persons and the second dot point reads:<br>- veterinary surgeons, veterinary nurses, animal welfare officers and others who provide care and treatment to animals<br>This is very broad and while it is accepted that there would be more definition about this in a regulation, nonetheless, the meaning and intent infers that access will be broadened out to a much wider range of people.<br>Veterinarians have training, knowledge and competency in using a wide range of drugs. In addition registered veterinarian found to be misusing drugs in any way can be counselled, or punished by the existing registration systems. Wildlife carers and others who are often self employed can and will do harm to the system of regulating drugs and residues in animals and the environment if there is no similar regulatory system to oversight their activities. Therefore restricting the possession and use to those professions where competency standards and regulatory systems exist will achieve the appropriate balance of public health objectives and reduction in regulatory burden. | It is of concern to the Australian Veterinary Association (AVA) that<br>(a )if non veterinarians administer drugs without the direct supervision of a veterinarian whether it is in husbandry (eg lay equine dental service providers), veterinary nursing or in other animal care positions, there are potentially serious welfare issues for the animal<br>(b) if institutions are able to include persons of limited training and knowledge to use restricted and controlled drugs for use in research experimentation and teaching, there can be serious welfare issues. The current Scientific Use Code specifies that if pain and distress are predicted or unavoidable consequences of a project, methods for minimising such pain and distress must be incorporated into the design of the project, including using pharmacological agents and non-pharmacological measures for avoiding and minimising pain and distress. However, there are few if any guidelines to ensure that persons using these drugs have the knowledge to do so which can adversely affect the welfare of animals and<br>(c) the use of antibiotics can certainly lead to anti microbial resistance if lay people working in institutions or other areas do not have the qualifications to diagnose the cause of the problem and implement treatment without the required knowledge | There are no specific additional controls other than restricted access; however because the legislation regarding misuse of veterinary drugs is across 3 acts, legislation would be clearer if<br>(a) Their relationship to the Veterinary Surgeon's Act and its restricted acts are in alignment. For example there is sometimes crossover if a lay person is performing a restricted act using a restricted drug under the two acts. If it is a breach of both Acts, it becomes a matter to decide who will prosecute and this is ok but confusing and may be an excuse not to pursue a breach by one or other parties. If however, the action is allowed in one Act and not the other (e.g a scenario where a vet nurse injects an anaesthetic) the potential for confusion compounds.<br>(b) The relationship with the Drug Misuse Act that the Justice Department administers is clarified. Also drugs should be on the same schedule. Recently a change in scheduling for anabolic steroids imposes a potential 25 year sentence for possession and supply but there is no reference to how this interacts with the Health Act where they are allowed. |

| Details | Respondent type | question1 | question2 | question3 | question4 |
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| Craig Manley, Moreton Bay Regional Council | Local government | NR | NR | Many local governments (particular smaller Councils) which administer immunisation programs rely on the existing endorsement for Environmental Health Officers to possess a restricted drug which exists under the current Health (Drugs and Poisons) Regulation 1996. This endorsement should be maintained in the new Act as these programs typically operate without full-time nurses. In many cases, it would not be possible for them to continue functioning if this endorsement were not continued. | NR |

| Details | Respondent type | question5 | question6 | question7 |
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| [redacted] SWNRM | Land management organisation | There is no gaps or omissions obvious at this stage | the key terms described are complete and concise | yes, the agricultural industry is overburden with standards and codes to adhere to such as the workplace health and safety act, the stock route and protection act and the environmental protection and biodiversity act, just to name a few |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University | NR | The definitions included in s15 (1)(b) for possessing a substance if a person becomes responsible for controlling the substance, whether or not the person has physical custody of the substance may be too broad. | Drugs Misuse Act 1986 and Regulations. |
| Agriculture - No contact details | Agriculture | None | Yes | The stock feed industry operates FeedSafe as the national QA accreditation program for feed manufacture, this is based on a Code of GMP endorsed by SCoPI. Feed mills operating in Queensland are required by the SFMCA to retain their accreditation and undergo annual third party audits of their sites.<br>This QA accreditation is targeted to reduce food and feed safety risks and covers use of in feed medicines. |

