

Health (Drugs and Poisons) Regulation 1996

What Wholesale Representatives Need to Know

March 2001

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Foreword

The *Health (Drugs and Poisons) Regulation 1996 – What Wholesale Representatives Need to Know* is a Queensland Health initiative intended to assist health professionals by defining current policy and providing interpretations of legislation for the management of drugs and poisons.

This document will help the Queensland wholesale drug industry meet the requirements of the *Health (Drugs and Poisons) Regulation 1996* as it relates to the management and supply of restricted drug and scheduled poison samples.

Queensland Health looks forward to further promoting and maintaining a strong working relationship with the Queensland drug wholesaling industry to realise its mission of promoting, maintaining and improving the health and well-being of all people in Queensland.

Dr John Scott
State Manager
Public Health Services
Queensland Health

March 2001

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Health (Drugs and Poisons) Regulation 1996

What Wholesale Representatives Need to Know

Overview

Wholesale representatives who carry and supply samples of restricted (Schedule 4) drugs and Schedule 2 and 3 poisons in Queensland, and their employers, are subject to regulatory controls under State legislation. In Queensland, the *Health (Drugs and Poisons) Regulation 1996* ("the regulation") is the legislation which provides controls over drugs and poisons.

This information booklet is part of Queensland Health's range of information documents for health professionals. It provides wholesale representatives and their employers with details of the regulation as it applies to them. It helps provide an understanding of Queensland's legislative requirements and their impact on wholesale representatives and employers. This booklet is not an extract from the regulation. The regulation should be used if legal interpretations are required.

Where the obligations of wholesale representatives supplying restricted drugs and scheduled poisons, or the obligations of employers of wholesale representatives are still unclear, one of the Population Health Services – Environmental Health Services listed in Appendix 6 of this booklet should be contacted.

Structure of the regulation

The regulation consists of five Chapters, each made up of Parts, Divisions, Sections and Subsections. Chapters 2, 3 and 4 contain many provisions which are replicated in each chapter in terms of controlled drugs, restricted drugs and poisons respectively.

The regulation also contains eleven appendices, cross-referenced to specific provisions in the regulation.

Chapter 3 - Parts 1, 2, 3, 5, 6, 7, 8 and 10, and Chapter 4 - Part 3 of the regulation are of particular importance to wholesale representatives.

Glossary of terms

<i>Chief executive:</i>	Chief Executive, Queensland Health.
<i>Endorsement:</i>	an authority, approval, certification, drug licence or wholesale representative licence.
<i>Inspector:</i>	a Queensland Health Environmental Health Officer.
<i>Primary pack:</i>	the pack in which a drug or poison and its immediate container or immediate wrapper or measure pack are presented for supply eg outer carton.
<i>the regulation:</i>	the <i>Health (Drugs and Poisons) Regulation 1996</i>
<i>Restricted drug:</i>	any substance (other than solasodine) included in Schedule 4 of the Standard. It includes alkaloids and alkaloidal glycosides of plants of the genus solanum for human therapeutic use.
<i>Restricted drug wholesaler:</i>	means a person who holds a restricted drug wholesalers licence granted under the regulation.
<i>Restricted drug manufacturer:</i>	means a person who holds a restricted drug manufacturers licence granted under the regulation.
<i>Schedule 2 poison:</i>	any substance included in Schedule 2 of the Standard.
<i>Schedule 3 poison:</i>	any substance included in Schedule 3 of the Standard.
<i>Standard:</i>	the <i>Standard for the Uniform Scheduling of Drugs and Poisons</i> published by the Commonwealth.
<i>Wholesale representative:</i>	a person who holds a wholesale representative licence.

General endorsements in relation to drugs and poisons

A person must not possess a restricted drug unless he or she is endorsed to possess that drug.

Similarly, a person must not supply a restricted drug without endorsement under the regulation.

Failure to comply with these requirements of the regulation is unlawful and significant penalties can be imposed for non-compliance.

