

## GUIDE TO POISONS AND THERAPEUTIC GOODS LEGISLATION FOR PHARMACISTS

**This Guide is a summary only**, and should be used in conjunction with the Poisons and Therapeutic Goods Act 1966 and the Poisons and Therapeutic Goods Regulation 2008 (obtainable from Fuji Xerox, Tel. (02) 9311 9899; also available on the Internet at [www.legislation.nsw.gov.au](http://www.legislation.nsw.gov.au)) and the NSW Poisons List.

Further information may be obtained from the Duty Pharmaceutical Officer, Pharmaceutical Services, Legal and Regulatory Services Branch, NSW Ministry of Health, Locked Mail Bag 961 North Sydney NSW 2059, Tel. (02) 9391 9944, Fax. (02) 9424 5860 or by email: [pharmserv@doh.health.nsw.gov.au](mailto:pharmserv@doh.health.nsw.gov.au).

**NOTE:** Wherever the term “**authorised practitioner**” is used in this Guide (other than in relation to Schedule 8 drugs), unless otherwise indicated, it refers to medical practitioners, dentists, veterinary practitioners, nurse and midwife practitioners authorised under section 17A of the Poisons and Therapeutic Goods Act, optometrists authorised under section 17B of the Poisons and Therapeutic Goods Act, and podiatrists authorised under section 17C of the Poisons and Therapeutic Goods Act.

### 1 THE POISONS LIST

The Poisons List is the list of substances to which the Poisons and Therapeutic Goods Act and Regulation apply. It consists of eight schedules (Schedule 1 is empty, so reference to it has been omitted). The schedules align closely with those shown in the publication, “Standard for the Uniform Scheduling of Medicines and Poisons” (SUSMP), published by the Commonwealth under the Therapeutic Goods Act 1989 (available at: <http://www.tga.gov.au/publication/poisons-standard-susmp>). Following is a summary of the nature of the substances in each schedule. The requirements for the storage, supply, labelling, recording etc for Schedules 2, 3, 4 and 8 are detailed later in this Guide.

#### **Schedule 2**

Substances which are dangerous to life if misused or carelessly handled, but which should be available to the public for therapeutic use or other purposes without undue restriction.

#### **Schedule 3**

Substances which are for therapeutic use and:

- i. about which personal advice may be required by the user in respect of their dosage, frequency of administration and general toxicity,
- ii. with which excessive unsupervised medication is unlikely; or
- iii. which may be required for use urgently so that their supply only on the prescription of an authorised practitioner would be likely to cause hardship.

#### **Schedule 4 (Restricted Substances)**

Substances which in the public interest should be supplied only by, or upon the written prescription of, an authorised practitioner.

#### **Schedule 5**

Poisonous substances of a dangerous nature commonly used for domestic purposes which should be readily available to the public but which require caution in their handling, use and storage.

#### **Schedule 6**

Substances which should be readily available to the public for agricultural, pastoral, horticultural, veterinary, photographic or industrial purposes or for the destruction of pests.

#### **Schedule 7**

Substances of exceptional danger which require special precautions in their manufacture, packaging, storage and use.

#### **Schedule 8 (Drugs of Addiction)**

Substances which are addiction producing or potentially addiction producing. Possession, supply, prescribing and use are strictly limited.

#### **Other Controls**

Provision is also made for individual substances to be rigidly controlled by subjecting their use or supply to special authority.

**IMPORTANT NOTE:** It is illegal for pharmacists (including members of their staff) to supply any scheduled substance (on prescription or otherwise) for therapeutic use in a quantity or for a purpose not in accordance with recognised therapeutic standards of what is medically appropriate in the circumstances. Similarly, where the scheduled poison is not for therapeutic use, it may be sold only for either the purpose stated on the label or its normal use. Penalties apply.

## **2 SCHEDULE 2**

### **2.1 Sale**

Retail sale only by authorised practitioners, pharmacists and persons licensed as "poisons sellers" (country stores remote from a pharmacy).

Wholesale sale of therapeutic substances may be made only by persons licensed or authorised to do so under the Poisons and Therapeutic Goods Regulation.

### **2.2 Storage**

Must be kept apart from food.

## 3 SCHEDULE 3

### 3.1 Sale

Retail sale only by authorised practitioners and pharmacists, including pharmacy interns working under the direct personal supervision of a pharmacist. Where a sale is made from a pharmacy other than on prescription, the pharmacist must personally hand the substance to the person and give the person the opportunity to seek advice as to the use, dosage and possible toxicity of the substance. The latter does not apply in the case of:

- a) the supply of salbutamol or terbutaline in metered aerosols to a person holding an approved current asthma management certificate for use by them in emergency asthma management, or
- b) the supply of adrenaline to a certificated first-aider in single use automatic injectors delivering 0.3mg of adrenaline for anaphylaxis first aid. (see also "Recordable Substances" below).

Wholesale sale of therapeutic substances may be made only by persons licensed or authorised to do so under the Poisons and Therapeutic Goods Regulation.

### 3.2 Storage

Must be kept **genuinely** out of public access e.g. in the dispensary or storeroom or in cabinets which are kept locked when not in immediate use. It is the pharmacist's responsibility to ensure that this is done.

### 3.3 Labelling

The product must be labelled with the name and address of the pharmacy if not supplied and fully labelled as a dispensed medicine.

### 3.4 Recordable Substances

Additional requirements apply to the following substance;

pseudoephedrine when included in Schedule 3.

**A record** of the following details of each supply must be made in an approved recording system (refer to TG 50 in "Further Information" on the last page of this Guide):

- name and address of patient (or if for animal use, the name and address of the animal's owner);
- name, strength and quantity of the substance;
- date of supply;
- name of the pharmacist who supplied the substance;
- a unique reference number (from approved recording system).

## 4 SCHEDULE 4

### 4.1 Sale

Retail sale by authorised practitioners and by pharmacists on the prescription of such a practitioner.

Wholesale sale may be made only by persons licensed or authorised to do so under the Poisons and Therapeutic Goods Regulation.

### 4.2 Storage

Must be kept in the dispensary or other area to which customers do not have access. It is the pharmacist's responsibility to ensure that this is done.

### 4.3 Prescription

Must include the following particulars in ink in the prescriber's legible handwriting:

- (a) the date on which it is issued;
- (b) the patient's name and address (or, if for animal treatment, the owner's name and address and species of animal);
- (c) the name, strength and quantity of the restricted substance;
- (d) the number of repeats if the prescription is to be dispensed more than once (some prescriptions require repeat intervals – see “additional requirements” below);
- (e) adequate directions for use; and
- (f) the prescriber's signature.

