

INFORMATION FOR PHARMACISTS

This fact sheet is intended to provide information to pharmacists about legislative amendments and a regulatory update on activities undertaken by Queensland Health's Pseudoephedrine Enforcement Taskforce.

Legislative amendments to the Health (Drugs and Poisons) Regulation 1996

Introduction

Amendments, effective from 28 January 2011, have been made to the *Health (Drugs and Poisons) Regulation 1996* (**the Regulation**). These amendments ensure the continued effective and efficient operation of the Regulation and have resulted in the removal of some unnecessary or unduly onerous requirements from the Regulation.

The regulatory controls detailed in the amendments support the objectives of the Regulation by protecting the public from the health risks associated with inappropriate use of drugs and poisons and minimising the risk of those substances being diverted for unlawful purposes.

General amendments applying to all pharmacists

The following information (including reference to the relevant section/s) summarises legislative amendments applying to pharmacists working in community pharmacies and/or institutions eg. Hospitals.

- new meaning for supervision and personal supervision which clarifies that supervision of specified activities involving drugs and poisons may be undertaken by using appropriate forms of technology [s.5A]
- extending the authorisations for the pharmacy profession to have access to specified drugs and to carry out specific functions in the practice of their profession, or for teaching or research purposes, including for trainee pharmacists [ss. 64(2), 74 (3), 171(1)(f), (2) & (4), 189(2) & (3), 243 (3)]
- prohibiting a controlled drug being dispensed more than 6 months (rather than 1 year) after the prescription for the drug has been written. [s.82 (2)(f)] This ensures national consistency in relation to this issue.
- removing unnecessary or unduly onerous requirements in the Regulation regarding the labelling of dispensed medicines [ss.85 (3)(c), (3A) & (4)(b), 198(3)(c), (4)(b) & (6)]
- prohibiting the sale of drugs and poisons after their expiry date [ss. 85A, 198A, 276A]
- requiring controlled drug stocks to be checked by a pharmacist if they take over the management of a dispensary for more than 7 days (rather than 7 days or more) [s.88 (1)]
- requiring that only certain specified categories of persons are authorised to check and inspect the stock and records of controlled drugs at a pharmacy [s.119 (2)(b)]
- allowing wholesale representatives to give samples of restricted drugs or poisons to pharmacists [ss.148, 149(2), 153, 267A]
- changes to dispensing generic drugs where the drug has no brand name [ss.83 (1),(3) & (4), 195 (1), (3) & (4), 198 (4)(b), 275 (1), (3) & (4)]
- expanding the requirement for the dispenser to report to Queensland Health's Chief Executive when dealing with prescriptions in circumstances where the quantity or volume of a s.197 restricted drug (which now includes anabolic steroids) is greater than appears to be reasonably necessary [ss. 197 (3),(4) (5)]
- allowing the option to label dispensed medicines with the name and address of the business from which the dispensed or supplied medicine is sold [s.198 (3)(c)]
- allowing the option not to include warnings on the label if such warnings appear on the dispensed or supplied medicine's container and are clearly visible after the dispensing label is attached to the container [s.198(6)]
- removing the requirement to send regulated restricted drug purchase orders and prescriptions to Queensland Health's Chief Executive [s.203]
- removal of the stand alone requirement for Queensland Health to grant written approvals for approved dispensers. These are now granted under s.18 (1) of the Regulation.
- allowing pharmacists to destroy or otherwise dispose of S2 or S3 poison [s.257 (1)]
- allowing persons over 16 years of age to perform duties as a pharmacy assistant [s.258]
- prohibiting regulated poisons being destroyed unless authorised to under s.271 [s.271(1)]
- requiring reporting to Queensland Health of the actual or suspected theft, loss or misappropriation of controlled drugs or pseudoephedrine [ss. 116A, 285B]
- allowing asthma medications to be sold to children over 14 years of age [s.286(4) &(5)]
- amendments to Appendix 9 (dictionary) eg. Acceptable form of identification.

Specific amendments for pharmacists working in institutions

The following information summarises legislative amendments applying to pharmacists working in institutions eg. Hospitals. These are in addition to the amendments summarised above.

- responsibilities for checking and reporting on the accuracy of controlled drugs stock and records eg. Stock must be checked by a responsible person (as defined), at reasonable intervals ie. an interval no more than one month (rather than at least once a week) [ss.110(1)(b),(2),(3) &(4), 116A]
- requiring that only certain specified categories of persons are authorised to check and inspect the stock and records of controlled drugs in hospitals and other institutions [s118 (2)(c)];
- extending the authorisation for the pharmacy profession to have access to specified drugs and to carry out specific functions in the practice of their profession [ss.163A, 164 (1)(c)(ii)]
- requiring that only certain specified categories of persons are authorised to carry out specific functions [ss.183, 186(1)(c) & (2)(a), 188A(c) & B(c)]
- changes to dispensing generic drugs at a public sector hospital, where the drug has no brand name [ss.83 (2) 195(2), 275(2)]
- requiring reporting of the actual or suspected theft, loss or misappropriation of controlled drugs at institutions [s.110 (2)(c)].