Specific requirement for endorsements

Employees of restricted drug wholesalers and/or restricted drug manufacturers, who display and supply samples of restricted drugs and Schedule 2 and 3 poisons to doctors, veterinary surgeons or dentists as part of their employment, must hold a wholesale representative licence.

A person who possesses drugs and poisons solely for delivery to legitimate clients of a restricted drug wholesaler or restricted drug manufacturer does not need a wholesale representative licence.

It is unlawful for wholesale representatives to possess or supply restricted drugs and Schedule 2 and 3 poisons unless they are licensed to do so. This endorsement is granted by the chief executive in the form of a wholesale representative licence.

The regulation restricts the granting of wholesale representative licences to suitable persons who are employed in a capacity that requires them to possess and display or supply restricted drug samples to specific health professionals.

Obtaining a wholesale representative licence

Prerequisites

Wholesale representatives applying for a licence must be employed by a holder of a current Queensland licence to manufacture restricted drugs or a licence to sell restricted drugs by wholesale.

Employers of representatives must, as a prerequisite to holding a licence, have a premises in Queensland suitable for licensing for the manufacture or wholesale sale of restricted drugs.

The chief executive must be satisfied that a wholesale representative applying for a licence is a suitable person to be allowed to possess restricted drugs. This criteria is assessed by Queensland Health on receipt of applications.

The application

An application for a licence must be made on the form approved for this purpose under the regulation (see Appendix 4). Application forms may be obtained from any of the Population Health Services – Environmental Health Services listed in Appendix 6. Separate applications must be made for individual applicants.

Applications must be accompanied by the prescribed fee in effect at the time of application. Current fees can be confirmed by contacting any of the Population Health Services – Environmental Health Services.

Application forms are two-sided. *Both sides must be completed* (see sample in Appendix 5). The front of the form must be completed by the wholesale representative and the back of the form is to be completed by the wholesale representative's employer.

When completed, an original copy of the application form, together with the application fee, should be forwarded to:

*Senior Licensing Officer
Drugs & Poisons Policy and Regulation Unit
Environmental Health Branch
Queensland Health
PO Box 2368
FORTITUDE VALLEY BC QLD 4006*

A licence will not be processed until a fully completed and signed application is received with payment in full.

Applicant information

Name

The full name(s) of the applicant is required. Initials are insufficient.

Telephone

This should be the telephone number of the applicant, not the employer.

Date of birth

Provide the day, month and year of birth.

Address

Full residential address details are required. If the postal address is the same as the applicant's residential address, complete the residential address section and write "as above" in the postal address section.

If the wholesale representative licence is to be sent directly to the employer rather than to the wholesale representative, the employer's postal address should be inserted in the applicant's *postal* address section of the application form. The original licence must be given to the wholesale representative.

Premises information

The business name and street address of the premises where the drug samples are to be stored must be provided, along with a telephone number, where applicable.

Applicant declaration

By completing this part of the form, the applicant declares that he or she has knowledge of the legislative requirements of the regulation applying to wholesale representatives.

In particular, wholesale representatives must be familiar with Chapter 3 - Parts 1, 2, 3, 5, 6, 7, 8, & 10 and Chapter 4 - Part 3 of the regulation. The requirements of these sections of the regulation have been provided in the relevant parts of this booklet. It is expected that all wholesale representatives understand and comply with the requirements of the regulation.

Applicants must sign and date the application form. Unsigned forms submitted to Queensland Health will be returned to applicants. This creates unnecessary time delays in processing applications.

Employer information

Name

Employers must hold a current Queensland Health licence to sell restricted drugs by wholesale or to manufacture restricted drugs.

The full and correct name of the employer, appearing on the employer's licence, must be inserted on the application form.

Telephone number

A contact number which may be used by Queensland Health to obtain additional details regarding applications must be provided. This may be the

telephone number of the company's head office or of a regional office in Queensland or interstate.

Licence number

The number of the current licence held by the employer must be provided. Where the employer has licences for a number of premises in Queensland, the licence number applying to the specific premises from which the wholesale representative will operate should be provided.

