GUIDE TO POISONS AND THERAPEUTIC GOODS LEGISLATION FOR MEDICAL, NURSE AND MIDWIFE PRACTITIONERS AND DENTISTS

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

Further information may be obtained from the Duty Pharmaceutical Officer, Pharmaceutical Services, NSW Ministry of Health, Locked Mail Bag 961, North Sydney NSW 2059, Tel: (02) 9391 9944; Fax: (02) 9424 5860.

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 surgeons, nurse and midwife practitioners authorised under section 17A, optometrists authorised under section 17B and podiatrists authorised under section 17C of the Poisons and Therapeutic Goods Act. In relation to Schedule 8 drugs, an “authorised practitioner” is a medical practitioner, nurse or midwife practitioner authorised under section 17A of the Poisons and Therapeutic Goods Act, dentist or veterinary practitioner.

THE POISONS LIST

The Poisons List is the list of substances to which the Poisons and Therapeutic Goods Act and Regulation apply. It is divided into eight schedules (Schedule 1 is empty, so reference to it has been omitted). This list, except for a very small number of variations, is based on the Commonwealth’s Standard for the Uniform Scheduling of Medicines and Poisons. The following is a summary of the nature of the substances in each schedule. The requirements for the storage, supply, labelling, recording, etc. for Schedules 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 and may be supplied only by authorised practitioners, pharmacists or persons licensed as "Poisons Licence Holders".

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 3 substances may be supplied only by authorised practitioners or pharmacists. Where such substances are supplied by a pharmacist, they must be personally handed to the patient by the pharmacist and give the person an opportunity to seek advice as to the use of the substance. Other conditions apply to certain substances.

**Schedule 4** (Restricted Substances)

Substances which in the public interest should be supplied only 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/or 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 substances to be rigidly controlled by subjecting their use or supply to special authority.

The majority of preparations available only on medical or dental authority fall into one of the following categories:

A. **RESTRICTED SUBSTANCES** (Schedule 4)

B. **RESTRICTED SUBSTANCES ON SPECIAL AUTHORITY**

C. **DRUGS OF ADDICTION** (Schedule 8)

**A. RESTRICTED SUBSTANCES** (Schedule 4)

**A1. Acquisition.** Restricted substances may be obtained by a medical practitioner or dentist:
(i) from a licensed wholesaler on a signed and dated order (on the letterhead) of the medical practitioner or dentist, or

(ii) from a pharmacy for emergency use on a signed and dated order (on the letterhead) of the medical practitioner or dentist.

A2. Storage. Must be stored in a part of the premises which is partitioned off or otherwise separated from the remainder of the premises and to which the public is not permitted to have access (e.g. a cupboard or drawer in a surgery).

A3. Prescriptions. A prescription for a restricted substance may be issued by a medical practitioner for use in medical treatment or by a dentist for use in dental treatment. It is valid for 12 months from the date of writing, except in the case of a prescription for an Appendix D substance (see A6), which is valid for 6 months only.

The prescription should be written legibly in ink in the prescriber's handwriting unless otherwise approved (see the Guide TG 184 entitled “Criteria for Issuing Non-Handwritten (Computer Generated) Prescriptions”) and must bear the following particulars:

(a) the date on which it is issued;
(b) the patient's name and address;
(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;
(e) in the case of prescriptions for anabolic/androgenic steroidal agents or the specified barbiturates, the time interval between any repeat dispensing ordered. (The specified barbiturates are amylobarbitone and pentobarbitone, but only where they are packed and labelled for injection; otherwise, these two drugs are in Schedule 8);
(f) adequate directions for use; and
(g) the signature of the prescriber.

The prescription must also show the prescriber's name and designation, and the address and telephone number of the surgery where the records of prescribing are kept in the patient medical records (or if issued at a hospital, the name, address and telephone number of the hospital). These particulars may be preprinted.

A prescription written by a dentist must be endorsed with the words "For dental treatment only".

Where, in the case of an emergency, a direction, either by telephone, electronic mail or facsimile, is given for the supply of a restricted substance, a prescription, endorsed to show that it is issued as confirmation of such a direction, must be written within 24 hours and forwarded within 7 days to the dispenser.

Where a prescriber wishes to exercise some control over the frequency at which repeats on a prescription are dispensed, an interval, even when this is not
obligatory as indicated above, between repeat dispensing should be written on the prescription, e.g. repeat twice at 10 day intervals. There is then an obligation on the pharmacist dispensing a repeat to ensure that at least that period of time has elapsed since the prescription was last dispensed.

It should be noted that all prescriptions for anabolic/androgenic steroidal agents and the specified barbiturates must be retained at the pharmacy dispensing the original prescription. Where repeats are ordered, the patient will therefore be required to return to the pharmacy at which the prescription was originally dispensed to obtain the repeats.

A4. Prescribing and Supply to be within Therapeutic Standards. A medical practitioner or dentist must not issue a prescription for, or supply, a restricted substance in a quantity, or for a purpose, that does not accord with recognised therapeutic standards of what is appropriate in the circumstances.