| Details | Respondent type | question5 | question6 | question7 |
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| Andrew Jones Mackay PHU | Public Health Unit | The release of the Regulation and Standards will show up any gaps. | Why in S 46(1)(a) where it refers to applicant and nominated person, does it not go into details on what constitutes a suitable nominated person where as 46 (2) does outline what a suitable applicant is?<br><br>Why is there no definition of the term "use"? The word appears to have different meanings throughout the Bill.<br><br>Why are definitions spread throughout the Bill rather than grouped all together in the Schedule 2 Dictionary?<br><br>Confusion on use of term "Prescribe" in Dictionary and S37. Ie S37 could be read that regulated activities may be issued on a prescription! | NR |
| B2BWorld Pty Ltd | Seller of complementary medicines | As previously stated, the List of substances that may be used in Listed Medicines needs to be updated first, and a system put in place to replace the present system for updating the list. The failure to update the list reflects significant cultural and bureaucratic deficiencies within the TGA and our healthcare management system in general.<br><br>People at the coalface in treating illnesses and improving people's health should have the dominant say on what substances should or should not be included on the list, and the list should be regularly updated at least twice a year to ensure Australians have access to the best available healthcare products. | no comment | no comment |
| Agriculture - No contact details | Agriculture | unsure | Yes | Yes many other standards and codes. |

| Details | Respondent type | question5 | question6 | question7 |
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| | Allied health peak body | The APA welcomes regulatory reform that allows Australiaâ€™s health system to be flexible enough to build on and fully use health practitionersâ€™ expertise so they can contribute to improving the patient experience. This Bill should enable continued evolution of scope to meet patient needs and promote collaboration across traditional professional boundaries.<br><br>The APA is seeking the Physiotherapy Board of Australiaâ€™s endorsement of physiotherapists for independent prescribing to achieve this goal. Independent prescribing is a model in which the practitioner is responsible for the clinical assessment of the patient and diagnosis of the condition and then prescribes therapy, without the requirement for supervision by another healthcare professional. Independent prescribing creates new ways of working to improve quality of services and the patient experience. It helps form partnerships across professional and organisational boundaries and builds care pathways that are cost-effective and sustainable, for example improving the transition from acute to community care.<br><br>The Health Practitioner Regulation National Law (National Law) regulates certain health practitioners and Section 94 provides for National Boards to endorse the registration of health practitioners to administer, obtain, possess, prescribe, sell, supply or use a scheduled medicine or class of scheduled medicines. At present, physiotherapists are not endorsed practitioners.<br><br>Endorsement for prescribing supports innovation in line with the outcomes of this Bill. Commonwealth and State and Territory legislation needs to enable the implementation of this mechanism, so there is no unreasonable regulatory barrier to improvement.<br><br>Further, the Pharmaceutical Benefits Scheme (PBS) does not make allowance for physiotherapists to prescribe medicines. Authorised PBS prescribers are medical practitioners, dentists, optometrists, midwifes and nurse practitioners.<br><br>Since Queensland will adopt the classification (schedules) for medicines and poisons under the national Poisons Standard, this alone might impact on whether non-medical practitioners can supply or administer drugs. | The APA believes that reform should remove barriers to innovation. To allow for this, we suggest that amendment be made to allow for independent prescribing by suitably qualified allied health practitioners, as well as under direction. We seek greater clarity about the Billâ€™s definition of â€˜regulated activityâ€™: â€œlawful direction to, authorisation or request that another person supply or administer the substance.â€ | NR |

| Details | Respondent type | question5 | question6 | question7 |
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| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner | see above | see above in regards to training as a health practitioner; and manufacture | NR |
| [redacted] | Pharmacist | No | I believe so. | No |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health | There may be an omission regarding delivery of pharmacy service via telehealth/videoconferencing. However, this potentially could fall under s37(2)(b) "require an eligible person to comply with a stated code, guideline, protocol or standard" with the onus on the Queensland Department of Health. | Clear | NR |

| Details | Respondent type | question5 | question6 | question7 |
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| Paul Lovelock University of Queensland | University | There is no specific reference to the Drugs and Poisons officer approval system that we currently use at the University (given the broad coverage of the draft this is understandable) but we would expect to maintain this system with continuing govt approval as an integral part of our organisational management plan. Can you confirm that this would be acceptable? | Generally yes, but can we please confirm that researchers and/or teaching personnel are also classified as 'eligible persons' under clause 36? | Yes there are many relating to laboratory and biological and chemical safety, codes of practice for safe use of plant, risk management etc |
| Ruth Hay, Queensland Health | Queensland Health | At this stage there does not appear to be any specific reference to the destruction of scheduled substances. Perhaps this is allowed to be addressed in individual maagement plans but there is a significant risk to public health and safety if scheduled substances are NOT disposed of appropriately and safely | There is no detail of who is/will be authorised to obtain scheduled substances. I understand the term "possess" is meant to encompass the role of obtaining but this is not clear from the definition on page 14 as its definition is to "receive and take custody of". This does not address how scheduled substances become ready to be received if nobody appears to be able to order them ie the term "obtain" in the current legislation.<br>Clause 16 (2) (d) makes specific reference to repacking which states that activities in repacking will be deemed as producing a substan e ie manufacturing. This will be of significant concern to those staff currently authorised to repack medicines into a smaller container or dose administration aid who will no longer be able to do so as they will be manufacturing and not licensed to do so. this will take this current essential role and task backwards with respect to the benefit provided to patients. There must be specific exclusion for authorised staff to undertake this service for their patients | AHPRA professional standards are also designed to ensure professional practice causes no harm to patients |