Additional requirements apply to prescriptions for specified barbiturates and anabolic/androgenic steroidal agents (see section 4.11).

Where the prescription is computer-generated (see TG 184 in “Further Information” in section 14), only the signature needs to be in the prescriber's handwriting.

Prescription must also include:

- (a) name of prescriber (as registered to practice in Australia) and designation;
- (b) the address and telephone number of the premises at which the prescription is issued or, if issued at a hospital, the name, address and telephone number of the hospital;
- (c) if written by a dentist, the words, "For dental treatment only";
- (d) if written by a veterinary practitioner, the words, "For animal treatment only";
- (e) if written by an optometrist, the words “For optometrical treatment only”.

Where, in an emergency, instruction e.g. by telephone, electronic mail or facsimile is given to a pharmacist to supply a restricted substance, a prescription must be written in confirmation forthwith, endorsed as such, and forwarded to the dispensing pharmacist within 24 hours. If not received within 7 days the dispensing pharmacist must report this to Pharmaceutical Services (Tel. (02) 9391 9944). Care must be taken to avoid fraudulent use of this provision.

#### 4.4 Dispensing

A prescription for a restricted substance may NOT be dispensed if:

- (a) it is not correctly written as indicated above;
- (b) it is more than 12 months old (6 months if the drug is listed in Appendix D to the Regulation – see “Appendix D Substances” in section 4.10);
- (c) it is marked "cancelled" or all of the repeats have been dispensed;
- (d) where an interval for repeat is shown, the prescription is presented for dispensing at a shorter interval. Where a prescription bears no repeat instructions or does not clearly indicate the number of repeats ordered, it may be dispensed once only, then cancelled;
- (e) it is illegible or defaced;
- (f) it appears to have been altered otherwise than by the prescriber;
- (g) it appears to have been forged or fraudulently obtained.

In the case of (f) or (g) above, where the prescription is for an Appendix D substance, the prescription should be retained and the police informed immediately.

The person dispensing a prescription for a restricted substance must:

- (a) make a full record of the prescription in an approved recording system (refer TG 50 in “Further Information” on last page), and give it a prescription number;
- (b) stamp or write on the prescription the pharmacy name and address, the prescription record number and the date dispensed;
- (c) cancel the prescription on last dispensing;
- (d) retain the record specified in (a) for not less than two years.

In the case of Pharmaceutical Benefit prescriptions, the dispenser must record on the patient’s copy of the prescription the items required in (b) immediately above.

Additional requirements apply to the dispensing of prescriptions for “specified barbiturates” and anabolic/androgenic steroidal agents (See section 4.11).

Note: Specific requirements for dispensing from a copy of the National Residential Medication Chart are in section 4.5.

#### 4.5 Dispensing from a Copy of a Residential Medication Chart (RMC)

A medication chart that complies with the Commonwealth *National Health (Residential Medication Chart) Determination 2012*, in a format which has the characteristics of the National Residential Medication Chart, hereinafter referred to as “a compliant RMC”, can be used in NSW Residential Care Facilities (RCFs) funded under the Commonwealth *Aged Care Act 1997*. A compliant RMC permits both the prescribing and dispensing of Pharmaceutical Benefits Scheme (PBS) medications and non-PBS medications, with some exceptions.

A duplicate copy of a compliant RMC may be used by pharmacists to dispense unscheduled, Schedule 2, Schedule 3 and most Schedule 4 medications in compliance with clauses 34A, 35 and 39 of the Poisons and Therapeutic Goods Regulation 2008.

A duplicate copy of a RMC may NOT be used by pharmacists to dispense Schedule 8 medications, or the following Schedule 4 medications:

- anabolic-androgenic steroids,
- amylobarbitone or pentobarbitone injections,
- clomiphene,
- cyclofenil,
- dinoprost,
- dinoprostone,
- acitretin,
- etretinate, and
- isotretinoin.

Schedule 8 medications and the above Schedule 4 medications may only be dispensed on the presentation of a valid traditional hand-written or computer-generated prescription (see section 4.4).

Pharmacists may otherwise dispense medications from a duplicate copy of a compliant RMC.

The duplicate copy of the compliant RMC may be provided by the RCF to the pharmacist as either:

- a) a photocopy, or
- b) a facsimile, or
- c) electronically as a scanned image.

#### **4.5.1 Validity as a prescription**

The duplicate copy of a compliant RMC is valid as a prescription for dispensing only when:

- a) The duplicate copy is complete, clear and legible, and
- b) The resident's name and address are included, and
- c) The name, address and telephone number of the RCF are included, and
- d) The prescriber's name and designation are included, and
- e) The medication is ordered only by a medical practitioner, and
- f) The order is for an unscheduled, Schedule 2, Schedule 3 or Schedule 4 medication, other than;
  - anabolic-androgenic steroids, or
  - amylobarbitone or pentobarbitone injections, or
  - clomiphene, cyclofenil, dinoprost, dinoprostone, acitretin, etretinate, or isotretinoin, and
- g) The relevant 'Medicine' order section of the compliant RMC has been handwritten by the medical practitioner with;
  - (i) The date of prescribing, and
  - (ii) The name and form (if not readily apparent) of the medication, and
  - (iii) The strength (if not readily apparent) of the medication, and
  - (iv) The route administration (if not readily apparent) of the medication, and
  - (v) Adequate directions for use (Note: This may include a dose with the daily frequency, or the times during the day, for administration of the medication), and
  - (vi) The period during which the medication is to be used or administered, being a period that ends on a date that is no more than 4 months from the date of

- first use of the relevant compliant RMC for the patient (Note: This may be achieved with a start date and stop date for the administration of the medication), and
- (vii) The prescriber's name and signature.

If a duplicate copy of a compliant RMC received by a pharmacist does not include all the above details it is not a valid prescription. To dispense medication on an invalid RMC is an offence under the Poisons and Therapeutic Goods Act 1966.

In the event of an incomplete duplicate copy of a compliant RMC being received for dispensing, as necessary, a pharmacist may:

- a) Contact the prescriber for emergency supplies, (see section 4.3), or
- b) Where the pharmacist cannot contact the prescriber, the pharmacist may dispense a quantity of the medication (other than a medication included in Appendix D to the Poisons and Therapeutic Goods Regulation 2008) to equate with that required for three day's treatment (see section 4.7).