Address

The street address provided should be the street address of the employer appearing on the employer's licence. This should be the *head office* address and not the address of the Queensland premises, unless the two are the same.

A postal address is also required. If the postal address is the same as the employer's street address, complete the street address section and write "as above" in the postal address section.

Employer declaration

Completion of this section of the form by employers certifies that applicants are employed by them and have the required knowledge of the regulation.

The employer declaration must be signed by a person authorised within the organisation to sign such documents. Unsigned application forms forwarded to Queensland Health will be returned for completion.

Who should retain licences

Wholesale representative licences should be retained by the person to whom it was granted. Employers may keep photocopies of licences granted to their wholesale representatives but the original licence should be held by the representative at all times.

About the licence

Expiry and renewal of licences

Wholesale representative licences are valid for a period of one year from the day of granting, unless sooner suspended, cancelled, replaced or surrendered.

Recent amendments to the regulation allow for the renewal of endorsements in relation to wholesale representatives. Whilst renewal notices are generally issued by Queensland Health approximately one

month before licences are due to expire, it is the responsibility of licence holders to ensure they hold a current licence. **Prior to expiry of a licence**, an application for renewal of that licence should be forwarded to Queensland Health, together with the relevant application fee.

NB: It is unlawful for representatives to possess or supply restricted drug or scheduled poison samples without a current licence.

Specific limitations on licences

Wholesale representative licences are only valid whilst the representative is employed by the nominated employer. The representative must be employed in a capacity which requires his or her possession and display or supply of restricted drug and scheduled poison samples.

Wholesale representative licences are only valid whilst employers' Queensland licences to manufacture or sell restricted drugs by wholesale are current. If employers' licences expire or are cancelled, all wholesale representative licences for persons employed by them immediately become invalid.

Quantity of drugs possessed

Wholesale representative licences allow wholesale representatives to personally possess a maximum of 400 primary packs of restricted drugs, 400 of Schedule 2 poisons and 400 of Schedule 3 poisons. Of these, no more than 100 primary packs may be of the same description.

The limit of 1 200 primary packs of samples applies to every restricted drug/poison sample issued to the wholesale representative by the employer. This total does not include the bulk restricted drug/poison stocks held by an employer at a licensed premises.

Supply of samples

Licensed wholesale representatives may display and supply samples of restricted drugs and Schedule 2 and 3 poisons to dentists, doctors or veterinary surgeons only.

Wholesale representatives are not permitted to possess or supply controlled (Schedule 8) drugs or regulated restricted drugs as samples.

A full list of regulated restricted drugs is provided in Appendix 2 of this booklet.

Changes to licences

If a wholesale representative ceases to be employed by the employer specified on his or her wholesale representative licence, the licence becomes invalid. In this instance, the wholesale representative should surrender the licence by posting it to the Licensing Officer, Environmental Health Unit (see page 8). The licence should be accompanied by a letter which explains that the wholesale representative is surrendering the licence and outlines reasons for the surrender.

If a wholesale representative gains employment with a different employer to that stated on his or her licence, the licence is not valid for employment with the new employer. An application for a new wholesale representative licence must be made. Again, the invalid licence should be surrendered.

Should any other details of a wholesale representative specified in a licence change during the term of the licence, the wholesale representative should, by notification in writing, advise the Licensing Officer, Environmental Health Unit (see page 8) of the changes.

Special procedures apply under the regulation to have licences amended. Consultation with the Licensing Officer, Environmental Health Unit will ensure appropriate changes are made to licences in accordance with legislative requirements.

Replacement of licences

If a wholesale representative's licence is lost, stolen or destroyed, the representative must apply for a replacement licence. These applications should detail the grounds for the request and should be in the form of a letter to the Director, Drugs and Poisons Services, Environmental Health Unit, GPO Box 48, Brisbane, QLD, 4001.

If a wholesale representative can confirm that his or her licence has actually been lost, stolen or destroyed, an identical replacement licence may be provided by the Department.