| Details | Respondent type | question5 | question6 | question7 |
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| Chris Raftery Qhealth | Nurse Practitioner | everything has gaps but on face value I think this covers most in balance | no | no |
| McDonald Holdings | Land management organisation | No but we hope that the legislative amendments will be a "living document" and will evolve accordingly for the benefit of regional landmanagers | Yes they are | Yes, we are such as the OHS and Stockroute and protection act for example |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service | S14: no inclusion of prescribing as a regulated activity - unless covered under 'give a lawful direction'<br><br>The regulated activities listed in S14 (a)- (e) are further defined in S15-19; however regulated activity to give a lawful direction S14(f) is the only thing not defined. For consistency this should be defined and may be where the word prescribe would be included.<br><br>No definition for the word 'prescribe' which presumably comes under giving a lawful direction. However, the word prescribe is then used throughout the legislation. The old issue of what is prescribe vs a written instruction has not been clarified and I think it needs to be. In fact, I think it should all be prescribe. | There is no definition of Wholesaling. This has been problematic in the past and will continue to be in the future unless its clear. Using a dictionary or common definition is even worse as it simply says to sell commodities in large quantities !<br><br>However the background paper of Sep 2014 page 12 includes a reasonable definition that links to the regulated activity of 'Supply'. I would recommend that this be added to the definitions in Schedule 2.<br><br>For Manufacture Exclusions: recommend to also exclude repackaging for medication compliance aids that may be done by a nurse, home carer;<br><br>And, repacking into smaller pack sizes for patients to take one or two doses as done by a doctor, nurse or pharmacists and used as emergency supplies. | No others than those already mentioned. |

| Details | Respondent type | question5 | question6 | question7 |
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| [redacted] Health Professional, sole trader | Naturopath | Yes. There is a gap between FSANZ foods and TGA therapeutics - substances derived or extracted from foods used (eg. rasberry ketones) used extensively overseas and bought extensively over the Internet in Australia with apparently good safety records.<br><br>FSANZ will not approve or has not assessed and no approval for TGA listings sort.<br><br>Needs addressing with common sense not bureacrac solutions that do not work | NR | NR |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | It is not clear that people and animals who are prescribed scheduled drugs by a veterinary surgeon (or medical practitioner) are able to have them in their possession and administer them. While this may be implied, the lawful possession and use of restricted and controlled drugs by lay people who are prescribed these drugs needs to be put in the Bill as a lawful use. For animals this should also include the person responsible for the animal's welfare, not just the owner | The different groups in these definitions seem to be on an equal footing but there would be a large difference in competence, training and skills of these different groups. Of concern is the general nature of the definition of an eligible person in 36 (1) (d) (ii) being "persons who lawfully provide treatment or care to animals" This encompasses just about the whole animal owning public and the AVA's understanding is that this does not intend to cover owners who have been prescribed treatment for their animals but rather lay operators who may derive an income from having access to drugs. For example, a veterinary nurse may set up a vaccination business outside of the supervision of the vet and if their administration and storage of the drug was faulty and the animal was not adequately immunised and died, there is no accountable body to address this inadequacy. Veterinarians are accountable to the Veterinary Surgeon's Board which can fine or refer to a tribunal (QCAT) for possible suspension. These concerns could be addressed if eligible people under this category had to be directly supervised by a registered veterinary surgeon who was ultimately responsible for their actions.<br><br>Of note is that health practitioners are referred to as registered health practitioners but veterinary surgeons do not have the word registered in front of them. The definition states that the term veterinary surgeon means registered but it would be simpler to delete the definition and just put registered. The definition may need looking at in light of the National Recognition of Veterinary Registration as technically someone registered in another state of Australia is deemed to be able to practice in Queensland albeit but their name does not appear on the roll as being registered in Qld under the Veterinary Surgeon's Act. This may be just a matter of wording. | AVA Code of Conduct<br>Veterinary Surgeon's Act<br><br>Drug Misuse Act<br>Scientific Use Code<br>Animal Care and Protection Act |