#### **4.5.2 Medications Requiring a Traditional Prescription in All Cases**

Some medications must in all cases be prescribed on a traditional prescription.

An order for these medications on a compliant RMC does NOT constitute a legal prescription.

The dispensing pharmacist must dispense, record and retain the traditional (hand written or computer-generated) prescription (see section 4.4). The applicable medications are:

- Schedule 8 medications
- anabolic-androgenic steroids,
- amylobarbitone or pentobarbitone injections,
- clomiphene,
- cyclofenil,
- dinoprost,
- dinoprostone,
- acitretin,
- etretinate, and
- isotretinoin.

#### **4.5.3 Recording, Endorsement, Cancellation and Retention of Compliant RMC**

A pharmacist utilising a compliant RMC to supply medications must have a procedure in place to provide assurance that retained duplicate copies of the compliant RMC are contemporary and accurately reflect medications dispensed to patients.

The pharmacy's primary dispensing program must include the current medication order for each patient. Care should be taken to ensure that the current medication order is also recorded in the secondary program (where used) to label medication packed in a dose administration aid.

The dispensing pharmacist must endorse on the duplicate copy of the compliant RMC:

- a) The date on which the particular medication is dispensed, and
- b) The pharmacy's unique prescription reference number pertaining to the dispensing of the particular medication on that date, and
- c) The name and address of the pharmacy.

The dispensing pharmacist must endorse each particular medication order on the duplicate copy of a compliant RMC with the word 'CANCELLED' on the last occasion the particular medication is dispensed.

The duplicate copy of each compliant RMC must be retained at the dispensing pharmacy for a period of two years from the date the most recent medication was dispensed.

The Australian Commission on Safety and Quality in Health Care has published NRMCMaterials at <http://www.safetyandquality.gov.au/our-work/medication-safety/medication-chart/nrmc/>, which includes the '[National Residential Medication Chart \(NRMCM3\) User Guide for Pharmacists](#)'.

#### 4.6 Continued Dispensing

In the case of a restricted substance covered by the Commonwealth's *National Health (Continued Dispensing) Determination 2012*, a pharmacist may supply only the standard PBS quantity of:

- An oral contraceptive, or
- Cholesterol lowering agent (specifically HMG-CoA reductase inhibitors)

in accordance with the conditions specified in the Determination. These conditions include:

- (a) that no other supply under the Determination has been made to that patient in the previous 12 months;
- (b) the patient is in immediate need of the substance for the continuation of treatment;
- (c) it is not practicable to obtain a prescription;
- (d) the patient's therapy is stable;
- (e) the patient has been taking the substance regularly for an uninterrupted period, obtained under the Commonwealth Pharmaceutical Benefits Scheme;
- (f) since the start of that period, the prescriber has assessed the person's condition and decided the patient needs ongoing treatment with the substance;
- (g) the last supply made to the patient was through a valid prescription;
- (h) the medicine is safe and appropriate for that patient at that time; and
- (i) the pharmacist records the information that he/she used to support his/her decision to supply the substance, and sends that information and details of the supply to the most recent prescriber.

Additionally, such continued supply of the specified restricted substances only applies under the following conditions:



- The supply is made in accordance with the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists*, issued by the Pharmaceutical Society of Australia, and
- The pharmacist is an approved pharmacist within the meaning of the *National Health Act 1953* of the Commonwealth (to supply PBS medicines).

#### 4.7 Emergency Supply

If a pharmacist is satisfied that there is an immediate need to supply a restricted substance, **other than an Appendix D substance**, which has been previously prescribed for a person (not an animal, but see section headed “benzylpenicillin” below) for continuation of current essential medical treatment of that person and it is impracticable to obtain a prescription for that restricted substance, the pharmacist may supply not more than three days' treatment of that restricted substance without a prescription. In the case of a pre-packed liquid preparation, cream or ointment, pressurised aerosol container or an anovulant, the smallest standard pack may be supplied.

Before making an emergency supply the pharmacist must make a record in an approved recording system (refer to TG 50 in “Further Information” on the last page) that shows:

- (a) the name and address of the person being supplied;
- (b) the name, strength and quantity of the restricted substance;
- (c) the directions for use of the substance as determined by the pharmacist;
- (d) the name and address of the authorised practitioner who, the pharmacist is satisfied, last prescribed that restricted substance for that person;
- (e) the date of the supply;
- (f) a unique reference number for the supply; and
- (g) the name of the pharmacist by whom the substance was supplied.

Any restricted substance thus supplied must be labelled as for a dispensed medicine (see the “Labelling of Dispensed Medicines” section towards the end of this Guide) and have included on the label the words “EMERGENCY SUPPLY”.

A pharmacist may supply an authorised practitioner with a restricted substance, including an Appendix D substance (see section “Appendix D Substances” further on in this Guide), for emergency use but only on production of a written order signed and dated by the practitioner. Any such supply should be fully recorded, as for a prescription, in the pharmacy recording system and the order given a number.

A pharmacist may also supply the director of nursing at a nursing home with manufacturers' original packs of drugs approved from time to time by the Secretary, NSW Health for emergency use in the nursing home. A written order signed by the director of nursing is required. The products are not required to be labelled as dispensed medicines, but should show the name of the pharmacy from which they were supplied.

#### **4.8 Benzylpenicillin (Clause 48)**

This clause applies to benzylpenicillin, including procaine penicillin, in preparations for use by intramuscular injection in animals. It does not apply to mixtures with other antibiotics such as streptomycin.

The standard conditions of supply, prescribing and dispensing apply as for other restricted substances for animal treatment.

However, where the purchaser satisfies a pharmacist that the preparation is needed for the urgent treatment of an animal and that in the circumstances it is not reasonably practicable to obtain a veterinary prescription, the pharmacist may supply such substance without prescription provided the purchaser is known to the pharmacist and aged at least 18 years. In order to be satisfied as to the need for the product, a pharmacist would be expected to make whatever enquiries are necessary to ensure the validity of the purchaser's statement. Any such supply is to be both fully recorded in an approved recording system and labelled in the manner set out in the above section on "Emergency Supply".

#### **4.9 Pharmacist Initiation and Administration of Influenza Vaccine**

A registered pharmacist initiating and administering influenza vaccine under his/her own authority to a person aged 18 years or older in a NSW retail pharmacy must comply with the following three components of clause 48A of the *Poisons and Therapeutic Goods Regulation 2008* which prescribes rules for:

- A. Completing an accredited vaccination training course (see section 4.9.1),
- B. Conducting vaccinations under the 'NSW Pharmacist Vaccination Standards', available at <http://www.health.nsw.gov.au/pharmaceutical/pages/default.aspx> (see section 4.9.2), and
- C. Recording each vaccination (see section 4.9.3).