Recording restricted drug transactions

Records to be kept by employers

The following records must be maintained by employers when supplying or selling restricted drugs:

Drugs supplied to wholesale representatives

Employers must keep an accurate record, in an approved form, of each restricted drug supplied to their wholesale representatives.

Employers must retain these records for at least two years and must be able to produce them to Environmental Health Officers of Queensland Health, on demand.

Invoices

Employers must keep an accurate record of the particulars contained in all invoices for the sale of restricted drugs, together with the invoice number of each invoice.

'Return of transactions' for restricted drugs

A copy of each 'return of transactions' provided by wholesale representatives, as detailed below, must be kept by employers.

It is the responsibility of employers to check the details of the invoices and 'returns of transactions' provided to them by their wholesale representatives to ensure that all restricted drugs are accounted for at all times.

Where an employer has more than one licence and the employer's records are kept on a computer at a central or main office, the employer must keep records for each licence at the relevant business premises.

Records to be kept by representatives

The following records must be maintained by wholesale representatives who supply restricted drug samples:

Invoices

On each occasion that wholesale representatives supply restricted drugs, whether as samples to authorised persons or as returns to their employers, they must issue an invoice to the person supplied with the sample or, in the case of returns, to their employer. Invoices must include the following details:

- a unique number for the invoice
- the date of the supply or return of the restricted drug
- if the sample is supplied to a dentist, doctor or veterinary surgeon - the name and address of the person to whom the drug sample is supplied
- a description of the drug and the amount of the drug supplied or returned

Copies of all invoices issued by wholesale representatives must be forwarded to their employers within seven (calendar) days of issue.

'Return of transactions' for restricted drugs

All wholesale representatives must, in addition to copies of invoices, provide to their employer a 'return of transactions' for restricted drugs supplied. This is a detailed account of all restricted drugs received and supplied by them, and must provide the following information:

- period of the return
- the quantity or volume of each class of restricted drug in the representative's possession at the start (ie the quantity brought forward from the last period) and at the end of the period
- the quantity of each class of restricted drug received, supplied, or returned to the employer by the wholesale representative during that period. A separate record is required for each class of restricted drug
- the invoice number which refers to each individual receipt, supply or return of each restricted drug. This invoice number may refer to:

invoices for samples of restricted drugs supplied to doctors, veterinary surgeons or dentists

invoices for stock returned to the employer

invoices for sample replacement stock forwarded by the employer.

An example of a 'return of transactions' for restricted drug samples is provided in Appendix 1, as a guide.

Wholesale representatives must keep a copy of the 'return of transactions' for two years.

The 'return of transactions' must be forwarded to the employer by the wholesale representative at least every seven (calendar) days.

The flowchart in Appendix 3 summarises the record-keeping process required of both employers and wholesale representatives.

False, misleading or incomplete entries

A wholesale representative must not record entries which he or she knows to be false, misleading or incomplete.

Alteration of transaction entries

Entries in restricted drug records cannot be cancelled, changed or obliterated. However, the person who made the entry may *correct* an entry by using a *signed and dated* marginal note or footnote giving the correct details.

Records of restricted drugs must be retained for at least two years from the date of the last entry and the records must be kept in good condition, as far as is practicable.

Storage of drugs

Security

Except when being displayed or supplied to authorised persons, restricted drugs held by wholesale representatives must be stored under lock and key in a secure place. *The restricted drugs must not be visible to the public.* The keys to the secure place must remain in the personal possession of wholesale representatives.

Schedule 2 and 3 poisons must not be accessible to the public and must be kept out of the reach of children. Wholesale representatives are strongly encouraged to treat Schedule 2 and 3 poisons in a similar manner to restricted drugs.

These storage requirements apply to samples stored by wholesale representatives at their residence, at their employer's licensed premises or in their motor vehicle.

To ensure drugs and poisons held by wholesale representatives are not visible to the general public, storage in station sedans is not recommended. Storage in standard passenger sedans should be limited to the locked boot section of the vehicle. All vehicles used to carry samples should be securely locked when unattended.