| Details | Respondent type | question5 | question6 | question7 |
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| Craig Manley, Moreton Bay Regional Council | Local government | NR | NR | NR |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| [redacted] SWNRM | Land management organisation | yes, the key offence addresses all parameters to ensure public health and safety | the proposed penalties are reasonable given the poisons clarification of 1080 as a S7 poison | the new bill reduces the need to have various depts ( such as local council) organised to undertake 1080 baiting on different properties. The new bill streamlines the process for land managers to take immediate action for mitigating wild dogs and feral pests | yes, they are | yes, it does | yes, they are | two weeks or 14 days to become compliance from issuing of notice |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University | NR | NR | This is extremely difficult to ascertain as the accompanying regulations have not been released with the draft Bill outlining how some of this is meant to be actually put in practice. | They may be, but without the further detail provided by the regulations it is extremely difficult to ascertain.<br>There also needs to be clarity around the approvals in relation to manufacturing in the research environment. Does the Vice Chancellors Delegated Authority and the Drugs officer combine into one approval with the same intention of current process? | NR | These may be appropriate, but may introduce a level of difficulty in a university / research environment. | NR |
| Agriculture - No contact details | Agriculture | Yes agree | Yes agree | We see no change in feed mills requiring to hold wholesale licences for inclusion of S4 medicines in animal feeds. | Wholesale licences and the regulations relating to their administration need to remain consistent with other States regulations. | We agree that the proposed Act recognises the Commonwealth Agricultural and Veterinary Chemicals Code Act 1994 (AgVet). | Unknown | We note reference to medicated stock feed manufacturers. The majority of medicated stock feed will not require a manufacturers registration as the veterinary chemical product will be mixed in feed and this "medicated feed" is supplied under wholesale licence. The medicated feed itself does not become a veterinary chemical product, refer Commonwealth Agricultural and Veterinary Chemicals Code Act 1994 (AgVet). Based on the existing access stock feed manufacturers have to wholesale licences, we see no change or transition arrangements being required. |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
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| Andrew Jones Mackay PHU | Public Health Unit | Yes but severity of penalties is not reflective of public health and safety (see next response). | No. Penalties for Sections 27 - 30 should be greater than 200PUs as these relate to administration and supply offences. As these are the points at which actual harm may occur to people so therefore penalties should be more. | NR | NR | NR | NR | 12 months max |
| B2BWorld Pty Ltd | Seller of complementary medicines | no comment | no comment | no comment | no comment | no comment | no comment | no comment |
| Agriculture - No contact details | Agriculture | Yes | Yes | No | Yes | Yes | Yes | 3 months state wide. |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| | Allied health peak body | NR | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner | NR | NR | NR | I am still concerned as to the proposed removal of the Drug Therapy Protocols for authorised and endorsed health practitioners - I am concerned at the statement on page 7 of the 'Overview' document that states "this approach is considered to be cumbersome and lacking in transparency", and would like clarification on what this means. I certainly do not see this as lacking transparency.<br><br>I have a very good knowledge of the use of drug therapy protocols in Queensland since they were introduced in 1999, I see the removal of these as a risk to patient safety.<br><br>I will provide directly to Julie Stokes (as a separate document) further background history behind the development and purpose of the Drug Therapy Protocols, and how they have enabled a consistent, evidence based and safe approach to patient care, along with the anticipated risks if removed. | NR | NR | NR |
| [redacted] | Pharmacist | Yes | Yes | I believe so. | Yes | Yes | Yes | I would have thought that 12-18 months would be sufficient. However I believe a longer time should be given upon application with a reasonable explanation. |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health | Yes | NR | NR | Yes | Yes | yes | NR |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
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| Paul Lovelock University of Queensland | University | Yes, believe so. | Yes. Also the offence provisions relating to cross-coverage by other authorities and approvals is a positive step. | Potentially, yes, but this will depend on the model the University settles on for its management plan. The proposal to be able to issue an approval to a University to encapsulate activities carried out by different areas within the organisation has merit, if it is incorporated into the management plan.<br><br>The proposal to allow amendment of license/approvals is a positive step and should save time in preparing approvals.<br><br>Currently there is no cost for approvals and compliance (other than admin costs), so the new system will cost the organisation more if there is no fee waiver for research/teaching purposes. | Based on the information provided, the approvals system seems appropriate and reasonable. | Yes, this is a positive step. | Insufficient expertise to comment | Depends on the scope and magnitude of changes, we are not manufacturers so cannot comment. |
| Ruth Hay, Queensland Health | Queensland Health | NR | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| Chris Raftery Qhealth | Nurse Practitioner | yes | seems reasonable | avoids duplication, engages national consistency, this is all good | on face value yes | not enough detail | could not locate this in the paper | it is the time that systems in gov end to be calibrated, however for end user, a lead in time of 6-9 months if often required |
| [redacted] McDonald Holdings | Land management organisation | YES and we are satisfied | They are reasonable | Yes | YES they are | YES | YES | 14 days |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service | Yes. Wordy, but I think its adequately covered. Just unclear what a 'reasonable excuse' is compared with actually being authorised to do something.<br><br>Is the Act allowing for people who are not authorised to undertake a regulated activity, provided they have a good excuse? This may be a good thing, but who makes the decision that its reasonable? | S27: Direct another person... A higher penalty, as this could involve a position of power and imbalance that I believe is deserving of a much greater penalty.<br><br>Otherwise OK. | Yes. | Seems appropriate, although not affected by most. | NR | Yes.<br><br>S72 - do the police have a full and long lasting record of people for whom a criminal history check was conducted and can then cross reference any person who comes up years later with a criminal record? | NR |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| [redacted] Health Professional, sole trader | Naturopath | NR | NR | NR | NR | NR | NR | NR |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | The offences relate to supply and administering medicines "in the authorised way". However, it is difficult to see what is meant by this - without more clarification of what the authorised way is, the AVA cannot comment on whether the offences cover the scope of harms that need to be addressed. | As for (8) | No comment | No comment | The Scientific Use Code is recognised under the Animal Care and Protection Act 2001 but this code is not specific in terms of who can use scheduled drugs. There is a real potential for harm to animals here if drugs are not administered by a registered veterinary surgeon. The creation of "entities" where the Institution can write their own management plan may work in a mature system but ethics committees are very early in their establishment and are not audited by the government due to resource restraints. Unless compliance is rigorously enforced, there is the potential for welfare concerns for animals and if given the right to administer antibiotics, the risk of anti microbial resistance. | No comment | No comment |