Pseudoephedrine enforcement taskforce update

The pseudoephedrine (PSE) enforcement taskforce continues to operate to reduce the diversion of PSE medicines to the illicit drug market via monitoring compliance of health practitioners, undertaking intelligence gathering and timely investigative interventions (including audits of community pharmacies and doctors) throughout Queensland. More recently the scope of these investigations has included other medicines subject to misuse or diversion including performance enhancing substances such as Anabolic Agents (steroids), and Human Growth Hormone.

While the diversion of drugs of addiction obtained on prescription has long been an issue of significant public health concern, the diversion of PSE medicines also represents a significant ongoing risk to the community. This is based upon the ease with which PSE can be converted into methamphetamine and the consequential harm it causes to the physical and mental health of individuals.

The intelligence gathered by the taskforce indicates a multi-agency approach with significant ongoing investigative work, is required to continue to address this problem.

Since 2006, 38 health practitioners have had their endorsements to either prescribe or dispense scheduled medications suspended or cancelled because they have acted outside of their respective legislative endorsements. Each case was subsequently forwarded to Australian Health Practitioner Regulation Agency for their attention.

As PSE enforcement taskforce audits continue throughout Queensland, pharmacists are reminded to ensure:

- a Quality Standard for the dispensing of PSE medicines (as well as all other scheduled substances) has been adopted or developed by the pharmacy, that is consistent with the principles detailed in S. 4A of the Regulation
- the Quality Standard is being actively implemented/practiced, as required and is available for assessment by officers of the taskforce
- the pharmacist dispensing or supplying PSE establishes that the patient has a genuine therapeutic need for the medication
- all sales of PSE medicines are entered into an electronic record (for example Project Stop) as required under s.285A of the Regulation
- the number of PSE medicine primary packs (boxes) are entered into Project Stop as the quantity entered and not the number of tablets
- interstate, overseas and locum pharmacists are made aware of their obligations under the Regulation with regards to PSE and the requirement to use an electronic recording system such as Project Stop.

Further Information

1. Copies of the Amendment Regulation and the Regulation may be accessible electronically from the Queensland Government legislation websites detailed below:
 - *Health (Drugs and Poisons) Amendment Regulation (No. 1) 2011*
www.legislation.qld.gov.au/LEGISLTN/SLS/2011/11SL004.pdf
 - *Health (Drugs and Poisons) Regulation 1996* [As in force on 28 January 2011, Reprint no. 10D]
www.legislation.qld.gov.au/LEGISLTN/CURRENT/H/HealDrAPoR96.pdf
2. Information about medicines and poisons, as it applies to health practitioners, industry and the public can be found on Queensland Health webpages detailed below:
 - Pharmaceutical and Medicines
www.health.qld.gov.au/health_professionals/medicines
 - Poisons and Pest Management
www.health.qld.gov.au/industry/poisons_pest
 - Pharmacy Ownership
www.health.qld.gov.au/health_professionals/pharmacyownership.asp
3. Contact your local Queensland Health Public Health Unit (PHU) if you have any further questions regarding legislative requirements (PHU contact details below).

Queensland Health Public Health Units – Environmental Health

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Brisbane Northside	3624 1111	EH_BrisbaneNorth@health.qld.gov.au
Brisbane Southside	3000 9148	EH_BrisbaneSouth@health.qld.gov.au
Bundaberg – Wide Bay	4150 2780	EH_WideBay@health.qld.gov.au
Cairns	4226 5555	EH_Cairns@health.qld.gov.au
Gold Coast	5668 3700	EH_GoldCoast@health.qld.gov.au
Hervey Bay – Wide Bay	4184 1800	EH_HerveyBay@health.qld.gov.au
Ipswich – West Moreton	3413 1200	EH_WestMoreton@health.qld.gov.au
Logan	3412 2989	EH_Logan@health.qld.gov.au
Longreach – Central West QLD	4652 6000	EH_CentralQueensland@health.qld.gov.au
Mackay	4911 0400	EH_Mackay@health.qld.gov.au
Mt Isa & Gulf	4744 9100	EH_CentralQueensland@health.qld.gov.au
Redcliffe – Moreton Bay	3142 1800	EH_MoretonBay@health.qld.gov.au
Rockhampton – Central QLD	4920 6989	EH_CentralQueensland@health.qld.gov.au
Charleville – South West QLD	4656 8100	EH_DarlingDowns@health.qld.gov.au
Sunshine Coast	5409 6600	EH_SunshineCoast@health.qld.gov.au
Toowoomba – Darling Downs	4631 9888	EH_DarlingDowns@health.qld.gov.au
Townsville	4753 9000	EH_Townsville@health.qld.gov.au
Torres Strait & Northern Peninsula	4069 0400	EH_Cairns@health.qld.gov.au

4. For enquiries relating to PSE or information you may have concerning the inappropriate prescribing or supply of PSE or other scheduled medicines subject to diversion or misuse, such as performance enhancing substances, please contact the PSE enforcement taskforce, located within the Drugs and Poisons Policy and Regulation Unit.

Drugs and Poisons Policy and Regulation Unit

Environmental Health Branch

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