Temperature control

Storage facilities (licensed premises, motor vehicle, residential premises) should protect samples from deterioration. The conditions for storage of samples should be compatible with the storage conditions specified on product labels.

Where drug samples require refrigeration to achieve recommended storage temperatures, this must be provided and monitored to ensure deviation outside of the recommended storage temperature range does not occur.

Contamination prevention

The storage of restricted drug and poison samples should protect the samples from contamination at all times. Storage facilities should not be used for other purposes which may contaminate drug samples.

All wholesale representatives should be familiar with the Australian *Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* published by the Commonwealth Department of Health and Aged Care and available from the Therapeutic Goods Administration, PO Box 100, WODEN, ACT, 2606.

Accountability for drugs and poisons

It is recommended that employers monitor records provided to them by their wholesale representatives. Discrepancies in drug records and stocks which cannot be resolved should be reported to a Population Health Services – Environmental Health Service (see Appendix 6).

Wholesale representatives must be able to account for each and every drug which is, or should be, in their possession. Additionally, every restricted drug which has passed into their possession at any time *within the past 12 months* must also be accounted for.

This imposes the need for wholesale representatives to maintain accurate and complete records of every transaction. It also reinforces the importance of employers checking 'returns of transactions' and invoices provided by their wholesale representatives.

Failure of wholesale representatives to account for any restricted drugs to the satisfaction of an inspector may result in suspension or cancellation of licences.

Production of documents

If requested by an inspector (a Queensland Health Environmental Health Officer), wholesale representatives must produce for examination any documents in the representative's possession relating to restricted drugs which have been in the representative's possession at any time within the year prior to the request.

Loss or theft of samples

Wholesale representatives must immediately report the loss or theft of restricted drugs to their employer and the nearest police station.

Powers of inspectors

Inspectors (Queensland Health Environmental Health Officers) may enter and inspect any place where drugs or poisons are, or are reasonably suspected of being kept by wholesale representatives or their employers.

Upon entry to the premises, inspectors can inspect or examine or remove for examination, any drug or poison held by wholesale representatives or their employers. Inspectors may remove any drugs or poisons for analysis or seize the drugs or any articles which they believe to be drugs or poisons.

Inspectors can also inspect, copy and take extracts from any records, books, prescriptions or other documents relating to drugs or poisons held at a place by wholesale representatives or their employers.

Appendix 1

Sample "return of transactions " record requirements

Drug: DOXYCYCLINE 100 mg Tablets			Representative: J.P. Smith		
Start of period: 12/01/2001			End of period: 16/01/2001		
Balance brought forward: 75					
Date of transaction	In	Out	Balance on hand	Invoice number	Comments
12/01/2001	25		100	QH123	new stock
12/01/2001		5	95	RP089	
13/01/2001		3	92	RP090	
13/01/2001		40	52	RP091	returns
Stock balance for end of period: 52					