| Details | Respondent type | question8 | question9 | question10 | question11 | question12 | question13 | question14 |
|---|---|---|---|---|---|---|---|---|
| Craig Manley, Moreton Bay Regional Council | Local government | NR | NR | Scheduled Substance Management Plans should be focused on managing real risks and should not introduce unnecessary red tape. | Many local governments (particular smaller Councils) which administer immunisation programs rely on the existing endorsement for Environmental Health Officers to possess a restricted drug which exists under the current Health (Drugs and Poisons) Regulation 1996. This endorsement should be maintained in the new Act as these programs typically operate without full-time nurses. In many cases, it would not be possible for them to continue functioning if this endorsement were not continued. | NR | NR | NR |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| [redacted] SWNRM | Land management organisation | no there are no persons or entities that should be exempt | no, i will not be adversely affected, on the contrary, i will will be benefiting from land managers ability to pro actively set baits for feral pests as it will reduce the overall predation on the grazing industry | 2 weeks or 14 days | all herbicides/pesticide are keep in storage that is compliant to current safe handling and storage of chemicals including wash down bays, MSDS information, PPE gear and chemical use registers | a small cost only as we will work with regional NRM groups such as SWNRM to ensure a complete and compliant process is adhered to and implemented going forward | two weeks or 14 days |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University | NR | NR | NR | The Queensland University of Technology supports the implementation of a Management Plan in principle, but further detail around the how's and when's would be useful. The Queensland University Safety Association has also discussed the function of Management Plans. | It is difficult to anticipate the cost, but it will be related to the development of the plan(s) and monitoring of said plans and the introduction of criminal checks and to what level we need to extend the criminal checks. Also, another difficulty in providing feedback to the is we are unaware if there will be a cost associated with the granting of General Approvals. | One year as a minimum for the consultation process and subsequent development and implementation of the management plan. |
| Agriculture - No contact details | Agriculture | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| Andrew Jones Mackay PHU | Public Health Unit | NR | NR | 12 months max | NR | NR | 6 months max |
| [redacted] | Seller of complementary medicines | I am inherently opposed to the idea of TGA laws being automatically applied in Queensland.<br><br>We went down that road with ASIC, which is a recognised abysmal regulatory failure after having had about 20 years to get it's act together.<br><br>ASIC is so bad in fact there are widespread calls for it to be axed.<br><br>ASIC has proven to be completely useless in protecting the public as shown by the Commonwealth Bank and Storm Financial disasters and the inability to stop them or deal with the perpetrators.<br><br>Prior to ASIC state Corporate Affairs Offices within the Justice Department of each state worked quite well and achieved much more than ASIC has ever achieved. | First, I will be denied access to 5-hydroxytryptophan manufactured in Australia for a Queensland Only 'Sole Trader' in accordance with TGA manufacturing requirements. I need 5-hydroxytryptophan for my health, and have been taking it safely for 13 years, having the HLA-B27 gene which makes me inherently susceptible to depression.<br><br>I will be forced to purchase 5-hydroxytryptophan from overseas increasing the risk to my health, as these products are cheaper for one reason only, that the manufacturing process is inferior to that applicable here in Australia.<br><br>Second, because I am passionate about helping people with their health, I have run a healthcare business for thirteen years, serving people who would rather spend their own money trying to stay healthy through largely preventative medicine with the same risk profile as products sold in Woollies, Listed Medicines, than being a burden on the public healthcare system.<br><br>I have no doubt these changes will have a significant adverse impact on my business, which is my livelihood.<br>However, given the uncertainty surrounding the likely outcomes of these changes, I cannot predict what they will be in the same way the people couldn't predict what the outcome of changing from State Corporate Affairs Offices to ASIC would be. | No-one knows what the TGA have in store for us once they obtain the power they are seeking from the Queensland Government. | I am not involved with Scheduled substances. I am involved with Listed Medicines on the ARTG. | no comment | no comment |