A5. Sale or Supply. Where a medical practitioner or dentist supplies or sells a restricted substance, including clinical samples, a record must be made showing:

(a) the date on which the medicine was supplied;
(b) the name and address of the patient; and
(c) the name, strength and quantity of the restricted substance supplied.

This record must be kept at the prescriber’s surgery, office or hospital and be made available for inspection if required.

The label on the container of any restricted substance supplied must include:

(a) the words "KEEP OUT OF REACH OF CHILDREN" in red on a white background;
(b) where the medicine is for external use, the word "POISON" or the words “FOR EXTERNAL USE” in red on a white background;
(c) the approved name, strength and quantity of the medicine and (unless the medicine is a preparation compounded extemporaneously to the prescriber’s own formula) its proprietary name also;
(d) adequate directions for use, which should be as explicit as possible;
(e) the patient’s name;
(f) the name and address of the medical practitioner or dentist; and
(g) any necessary or appropriate warnings about the risk of impairment of driving ability or the concurrent consumption of alcohol associated with the medicine.

A6. Appendix D Substances. Some restricted substances which may be abused and/or which are liable to cause dependence are listed in Appendix D to the Poisons and Therapeutic Goods Regulation (See summary below. The full list, TG14, is referred to in the list of brochures available on the Internet on the last page of this Guide). A medical practitioner or dentist must immediately report the loss or theft of an Appendix D substance to Pharmaceutical Services by completing the online ‘Notification of Loss or Theft of Accountable Drugs (S8 and
S4D substances) located on the Internet at:
and, in the case of theft, to the Police.

There is an obligation on a patient requesting a medical practitioner or dentist to supply or prescribe an Appendix D substance, to disclose the amount of that substance or any other Appendix D substance(s) that they have been prescribed or supplied with over the last 2 months. When such a request is made, if the information is not voluntarily disclosed by the patient, it is appropriate to ask them directly and, in any case, record the response on the patient’s file.

Substances in Appendix D include, for example:

- amylobarbitone when packed and labelled for injection
- anabolic/androgenic steroidal agents
- barbiturates not elsewhere specified in Schedule 4 of the Poisons List (e.g. methylphenobarbitone, phenobarbitone, thiopentone)
- benzodiazepine compounds (e.g. clonazepam, diazepam, midazolam, nitrazepam, oxazepam, temazepam, etc.)

(Note: Alprazolam and flunitrazepam are in Schedule 8)

- dextropropoxyphene preparations when included in Schedule 4
- diethylpropion
- ephedrine
- pentobarbitone when packed and labelled for injection
- phentermine
- pseudoephedrine preparations when included in Schedule 4.

Each time a medical practitioner or dentist prescribes an Appendix D substance they must make a record of:

- the date of the prescription
- the patient’s name and address
- the name, strength and quantity of the substance
- the number of repeats (if any) and repeat intervals, see A3(e)
- the directions for use (as written on the prescription)

This record, which would normally be made in the patient’s file, must be kept at the prescriber’s surgery, office or hospital and made available for inspection if required.

Unauthorized possession of an Appendix D substance is an offence.

Persons authorised to have possession of Appendix D substances include “authorised practitioners”, pharmacists, a nurse in charge of a ward in a public...
hospital, licensed wholesalers and a person for whom a prescription for that substance has been issued by an “authorised practitioner”.

B. RESTRICTED SUBSTANCES ON SPECIAL AUTHORITY

The substances listed below may be prescribed only by medical practitioners having the prior authority of the NSW Ministry of Health. However, medical practitioners with specified qualifications and, in some cases, in specified circumstances, are automatically authorised to prescribe the following drugs for any of their patients unless specifically restricted. (Note: Separate Pharmaceutical Benefits authority may also be necessary).

The drugs concerned and a summary of the qualifications required are as follows:

- **acitretin, etretinate, isotretinoin for oral use** - FACD
- **clomiphene, cyclofenil** - FRCOG, FRANZCOG, FRACP (practising endocrinology in a Specialist Endocrinology Unit)
- **dinoprost, dinoprostone (other than vaginal gel)** - FRCOG, FRANZCOG
- **dinoprostone vaginal gel** - FRCOG, FRANZCOG (other practitioners having obstetric privileges at a hospital equipped to carry out foetal monitoring and emergency delivery may apply for individual authority)
- **follitropin beta, luteinising hormone, urofollitropin (human FSH)** - specialist endocrinologists
- **tretinoin for oral use** - specialist haematologists

The medical practitioner must indicate clearly on the prescription:

- their qualification, and
- the words “ISSUED UNDER CLAUSE 37 OF THE POISONS AND THERAPEUTIC GOODS REGULATION 2008” or words to that effect (for example “Clause 37”).

Practitioners, who were previously individually authorised, may continue to use their current CL……, RA……, PG(T)……, (as the case may be) endorsement in lieu of the above.
C. DRUGS OF ADDICTION (Schedule 8)

C1. Acquisition. Drugs of addiction may be obtained by a medical practitioner or dentist:

(i) from a licensed manufacturer or wholesaler on a signed and dated order (on the letterhead) of the medical practitioner or dentist;

(ii) from a pharmacy for emergency use on a signed and dated order (on the letterhead) of the medical practitioner or dentist.