Appendix 2

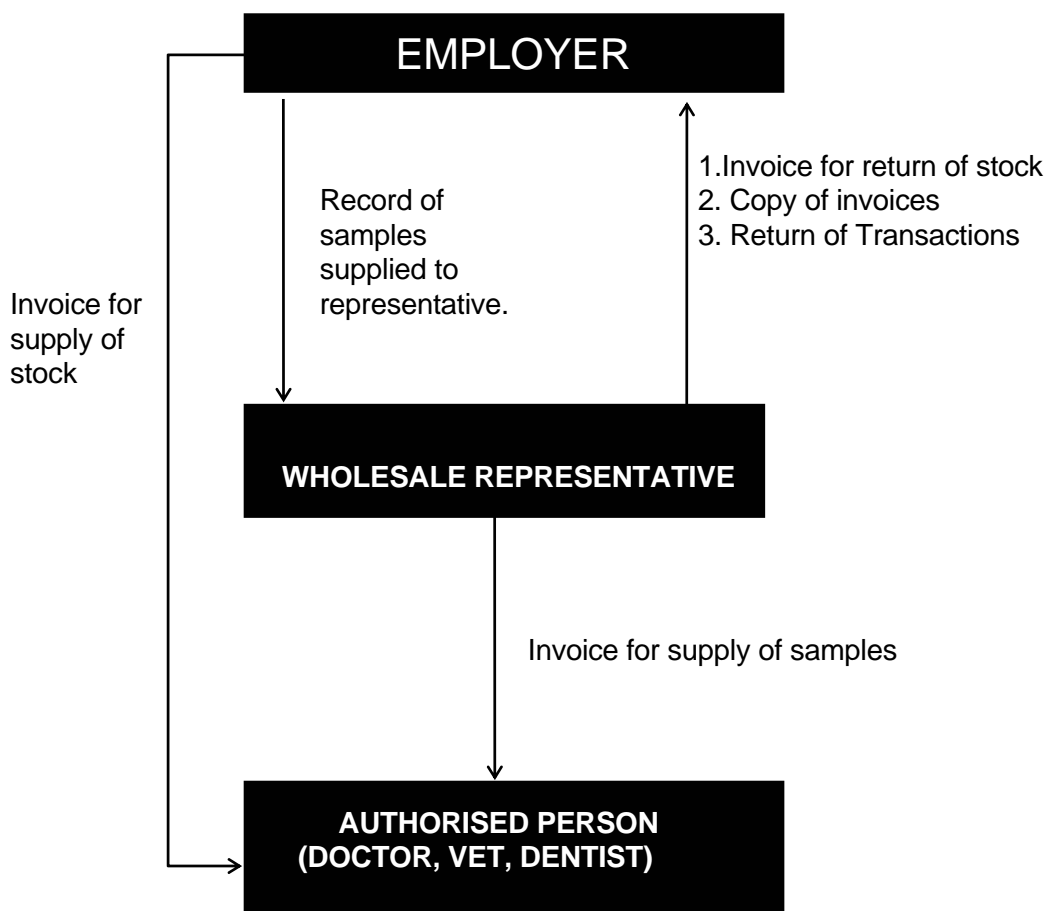
REGULATED RESTRICTED DRUGS

Regulated restricted drug includes any of the following restricted drugs:

acitretin
clomiphene, cyclofenil or another substance specifically prepared to stimulate ovulation
clozapine
dinoprost
dinoprostone
etretinate
isotretinoin
luteinising hormone
thalidomide
tretinoin
urofollitrophin (human follicle stimulating hormone).

Appendix 3

Recording relationships for wholesale representatives and employers



Appendix 4
Health Act 1937
Health (Drugs and Poisons) Regulation 1996

APPLICATION FOR A LICENCE AS A WHOLESALE REPRESENTATIVE

APPLICANT INFORMATION

Name
(First Name) (Last Name)

Telephone () Date of Birth

RESIDENTIAL ADDRESS

.....
.....

Suburb/Town Post Code

POSTAL ADDRESS (if different to above)
.....
.....

Suburb/Town Post Code

PREMISES INFORMATION

State the street address at which drug samples are stored –

Business Name.....

Street Address.....

Suburb/Town.....

Post Code..... Telephone No. (.....).....

APPLICANT DECLARATION

I apply for a licence as a Wholesale Representative and enclose the prescribed fee of \$

I am familiar with the provisions of Chapter 3, Parts 1, 2, 3, 5, 6, 7, 8 & 10 and Chapter 4, Part 3 of the *Health (Drugs and Poisons) Regulation 1996*.

I declare that the above information is correct

.....
(Signature of Applicant)* (Date)

*Employer To Complete Information Overleaf

Changes to the information contained in this application should be notified in writing to the Licensing Officer, Drugs and Poisons Policy and Regulation Unit, PO Box 2368, Fortitude Valley BC QLD, 4006.

EMPLOYER INFORMATION

Name.....

Telephone ()

Licence Number (Wholesale Seller)Expiry Date.....