| Agriculture - No contact details | Agriculture | No | No | 1 month | accreditation documents<br>training schedule | $0 | 1 month |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| | Allied health peak body | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner | NR | NR | NR | NR | NR | NR |
| Peter Mayne | Pharmacist | No | No | I would have thought that 12-18 months would be sufficient. However I believe a longer time should be given upon application with a reasonable explanation. | Not applicable to me. | Not applicable to me. | I would have thought that 12-18 months would be sufficient. However I believe a longer time should be given upon application with a reasonable explanation. |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| Paul Lovelock University of Queensland | University | Insufficient expertise to comment | No | Up to 2 years | We have organisation policies and procedures for purchase, use, disposal, transport of scheduled substances, designated Drugs and Poisons officers holding approvals from EHU where appropriate. Internal auditing systems and manifesting requirements are in place.<br><br>Some respondents have asked for clarification on the management plans - will the Regulator require evidence of a management plan before each approval application is processed/approved?<br><br>If so, would it be acceptable to implement an organisation (University)-wide plan, and then submit approval applications for discrete sections of the organisation, which refer to the overall plan? | Insufficient expertise to estimate accurately, but costs will be significant and ongoing. Organisation has diverse operations across a number of locations. | 2 years |
| Ruth Hay, Queensland Health | Queensland Health | NR | NR | NR | NR | NR | NR |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| Chris Raftery Qhealth | Nurse Practitioner | could not locate 'who is approved'.. however, scope should include all personnel who are endorsed by regulatory authorities to prescribe and deliver medications and scheduled poisons including, doctors, nurse practitioners, pharmacists, dentists, vets, extended scope physios, prescribing midwives etc | consistency - good<br>finer points - unsure | 6-9 months | unsure - not my direct input | unsure | 3-6 months |
| [redacted]<br>McDonald Holdings | Land management organisation | properties that are in foreign ownership in qld. these properties should still go through historically avenues such as biosecurity QLD and local government. | No, we will benefit from the new immediate access of poisons listed for pest management | 14 days | property has a vegetation/lifestock management plan and a strict work plans with appropriate OHS considerations | negligible as we feel this is an essential tool for land managers to better enhance pest management | 14 days |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service | Unclear | Unclear. | NR | Policies and procedures that would generally cover most of the requirements.<br><br>Would need to add some additional components such as information and training;<br><br>Question re S93 (1) (a) stating the scheduled substance and S93 (4) that allows for more than one scheduled substance. Should the Act state that a single plan may apply to ALL scheduled substances without stating which one/s? | Man-hours and significant training requirements. | 3-6 months |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| [redacted] Health Professional, sole trader | Naturopath | Sole Trader Complementary Medicines to be exempted. The evidence for appropriate governance is their historical track record of safety for Qld Sole Trader products. | Australian manufacturers will be adversely affected by eliminating the Qld Sole Trader exemption.<br><br>Supplement production is increasingly being moved offshore to China and sold in Australia without 'made in China' labelling. (have a look on a Supermarket or Health Food Store shelf ) The 'made in China' claim has a negative effect on consumer perceptions but without 'country of origin' labelling the product Sponsor benefits from cheaper costs and greater sales but this is at a cost to local manufacturers.<br><br>Qld Only Sole Trader products have much smaller production runs that the China production runs and are made in Australia, which helps support the local manufacturing industry.<br><br>Removing the Qld Sole Trader manufacturing market will place further strain on these manufacturers. | 3 years. | NR | NR | NR |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | No comment | No comment | No comment | If entities include research institutions, then paperwork would likely need to be developed. | Cost should not be factor in setting up a plan to manage significant risks. | 6 months |