##### **4.9.1 Pharmacist Training**

The pharmacist must complete a training course accredited to accord with the Australian Pharmacy Council 'Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines' (current version).

The training course must be conducted by an accredited Continuing Professional Development Accrediting Organisation.

Training courses for pharmacists are currently provided by the Pharmaceutical Society of Australia and Pharmacy Guild of Australia. Pharmacists should contact the Society and/or the Guild for further information on course availability.

Pharmacists that have completed previous training on conducting vaccinations, including interstate, should contact the training provider to ascertain if the course meets the NSW requirements under the NSW *Poisons and Therapeutic Goods Regulation 2008*.

##### **4.9.2 Practice Standards**

The following are requirements under the 'NSW Pharmacist Vaccination Standards': -

## General Requirements

The pharmacist must hold a certificate confirming competency to vaccinate following completion of an accredited training program (see section 4.9.1).

The pharmacist must obtain a cardio-pulmonary resuscitation (CPR) certificate annually.

The pharmacist must vaccinate a person and provide management of an adverse event within the scope of pharmacist practice, professional knowledge and expertise.

The pharmacist must comply with the following:

- a) *'The Australian Immunisation Handbook'* (current edition) – Australian Government Department of Health, and
- b) *'National Vaccine Storage Guidelines – Strive for 5'* (current edition) – Australian Government Department of Health.

The pharmacist should adopt or follow the following professional guidelines:

- a) *'Practice guidelines for the provision of immunisation services within pharmacy'* (current edition) – Pharmaceutical Society of Australia, and/or
- b) *'Guidelines for Conducting Immunisation Services within a Community Pharmacy Environment'* (current edition) – Pharmacy Guild of Australia.

The pharmacist must ensure that when administering influenza vaccine an appropriately trained pharmacy staff member is present.

## Pharmacy Premises and Equipment

The pharmacist must conduct the vaccination in an immunisation service room, consulting room or immunisation area of the pharmacy premises. The room or area may be dedicated for the purpose or an existing consulting room used. The room or area is not to be used as a dispensary, storeroom, staff room or retail area.

The immunisation service room, consulting room or immunisation area must be consistent with the following:

- a) Not permit the vaccination to be visible or audible to other persons in the pharmacy,
- b) Have adequate lighting,
- c) Be maintained at a comfortable ambient temperature,
- d) Have a hand sanitisation facility,
- e) Have ready access to a hand washing facility,
- f) Have sufficient floor area, clear of equipment and furniture, to accommodate the person receiving the vaccination and an accompanying person, and to allow the pharmacist adequate space to manoeuvre, and
- g) Have sufficient bench space (with an impervious surface), a chair and a first aid couch (or similar).

The pharmacist must have the following equipment consistent with;

- *'The Australian Immunisation Handbook'* (current edition), and
- *'National Vaccine Storage Guidelines – Strive for 5'* (current edition):

- a) A temperature-monitored refrigerator manufactured (either exclusively or principally) for the purpose of storage of vaccines,
- b) All necessary consumables required for vaccine administration,
- c) An appropriately sized sharps container to dispose of clinical waste including used syringes and needles,
- d) An in-date and complete anaphylaxis response kit,
- e) An emergency response protocol (preferably laminated) on display,
- f) *'The Australian Immunisation Handbook'* (current edition),
- g) *'National Vaccine Storage Guidelines – Strive for 5'* (current edition), and
- h) A process to regularly monitor on-line updates to *'The Australian Immunisation Handbook'* (current edition), including prior to administering influenza vaccine.

### **Patient Consent and Eligibility**

The pharmacist must obtain written consent from the person before the vaccination and must retain this consent for seven years (in accordance with the Health Records Information and Privacy Act).

The pharmacist must not vaccinate a person with a contra-indication or precaution to vaccination listed in the *'The Australian Immunisation Handbook'* (current edition).

### **Reporting to the Person's General Practitioner**

The pharmacist must provide a copy of the person's record of vaccination (as specified in section 4.9.3) directly to the general practitioner nominated by the person to receive the information.

### **Post Vaccination Care of the Patient**

The pharmacist must advise the person to remain on the pharmacy premises for 15 minutes post vaccination and must advise the person of possible risks in leaving earlier than 15 minutes.

The pharmacist must either observe, or direct an appropriately trained pharmacy staff member to observe, the person for 15 minutes post vaccination to monitor for acute adverse events or anaphylaxis.

The pharmacist must make notes in the record of vaccination (as specified in section 4.9.3) when the person leaves the pharmacy premises earlier than 15 minutes post vaccination.

### **Management of Adverse Events**

The pharmacist must be competent to manage anaphylaxis post vaccination including use of adrenaline consistent with *'The Australian Immunisation Handbook'* (current edition).

The pharmacist must ensure an ambulance is called to attend a person who experiences anaphylaxis post vaccination.

Immediately after the response to an adverse event is effected, the pharmacist must notify the adverse event to the local Public Health Unit by telephone on 1300 066 055.

### 4.9.3 Recording Vaccinations

The pharmacist must record the vaccination with the following information: -

- a) The person's name, address, date of birth and contact details,
- b) The name and contact details of the person's primary medical practitioner,
- c) The brand, batch number and expiry date of the vaccine,
- d) The part of the body to which the vaccine was administered,
- e) The date on which the vaccine was administered,
- f) The pharmacist's name and contact details and his or her certificate of accreditation number,
- g) The address of the pharmacy at which the vaccination was administered, and
- h) A unique reference number for the supply and administration.

A copy of this record should be kept at the pharmacy for seven years. The pharmacist should make this record in the pharmacy's computer dispensing system in the first instance, as for a medication dispensed on prescription. A printed or scanned copy of the record may be retained at the pharmacy after the two year retention period required under the *Poisons and Therapeutic Goods Regulation 2008*.

### 4.10 Appendix D Substances

Possession, without authority, of restricted substances listed in Appendix D is illegal. Persons authorised to be in possession of Appendix D substances are:

- (a) licensed wholesale dealers, for the purpose of wholesale dealing (i.e. supply to authorised persons);
- (b) authorised practitioners and pharmacists;
- (c) directors of nursing of hospitals that do not employ a chief pharmacist;
- (d) medical superintendents of hospitals;
- (e) analysts appointed under the Poisons and Therapeutic Goods Act;
- (f) certain other specially authorised persons, for use in connection with their occupations;
- (g) persons for whom a prescription for that substance has been issued by an authorised practitioner to the extent authorised in the prescription.