(This must be the Poisons licence number of the premises from where samples are obtained. Please ensure that this licence has not expired.)

STREET ADDRESS

.....

.....

Suburb/Town Post Code

POSTAL ADDRESS (if different to above)

.....

.....

Suburb/Town Post Code

EMPLOYER DECLARATION

I certify that the applicant is employed in a capacity which requires him/her to be in possession of restricted drugs and Schedule 2 and 3 poisons for the purpose of display and/or supply to medical, veterinary and/or dental practitioners.

I endorse and recommend this application.

I am familiar with the provisions Chapter 3, Parts 1,2,3,5,6,7,8 & 10 and Chapter 4, Part 3 of the *Health (Drugs and Poisons) Regulation 1996*.

I declare that the above information is correct.

.....
(Signature of Employer)

.....
(Position held by Signatory)

.....
(Date)

EMPLOYER INFORMATION

Name John's Pharmaceutical Company Pty Ltd

Telephone (07) 3333 9999

Licence Number (Wholesale Seller) W3333 Expiry Date 31/10/01

STREET ADDRESS

99 Chemical Street

Suburb/Town Bigtown Post Code 1234

POSTAL ADDRESS (if different to above)

PO Box 99

Suburb/Town Bigtown Post Code 1234

EMPLOYER DECLARATION

I certify that the applicant is employed in a capacity which requires him/her to be in possession of restricted drugs and Schedule 2 and 3 poisons for the purpose of display and/or supply to medical, veterinary and/or dental practitioners.

I endorse and recommend this application.

I am familiar with the provisions Chapter 3, Parts 1,2,3,5,6,7,8 & 10 and Chapter 4, Part 3 of the *Health (Drugs and Poisons) Regulation 1996*.

I declare that the above information is correct.

IM Boss
(Signature of Employer)

Personnel Manager
(Position held by Signatory)

30/6/98
(Date)

Appendix 6

Population Health Services – Environmental Health Services

Brisbane North

Bryden Street
Windsor Q 4030
Locked Bag 2
STAFFORD DC Q
4053

Ph: 3624 1111

Brisbane South

39 Kessels Road
Coopers Plains
PO Box 333
ARCHERFIELD
Q 4108

Ph: 3000 9148

Bundaberg

Bundaberg Base
Hospital
Bourbong Street
PO Box 185
BUNDABERG Q 4670

Ph: 4150 2780

Cairns

Ground floor
Aplin House
19 Aplin Street
PO Box 1103
CAIRNS Q 4870

Ph: 4050 3600

Hervey Bay

Hervey Bay Hospital
Nissen Street
PO Box 724
HERVEY BAY Q 4655

Ph: 4120 6000

Ipswich

Level 4, Ipswich
Hospital
Chelmsford Avenue
PO Box 73
IPSWICH Q 4305

Ph: 3810 1500

Mackay

Mackay Base Hospital
Campus
475 Bridge Road
MACKAY Q 4740
PO Box 5925
MACKAY MC Q 4741

Ph: 4968 6611

Maroochydore

150 Horton Parade
PO Box 577
MAROOCHYDORE
Q 4558

Ph: 5409 6600

Redcliffe

181 Anzac Avenue
KIPPA-RING Q 4021
PO Box 162
REDCLIFFE Q 4020

Ph: 3897 6480

Rockhampton

1st floor,
82-86 Bolsover Street
PO Box 946
ROCKHAMPTON
Q 4700

Ph: 4920 6989

Southport

10-12 Young Street
PO Box 267
SOUTHPORT BC
Q 4215

Ph: 5509 7222

Toowoomba

3 Bell Street
PO Box 1775
TOOWOOMBA
Q 4350

Ph: 4631 9888

Townsville

242 Walker Street
Locked Mail Bag No
4016
TOWNSVILLE Q 4810

Ph: 4753 9000

Drugs and Poisons Policy and Regulation Unit

Environmental Health
Branch
PO Box 2368
FORTITUDE VALLEY BC
Q 4006

Ph: 3328 9310