| Details | Respondent type | question15 | question16 | question17 | question18 | question19 | question20 |
|---|---|---|---|---|---|---|---|
| Craig Manley, Moreton Bay Regional Council | Local government | NR | NR | NR | NR | It is hard to know at this point how detailed and extensive the SSMP's would need to be. It would be beneficial if the State would release a template SSMP that could be adapted by service providers. | 12 months would provide sufficient time to develop the SSMP, obtain signoff and conduct the necessary training. |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| [redacted] SWNRM | Land management organisation | yes, this is best done by regional bodies or people in our area who can work with land managers to continuously improve their knowledge or, usage and storage, and documentation of materials listed under the proposed bill | self reporting regimes seem to be the most appropriate in this area | NR | |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University | Please make sure the auditors have some basic understanding of the materials we are handling and research practice. | Providing standard internal audit documents / tools would be beneficial to the University as it will provide us with a system to management our management plan(s). | What are 'monitored substances'?<br>When will the draft regulations be released for consultation? | |
| Agriculture - No contact details | Agriculture | For wholesale licences held by stock feed mills, the issue relates to having auditors that have a knowledge of how the industry operates. This is distinctly different to the wholesale of medicines for human health. Third party auditors for feed mills would be better to come from qualifies food safety auditors, equivalent to those that undertake third party audits for the FeedSafe program. It would be easy for the Department of Health to work with the SFMCA to have an added audit section for wholesale licence holders. Thus all sites would be audited annually by auditors expereinced in the stock feed industry without resource cost to the Department. | Refer above | It is better to work with existing industry programs than introduce another compliance standard. | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| Andrew Jones Mackay PHU | Public Health Unit | No under any circumstances | NR | NR | |
| B2BWorld Pty Ltd | Seller of complementary medicines | Certainly not in relation to Listed Medicines as they are low risk. In thirteen years in the industry having served thousands of customers I have not come across one case of a customer of ours being seriously affected by any of the Listed Medicines with which we have supplied them. On the contrary, they are generally delighted to be much healthier and no doubt have saved the public healthcare system untold millions. | I believe the present system works well and there are no need for any changes. | Unfortunately, Industry Standards are often arrived at following significant input from lobby groups, particularly in healthcare. The interests of practitioners, as opposed to patients, figure prominently in industry standards governing complimentary medicines, as it is in the practitioner's interest that people see them more often than they need to. There has been a huge push in recent years amongst suppliers of Practitioner Only complementary medicines and the practitioners who are their customers to develop selling policies, based in industry standards, forcing patients to see naturopaths for medicines which are low risk Listed Medicines, with the same risk profile as products sold in Woollies, simply to increase the income of naturopaths. Given the history in this industry, I do not support the use of standards, even best practice standards, as best practice is in the eye of the beholder. And often the interest of the beholder is not that of the patient.<br><br>As a specific example, the best practice standard for the display of information about complementary medicine products on the Internet requiring login access to information about Listed Medicines was put in place to prevent the public from accessing information not available on the ARTG.<br><br>This requirement was perverted for the commercial gain of naturopaths in clinics applying pressure on suppliers to force any information regarding Practitioner Only complementary medicines - even if it was just information already in the public domain from the ARTG and the price - to only be available through a login on the Internet, for the dominant purpose of limiting the access of the public to such products from online dispensers who were taking business away from naturopaths in their clinics; whose income is also derived from the sale of complementary products in their clinics. | |
| Agriculture - No contact details | Agriculture | I would like to see more auditing as well as consultation with small-medium buisness. | No | NR | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| | Allied health peak body | NR | NR | NR | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner | NR | NR | NR | |
| [redacted] | Pharmacist | Yes. | No | NR | |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health | Yes - accreditation processes. | NR | Telehealth, and in particular tele-pharmacy type services. Current scope of practice and credentialing for allied health professionals (in this case pharmacists) will need to incorporate telehealth. | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| Paul Lovelock<br>University of Queensland | University | This may incur significant costs on all stakeholders - in my experience of third-party audits on other compliance issues, high costs and in some cases, lack of expertise has detracted from the efficacy of the process. | Insufficient expertise to comment | This draft has generally been well received, other than some concern about the costs of approvals. One respondent has indicated that the approval duration be extended for research/teaching uses.<br><br>Other respondents have sought further information on the relationship between the management plans and approvals, which I mentioned earlier.<br><br>I have not received any comment from veterinarians or dentists on campus, so cannot provide any feedback on the draft legislation as it relates to those workgroups. They may have responded independently.<br><br>Thank you for the opportunity to contribute and comment on this draft. | |
| Ruth Hay, Queensland Health | Queensland Health | Third party auditors have little professional knowledge and skill in the practical application of legislation. This often causes circumstances of non-compliance, that when reassessed by individuals that do understand, are not deemed to be so. Third party auditors can only be used if they have an independant and professional point of reference to help assess their findings. | NR | The detail in these may help to address concern in the more open statements of the Act to ensure public safety is maintained | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| Chris Raftery Qhealth | Nurse Practitioner | with regulation - yes<br>open book flexibility - no | I think there would be efficiencies to be created, however I couldn't advise on this | consistency and transparency<br><br>the bill needs to flow simply but with quality<br>there needs to be min to no duplication<br><br>there needs to be equal rights to all health professionals involved not just "doctors" and "the rest"<br><br>better alignment to similar acts will improve efficiency and enhance understanding and key responsibilities<br><br>everyone is time poor including professionals and consumers, the revision needs to provide a clear solution to this for all | |
| McDonald Holdings | Land management organisation | we are of the belief that a third party should be consider to undertake regulatory alignment during the transition phase of the bill and it is important that the storage assessor is a locally employed facilitator | No, this is a good progression | We feel this is an appropriate evolution of the legislative requirement for landscape control of pest. This new amendment allows land managers to take proactive steps for pest mitigation in a timely manner | |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service | Yes - provided those parties have undergone significant and appropriate training on the contents and intent of the Act.<br><br>Auditors who have merely read the Act and then enter a place with no understanding of the business of that place are a detriment and impediment to good management of compliance.<br><br>Equally, experience shows that different auditors make different recommendations on the same matter. Consistency with interpretation is essential | NR | Requires clear information regarding electronic devices and activities including storage; records; electronic authorisation standards (signatures)<br><br>Needs to address expanded scope of practice for persons currently not considered eligible - whether that be by class, or by individual approval. | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| [redacted]Health Professional, sole trader | Naturopath | NR | NR | NR | |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | Yes, no limitations expect that costs to small businesses need to be considered in terms of their business sustainability. | In research institutions, using eligible people (vets) to perform the regulated activity is cost effective and minimises the need to have an entity licence. | It is not clear what records will need to be kept for veterinary clinics. For controlled drugs, the current system although time consuming delivers confidence that safeguards are in place. | |