The loss or theft of Appendix D substances from a person referred to in clauses (a) to (f) above must be reported to Pharmaceutical Services by completing the online 'Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)' located on the Internet at:

<http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

Where theft has occurred it is advisable to also notify the police.

Appendix D substances may NOT be supplied under the Emergency Supply arrangements outlined for other restricted substances.

Substances in Appendix D include the following (a complete alphabetical list can be accessed by referring to "Further Information" on the last page of this Guide):

- the “barbiturates” including;
  - Amylobarbitone when packed and labelled for injection (oral forms are in Schedule 8)
  - Methylphenobarbitone
  - Pentobarbitone when packed and labelled for injection (oral forms are in Schedule 8)
  - Phenobarbitone
  - Thiopentone
- anabolic/androgenic steroidal agents such as;
 

Androisoxazole	Drostanolone
Bolandiol	Ethyldienolone
Bolasterone	Ethyloestrenol
Boldenone	Fluoxymesterone
Bolmantalate	Formebolone
Calusterone	Formyldienolone
Chlorandrostenolone	Furazabol
Chloroxydienone	Hydroxystenozol
Chloroxymesterone	Mesabolone
Clostebol	Mestanolone
Dihydrolone	Mesterolone
Dimethandrostanolone	Methadienone
Dimethazine	Methandriol
Methenolone	Oxymesterone
Methylandrostanolone	Oxymetholone
Methylclostebol	Prasterone
Methyltestosterone	Quinbolone
Methyltrienolone	Silandrone
Mibolerone	Stanolone
Nandrolone	Stanozolol
Norandrostenolone	Stenbolone
Norebolethone	Testolactone
Norethandrolone	Testosterone except when in Schedule 6
Normethandrone	Thiomesterone
Oxabolone	Trenbolone except when in Schedule 6
Oxandrolone	Trestolone
- and the following substances;
 

Benzphetamine	Lorazepam
Bromazepam	Mazindol
Cathine	Medazepam
Chlordiazepoxide	Mefenorex
Clobazam	Meprobamate
Clonazepam	Midazolam
Clorazepate	Nalbuphine
Dextropropoxyphene when included in S4	Nitrazepam
Diazepam	Oxazepam
Diethylpropion	Paraldehyde
Doxapram	Phentermine
Ephedrine	Pipradrol
Ethchlorvynol	Prazepam
Ethinamate	Propylhexedrine
Fencamfamin	Pyrovalerone

Fenproporex  
Flurazepam  
Glutethimide

Temazepam  
Triazolam  
Zolazepam

#### 4.11 Specified Barbiturates and Anabolic/Androgenic Steroidal Agents – Schedule 4 Appendix B.

Additional requirements for prescribing, dispensing and prescription retention apply to the following substances:

- (a) the specified barbiturates;
  - amylobarbitone when packed and labelled for injection
  - pentobarbitone when packed and labelled for injection
- (b) anabolic/androgenic steroidal agents included in Appendix D.

Prescription must include an interval for repeat where repeats are ordered. Where a prescription bears no interval for repeat, it may be dispensed once only, and must then be cancelled and retained.

**The prescription must be retained at the pharmacy where it is first dispensed.** Where repeats are ordered, the patient must return for repeat dispensing to the pharmacy at which the prescription was first dispensed. Prescriptions are valid for 6 months only.

Prescriptions (or patient copies of Pharmaceutical Benefit prescriptions being sent for payment) must be kept apart from all other prescriptions (except prescriptions for drugs of addiction) and retained until two years after the date of last dispensing.

Note: Prescriptions for these medications require a traditional prescription when ordered on the National Residential Medication Chart – see section 4.5.

#### 4.12 Classified Restricted Substances

Special conditions apply to the supply of the following substances:

acitretin	follitropin beta
clomiphene	isotretinoin for oral use
cyclofenil	luteinising hormone
dinoprost	tretinoin for oral use
dinoprostone	urofollitrophin (human follicle stimulating hormone)
etretinate	

Supply only on the order or prescription of:

- (a) a medical practitioner belonging to a class of practitioners authorised generally to prescribe the particular substance e.g. FRANZCOG or FRCOG to prescribe clomiphene, cyclofenil, dinoprost, dinoprostone; FACD to prescribe acitretin, etretinate and isotretinoin. The prescription must show the prescriber's qualification and be endorsed "Issued under clause 37 of the Poisons and Therapeutic Goods Regulation 2008" or words to that effect;

- (b) a medical practitioner not included in (a) above but having the written authority of the NSW Ministry of Health to prescribe such substance. The prescription must show the prescriber's authority number, prefaced with the letters CL..., PG(T)... or RA..., as shown on the authority;
- (c) a person authorised by the Commonwealth Department of Health to issue prescriptions for the substance;
- (d) a veterinary practitioner.

Such authorities allow the holder to prescribe the drug concerned for any patient under their care, unless specifically restricted.

Authorities to prescribe or use human follicle stimulating hormone (urofollitrophin) for medical purposes are issued only to specialist medical practitioners in respect of particular patients, usually following endocrine function tests carried out at an endocrine laboratory. Urofollitrophin and luteinising hormone will normally be available only at hospitals where such laboratory facilities are available.

Normal Schedule 4 conditions apply to the dispensing of such prescriptions.

Note: Prescriptions for these medications require a traditional prescription when ordered on the National Residential Medication Chart – see section 4.5.

## **5 SCHEDULE 5**

### **5.1 Sale**

No licence, authority or qualification required of seller.

### **5.2 Storage**

Must be kept apart from food.

## **6 SCHEDULE 6**

### **6.1 Sale**

No licence, authority or qualification required of seller.

### **6.2 Storage**

Must be kept apart from human or animal food and in such a way that if its container breaks or leaks it cannot contaminate the food.

Must be stored at least 1.2 metres above the floor and at least 1.2 metres from any step, stairway, ramp etc to which the public have access (out of reach of young children) unless it is:

- (a) stored in a storeroom or other area to which customers do not have access;
- (b) packed in containers with child-resistant closures;
- (c) packed in containers with a capacity of 5 litres (or 5 kilograms) or more;
- (d) a hair dye contained in a container which has a capacity of 50 millilitres or less;



- (h) a cockroach bait enclosed in a welded plastics labyrinth; or
- (i) a therapeutic substance for internal use in animals.
- (j)

## 7 SCHEDULE 7

### 7.1 Sale

Special conditions apply to the supply or use according to the particular substance or class of substances. Some Schedule 7 substances may only be supplied and used in accordance with an authority issued under the Poisons and Therapeutic Goods Regulation 2008.

An authority is required to supply specified “highly dangerous substances” in Schedule 7. The recipient of such supplies must also be authorised under the Regulation to use the substances.

Highly dangerous Schedule 7 substances include arsenic, cyanides, fluoroacetamide, fluoroacetic acid, hydrocyanic acid, strychnine, thallium and any Schedule 7 substance that is listed in Appendix C of the current Poisons Standard.

Where an authority allowing the purchase of a Schedule 7 poison has been issued, it must be surrendered to the supplier who must retain it for two years.

It is an offence to supply “highly dangerous” Schedule 7 poisons unless authorised to do so under the Poisons and Therapeutic Goods Regulation 2008 and the purchaser is also so authorised.

### 7.2 Storage

Must be kept in a part of the premises to which the public does not have access (e.g. dispensary, storeroom or locked cupboard).

#### **NOTE ON DISPOSAL**

**It is an offence to dispose of any substance in Schedules 2 to 7 inclusive in any place or manner likely to constitute a risk to the public.**

## 8 SCHEDULE 8

### 8.1 Manufacture

Manufacture only by persons licensed or authorised for that purpose or by pharmacists in the ordinary course of their professional practice.

### 8.2 Supply

Sale or supply only by persons licensed or authorised to do so in the normal practice of their profession or business.

A licensed or authorised person must provide a signed order to the supplier of a drug of addiction and a signed and dated written acknowledgment of receipt of the drug.

A licensed manufacturer or wholesale distributor may supply a drug of addiction on the telephone or facsimile order of an authorised practitioner or pharmacist (NOT optometrist or podiatrist). Such a person, when ordering a drug of addiction by telephone or facsimile, must complete a written order and send it to the supplier in confirmation within 24 hours. If the supplier does not receive the written order within 7 days, the supplier is required to report this to Pharmaceutical Services (Tel. (02) 9391 9944).

A licensed manufacturer or wholesale distributor must, when packing a drug of addiction for delivery, wrap it in a separate package and enclose a docket listing the contents of the package. The package must be labelled "SCHEDULE EIGHT - CHECK CAREFULLY", then enclosed, either alone or with other goods, in an outer package which does not indicate that the contents include a drug of addiction.

### **8.3 Possession**

Unauthorised possession of a drug of addiction is illegal.

The following persons are authorised to have possession of a drug of addiction for the purpose of their particular profession unless in any particular case that authority has been withdrawn:

- a medical practitioner;
- a pharmacist engaged in the retail practice of pharmacy;
- a pharmacist employed in dispensing medicines at any public hospital or other public institution;
- a nurse practitioner authorised under section 17A of the Poisons and Therapeutic Goods Act;
- a midwife practitioner authorised under section 17A of the Poisons and Therapeutic Goods Act;
- a dentist;
- a veterinary practitioner;
- an authorised person in charge of a laboratory, for the purpose of analysis, research or instruction;
- an analyst appointed under the Poisons and Therapeutic Goods Act;
- the director of medical services of a hospital where no pharmacist is employed;
- the director of nursing of a hospital where no pharmacist is employed;
- the nurse or midwife in charge of a public hospital ward;
- a nurse or midwife employed in a hospital but only for the purpose of administering doses to patients in the hospital;
- a nurse or ambulance officer employed in aerial ambulance duties;
- any other nurse or midwife approved by the Secretary, NSW Health.

A person for whom a valid prescription for a drug of addiction has been issued is authorised to be in possession of that drug of addiction to the extent specified in the prescription.

### **8.4 Storage**

A pharmacist must keep all drugs of addiction separate from other goods (other than cash or documents) in a steel safe meeting the specified requirements and fixed to the

building. The safe must be kept securely locked when the drugs are not in immediate use and the key kept on the pharmacist's person and not left on the premises overnight.

### 8.5 Drug Register

All persons engaged in the manufacture, distribution, sale or supply of drugs of addiction must keep a drug register. A drug register may be purchased from Stream Solutions (email: [streamnsw\\_sales@stream.net.au](mailto:streamnsw_sales@stream.net.au)) or from some pharmaceutical wholesalers.

Records of all transactions must be entered in the register on the day of the transaction. It is an offence for a person to make an entry in the register that the person knows to be false or misleading.

Alterations, obliterations or cancellations of entries must not be made in the register. Any mistake may be corrected by a marginal or footnote, initialled and dated.

A separate page of the register must be used for each brand name and each strength of a drug of addiction.

The register must be kept on the premises where the drugs are stored.

The register must be retained for two years from the date of the last entry and made available for inspection if required.

Where a register is lost or destroyed the pharmacist must:

- (a) advise Pharmaceutical Services in writing of that loss and the circumstances in which it occurred;
- (b) carry out a stock-check and enter the details in a new register.

Lost or stolen drugs of addiction must be reported to Pharmaceutical Services by completing the online 'Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)' located on the Internet at:

<http://www.health.nsw.gov.au/pharmaceutical/Pages/lost-stolen-drugs.aspx>

The police should also be notified if a theft has occurred.

### 8.6 Stock-checks

Twice a year, during March and September, every person who is required to keep a drug register must carry out a full stock-check of all drugs of addiction in their possession. Immediately under the last entry on the relevant page they must write the date on which the check was made, the words "Balance on hand", the quantity actually held and must sign the entry. Any person who assumes control of a practice for one month or more must perform a similar stock-check irrespective of the time of the year.

### 8.7 Destruction

A drug of addiction obtained by a pharmacist for use in their profession as a pharmacist may be carried out by or under the direct personal supervision of a person authorised by the NSW Ministry of Health such as Pharmaceutical Services Senior Pharmaceutical Officers (Tel. (02) 9391 9944), Pharmacy Council inspectors or by a police officer.

However, a pharmacist who supplies restricted substances or drugs of addiction to a private hospital, nursing home or day procedure centre is also authorised to destroy unwanted drugs of addiction on the facility's premises and in the presence of the director of nursing. The destruction is to be recorded in the facility's drug register, and show the date, the pharmacist's name and professional registration number and countersigned by the director of nursing. The drugs must be safely and effectively destroyed.