| Details | Respondent type | question21 | question22 | question23 | |
|---|---|---|---|---|---|
| Craig Manley, Moreton Bay Regional Council | Local government | Auditing should remain a function of the State. Third party auditing has the potential to result in unnecessary cost impacts for business. | NR | NR | |

| Details | Respondent type |
|---|---|
| [redacted] WNRM | Land management organisation |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University |
| Agriculture - No contact details | Agriculture |

| Details | Respondent type |
|---|---|
| Andrew Jones Mackay PHU | Public Health Unit |
| [redacted] B2BWorld Pty Ltd | Seller of complementary medicines |
| Agriculture - No contact details | Agriculture |

| Details | Respondent type |
|---|---|
| | Allied health peak body |

| Details | Respondent type |
|---|---|
| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner |
| Peter Mayne | Pharmacist |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health |

| Details | Respondent type |
|---|---|
| Paul Lovelock<br>University of Queensland | University |
| Ruth Hay, Queensland Health | Queensland Health |

| Details | Respondent type |
|---|---|
| Chris Raftery Qhealth | Nurse Practitioner |
| McDonald Holdings | Land management organisation |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service |

| Details | Respondent type |
|---|---|
| [redacted] Health Professional, sole trader | Naturopath |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body |

| Details | Respondent type |
|---|---|
| Craig Manley, Moreton Bay Regional Council | Local government |

| Details | Respondent type |
|---|---|
| SWNRM | Land management organisation |
| Brian Logan Queensland University Safety Association and Queensland University of Technology | University |
| Agriculture - No contact details | Agriculture |

| Details | Respondent type |
|---|---|
| Andrew Jones Mackay PHU | Public Health Unit |
| B2BWorld Pty Ltd | Seller of complementary medicines |
| Agriculture - No contact details | Agriculture |

| Details | Respondent type |
| --- | --- |
| | Allied health peak body |

| Details | Respondent type |
|---|---|
| Sue Muirhead, Nurse Educator, Queensland Health | HHS rural and isolated practice practitioner |
| [redacted] | Pharmacist |
| Matt Page, Telehealth Support Unit, Queensland Health, | Department of Health |

| Details | Respondent type |
|---|---|
| Paul Lovelock<br>University of Queensland | University |
| Ruth Hay, Queensland Health | Queensland Health |

| Details | Respondent type |
|---|---|
| Chris Raftery Qhealth | Nurse Practitioner |
| McDonald Holdings | Land management organisation |
| Elizabeth Coombes Gold Coast HHS | HHS specialty service |

| Details | Respondent type | |
|---|---|---|
| [redacted] Health Professional, sole trader | Naturopath | |
| Laurie Dowling, Australian Veterinary Association Qld Division | Veterinary peak body | |

| Details | Respondent type |
|---|---|
| Craig Manley, Moreton Bay Regional Council | Local government |