In addition to the above, if requested to do so by a medical practitioner, dentist or veterinary practitioner a pharmacist may, at the pharmacist's discretion, destroy unwanted drugs of addiction on behalf of the relevant practitioner, either at the pharmacy or at the practitioner's practice and in their presence. The destruction must be recorded in the practitioner's drug register and show the date, the pharmacist's name and professional registration number and be signed by both parties.

## 8.8 Prescriptions

Prescriptions are valid only when written by medical practitioners, nurse practitioners, midwife practitioners, veterinary practitioners or dentists registered to practise in NSW. (Strict conditions and/or limitations apply to the prescribing of drugs of addiction by nurse practitioners, midwife practitioners and dentists).

Schedule 8 medications must be written on a separate prescription form i.e. no other preparation may be written on the same form.

The prescription must include in ink in the prescriber's legible handwriting:

- (a) date on which it is issued;
- (b) patient's name and address (or, if for animal treatment, the owner's name and address and the species of animal);
- (c) name and strength of the drug of addiction;
- (d) quantity of the drug of addiction in words and figures;
- (e) maximum number of times the prescription may be dispensed;
- (f) interval for repeat where repeats are ordered;
- (g) adequate directions for use; and
- (h) prescriber's signature.

Computer generation of items (a) - (g) is permitted in accordance with approved criteria (see TG 184 in "Further Information" on the last page of this Guide). Items (c) - (g) must be handwritten as well as computer generated on one copy of the prescription, to be retained at the pharmacy.

The prescription must also include:

- (a) prescriber's name and designation;
- (b) the address and telephone number of the premises at which the prescription is issued or, if issued at a hospital, the name, address and telephone number of the hospital;
- (c) if written by a veterinary practitioner, the words, "For animal treatment only";

- (d) if written by a dentist, the words, "For dental treatment only".

Where, in an emergency, instruction e.g. by telephone, electronic mail or facsimile, is given for dispensing a drug of addiction, a prescription must be written in confirmation forthwith, endorsed as such, and forwarded to the dispensing pharmacist within 24 hours. If not received within 7 days, the dispensing pharmacist must report this to the Pharmaceutical Services (Tel. (02) 9391 9944). Care must be taken to avoid fraudulent use of this provision.

Schedule 8 substances may NOT be supplied under the Emergency Supply arrangements outlined earlier for non-Appendix D restricted substances. However, a pharmacist may supply a medical practitioner, nurse practitioner, midwife practitioner, dentist or veterinary practitioner with a drug of addiction for emergency use but only on production of a written order signed and dated by the practitioner. Any such supply should be **fully** recorded, as for a prescription, in the pharmacy recording system and the order given a number and retained by the pharmacy.

Note: Prescriptions for Schedule 8 medications require a traditional prescription when ordered on the National Residential Medication Chart – see section 4.5.

## 8.9 Dispensing

A prescription for a drug of addiction may not be dispensed:

- (a) if it is not correctly written as indicated above;
- (b) if it is more than six months old ;
- (c) if, where repeats are ordered, the specified interval of time has not elapsed;
- (d) if it is marked "Cancelled" or all the repeats are used up;
- (e) if it is illegible or defaced;
- (f) if it is, or appears to be, forged, altered (otherwise than by the prescriber) or fraudulently obtained;
- (g) if it was written by a person whose authority to prescribe has been withdrawn and it had not been dispensed at least once prior to the date on which the authority was withdrawn.

Where a prescription bears no repeat instructions or does not clearly indicate the number of repeats ordered and interval for repeat, it may be dispensed once only, then cancelled and retained.

Where a prescription as described in (f) or (g) above is presented it must be retained and the police notified.

A prescription for a drug of addiction that meets all of the above requirements may still not be dispensed unless the pharmacist dispensing it:

- (a) is familiar with the prescriber's handwriting, or
- (b) knows the person for whom the drug has been prescribed, or
- (c) has verified with the purported prescriber that the prescription was written by them. (care must be taken to ensure that telephone numbers shown on prescriptions are the legitimate contact details of the purported prescriber).

If a pharmacist cannot be satisfied as to the authenticity of a prescription by any of the above means but has no reason for suspecting that the prescription is not genuine, the pharmacist may supply a sufficient quantity of the drug for up to 2 days' treatment pending verification, and retain the prescription.

The person dispensing a prescription for a drug of addiction is required to:

- (a) make a full record of the prescription in an approved recording system (refer TG 50 in "Further Information" on last page), and give it a prescription number;
- (b) stamp or write on the prescription the pharmacy name and address, the prescription recording number and the date dispensed;
- (c) cancel the prescription on the last dispensing;
- (d) enter the transaction in the drug register; and
- (e) retain the record specified in (a) for not less than two years.

The prescription must be retained at the pharmacy where it was first dispensed. Where repeats are ordered, the patient must return for repeat dispensing to the pharmacy where the prescription was first dispensed.

Prescriptions must be kept apart from all other prescriptions (except prescriptions for the "specified barbiturates" and anabolic/androgenic steroidal agents) and retained until two years after the date of last dispensing.

### **8.10 Psychostimulants (including dexamphetamine, lisdexamfetamine and methylphenidate)**

The following substances may be prescribed or supplied only with special authority:

- dexamphetamine
- lisdexamfetamine (Vyvanse®)
- methylphenidate (Concerta®, Ritalin®, Ritalin LA®)

In addition to the usual requirements for drugs of addiction, the following conditions apply to these substances:

1. Dentists, nurse practitioners, midwife practitioners or veterinary practitioners may not prescribe or supply either of the substances specified above in the normal practice of their profession. (The exception to this is that a veterinary practitioner may supply or administer methylphenidate tablets for animal treatment).
2. A medical practitioner may prescribe or supply a substance specified above only in accordance with an approval given by the NSW Ministry of Health. This means that all prescriptions for psychostimulants, for adults or children, presented for dispensing must be endorsed with one of the following:
  - CNS xxxxxxxxxx (i.e. unique number), or
  - S28c xxxxxxxxxx (i.e. unique number); or
  - Ref. No. xxxxxx-xx-xxxx (i.e. unique number-month-year).

A prescription for dexamphetamine, lisdexamfetamine or methylphenidate that is not endorsed as above cannot be dispensed.

These requirements are **in addition to** any PBS authority requirements and therefore apply to all prescriptions for dexamphetamine or methylphenidate, including non-PBS or 'private' prescriptions.

3. A pharmacist may dispense a prescription for a substance specified above only if it complies with the conditions stipulated in 2. above. Authority to prescribe such substances is required from the NSW Ministry of Health irrespective of any authority which may have been issued by a Commonwealth Department.

### 8.11 Long-Term Prescribing

A medical practitioner or nurse practitioner must obtain the written authority of the NSW Ministry of Health when he or she elects to prescribe a drug of addiction:

- for a drug dependent person, or
- for any other patient

for any of the following specified drugs of addiction continuously for longer than two months:

- any injectable drug of addiction
- buprenorphine (except transdermal patches)
- alprazolam
- flunitrazepam
- hydromorphone
- methadone

### 8.12 Application Forms

Forms to be used to apply for an authority to prescribe drugs of addiction are available from the Internet at: <http://www.health.nsw.gov.au/pharmaceutical> or by contacting the Monitoring and Compliance Section, Pharmaceutical Services during office hours on (02) 9424 5923.

On completion, the form along with any supporting documentation such as a second opinion from a specialist should be faxed to the Monitoring and Compliance Section, Pharmaceutical Services on (02) 9424 5889.

Such written authority for long-term prescribing is the medical practitioner's or nurse practitioner's responsibility. It is confidential between the Ministry of Health and the prescriber and the authority does not accompany the prescription.

### 8.13 Hallucinogenic Drugs

The following are available only to persons having the written authority of the Secretary, NSW Health to obtain and use them:

- dronabinol
- etorphine
- nabilone

## 9 SUMMARY

REQUIREMENTS	SPECIFIED BARBITURATES AND ANABOLIC STERIODS	DRUGS OF ADDICTION
Separate prescription forms		X
Intervals for repeats	X	X
Prescription must be retained for 2 years by Pharmacist <u>first</u> dispensing it, irrespective of whether repeats are ordered	X	X
Prescription to be filed separately from all general prescriptions	X	X
Dispensing must be recorded in drug register (full accountability)		X
Storage in a drug safe		X
Wilful destruction prohibited (this goes with accountability)		X

## 10 LABELLING OF PRE-PACKED STOCK

Some pharmacists pre-count commonly prescribed tablets or capsules in advance of actual dispensing. In all such cases, each container must be INDIVIDUALLY identified with the name, strength and quantity of the substance contained therein along with the batch number and expiry date. It is NOT sufficient to label the shelf on which the packed containers stand or a box in which they may be kept prior to dispensing. Failure to observe this requirement has been a common source of dispensing errors.

## 11 LABELLING OF DISPENSED MEDICINES

Dispensed medicines containing any poison, restricted substance or drug of addiction are exempted from the general labelling provisions required of manufacturers provided they are labelled with:

- (a) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
- (b) the name of the patient or, in the case of an animal, the species of animal and the name of its owner;
- (c) the directions for use set out in the prescription;
- (d) the pharmacy name and address;
- (e) where the medicine is for external use, the word "POISON" or the words "FOR EXTERNAL USE ONLY" in red on a white background;
- (f) the approved name, strength and quantity of the substance and, unless the preparation is a medicine compounded extemporaneously in accordance with the prescriber's own formula, its proprietary name;



- (g) the prescription reference number and the date of dispensing unless this is clearly identifiable from the prescription reference number;
- (h) in the case of a preparation for internal use containing a substance listed in Appendix K of the SUSMP one of the warning statements:
  - (i) "This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol"; or
  - (ii) "This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery"; or
  - (iii) "This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol".
- (i) in the case of the substance, quinine, the warning statement "WARNING: MAY BE FATAL TO CHILDREN";
- (j) in the case of the substances amphetamine, lisdexamfetamine, chlorphentermine, dexamphetamine, diethylpropion, ephedrine, methylphenidate, phentermine and propylhexedrine for oral use by a person 16 years of age or older, the statement, "This medication (medicine) may affect mental alertness or co-ordination or both. If affected, do not drive a motor vehicle or operate machinery".

These particulars are obligatory on all poisons, restricted substances and drugs of addiction dispensed on the prescription of an authorised practitioner and on medicines prepared extemporaneously by a pharmacist for a specific and individual case.

## 12 REGISTRATION OF THERAPEUTIC GOODS FOR SALE

The Commonwealth Therapeutic Goods Act generally requires that therapeutic goods, including medicines, whether for supply on prescription or over-the-counter, are registered or listed under that Act. This requirement is affirmed under the Poisons and Therapeutic Goods Act. Pharmacists should therefore ensure that all such goods meet this requirement which is indicated by the presence on the product label of a number, prefixed by the words "Aust R" or "Aust L". If required, information on the current status of any product should be sought from the Therapeutic Goods Administration on Tel. 1800 020 653.

## 13 OUT-OF-DATE STOCK

It is illegal under the Poisons and Therapeutic Goods Act to supply any medicine, whether on prescription or over-the-counter, including so-called "natural" remedies and those for veterinary use, after the expiry date shown on the label. There are no exceptions to this requirement, including giving them away or "specialling" them, even if the customer is advised beforehand that the goods have passed their expiry date.

## 14 FURTHER INFORMATION

Guidance on national packaging and labelling requirements for therapeutic goods (medicines) and poisons, including the use of child-resistant closures, may be obtained from the TGA website at: <http://www.tga.gov.au>

The following brochures may be obtained from Pharmaceutical Services, NSW Ministry of Health, Locked Mail Bag 961, North Sydney 2059, Tel. (02) 9391 9944 (Duty

Pharmaceutical Officer), Fax. (02) 9424 5860 or from the website:  
<http://www.health.nsw.gov.au/pharmaceutical>

Title	Document No.
Drugs of Addiction (Schedule 8)	TG 13
Schedule 4 Appendix D Drugs (“Prescribed restricted substances”)	TG 14
Approved Systems for Recording the Supply of Substances on Prescription Generally or in an Emergency to Health Professionals	TG 50
Criteria for Issuing Non-Handwritten (Computer Generated) Prescriptions	TG 184
NSW Opioid Treatment Program Community Pharmacy Dosing Protocol	TG 201

For further information or clarification of these guidelines, contact the Duty Pharmaceutical Officer, Pharmaceutical Services during office hours on (02) 9391 9944.

This guide has been produced by:

Pharmaceutical Services Unit  
 Legal and Regulatory Services Branch  
 NSW Ministry of Health  
 Telephone (02) 9391 9944  
 Fax (02) 9424 5860  
 Email: [pharmserv@doh.health.nsw.gov.au](mailto:pharmserv@doh.health.nsw.gov.au)  
 Website: <http://www.health.nsw.gov.au/pharmaceutical>