C2. Storage. Must be kept apart from all other goods (other than cash or documents) in a safe, cupboard, or drawer in a cabinet, which is securely attached to a part of the premises and which is kept locked when the drugs are not in immediate use. Emergency supplies may be carried in a bag, provided the bag is left in a locked room, locked cupboard, or locked vehicle when not in immediate use. A room etc is not "locked" if the key is left in the lock or is otherwise readily accessible to anybody.

C3. Accountability. A RECORD MUST BE MADE IN A DRUG REGISTER OF ALL DRUGS OF ADDICTION OBTAINED, SUPPLIED OR ADMINISTERED, irrespective of whether such drugs were obtained from a wholesaler, or from a pharmacist on an order for emergency use, or on a prescription written for a patient and held by the medical practitioner or dentist on behalf of the patient.

The record must be entered in the register in ink on the day on which the transaction takes place. A separate page must be used for each kind of drug of addiction and for each strength of the drug. No alteration may be made in the register, but any mistake may be corrected by a marginal or footnote, initialled and dated. The register must be kept on the premises in which the drugs of addiction are stored, it must be retained for a period of two years from the date of the last entry and made available for inspection if required. Details to be entered include:

(i) the date of the entry;

(ii) the name and address of the supplier (in the case of receipt) or the patient (in the case of administration or supply);

(iii) the quantity received, supplied or administered and the balance held after the transaction; and

(iv) the signature of the medical practitioner/dentist.

A "Register of Drugs of Addiction" can be purchased from most pharmaceutical wholesalers or from Fuji Xerox (Tel: 02 9311 9899). A pocket sized drug register can be purchased from RACGP, 1 Palmerston Cres, South Melbourne, VIC 3205 (Tel: 03 8699 0508). Alternatively, a bound exercise book in which the pages are numbered consecutively and which has columns ruled as shown below, could be used. Each preparation of a drug of addiction and each strength must be listed on a separate page.
 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 for each drug, they should write the date on which the check was done, the words "Balance on hand", the quantity actually held, and they should sign the entry. Any person who assumes control of a practice for one month or more should immediately perform a similar stock check irrespective of the time of year.

If a drug register is lost or destroyed, the medical practitioner or dentist must immediately:

- notify the Ministry of Health in writing of the fact and of the circumstances. The notification should be addressed to:
  
  Chief Pharmacist
  Pharmaceutical Services Unit
  NSW Ministry of Health
  Locked Mail Bag 961
  North Sydney  NSW  2059

  or may be faxed to (02) 9424 5860.

  (For advice, telephone the Duty Pharmaceutical Officer on 02 9391 9944.)

- count the quantity of drugs of addiction held and enter the particulars in a new register

A drug register must be kept for 2 years from the date of the last entry made in it.

If a medical practitioner or dentist loses (or has stolen from them) a drug of addiction, they must immediately notify Pharmaceutical Services by completing the online ‘Notification of Loss or Theft of Accountable Drugs (S8 and S4D substances)’ located on the Internet at:


and enter the relevant details in the drug register.

The police should also be notified where theft has occurred.
C4. **Prescriptions.** A prescription for the supply of a drug of addiction may be issued:

(i) by a medical practitioner only for use in the course of medical treatment; or

(ii) by a dentist for use in the course of dental treatment for a period not exceeding one month's continuous treatment of a patient

(a) in a hospital, with any drug of addiction; or

(b) not in a hospital, with only pentazocine or any drug of addiction appearing at that time on the list of preparations on the current Schedule of Pharmaceutical Benefits which may be prescribed by dentists.

A prescription for a drug of addiction written by a medical practitioner or dentist is **valid for a maximum of 6 months** from the date of writing, even if repeats are ordered.

The prescription should be written legibly in ink **in the prescriber's handwriting** unless otherwise approved (see the Guide entitled “Criteria for Issuing Non-Handwritten (Computer Generated) Prescriptions”, TG184, under “Further Information” on the last page of this Guide) and must bear the following particulars:

(a) the date on which it was written;

(b) the patient's name and address;

(c) the name and strength of the drug of addiction;

(d) the quantity to be dispensed, **in both words and figures**;

(e) if the prescription is to be dispensed more than once, the number of repeats and the minimum time **interval** between repeat dispensing;

(f) adequate directions for use; and

(g) the signature of the prescriber.

**Note:** The details (c) to (f) inclusive on a computer-generated prescription, as outlined in Guide TG184 referred to above, for a drug of addiction **must also** be handwritten by the prescriber. Where the prescription is in duplicate, the handwritten part must be on the duplicate copy, to be retained by the pharmacist.

The prescription must show the prescriber's name and designation and the address and telephone number of the surgery (or if issued at a hospital, the name, address and telephone number of the hospital). These particulars may be pre-printed.

A prescription written by a dentist must be endorsed with the words “For dental treatment only” which may be pre-printed on the form.

A separate prescription form is required for each preparation containing a drug of addiction. No other item may be written on the same form (including no other preparation containing a drug of addiction).

A medical practitioner or dentist must confirm any dose of a drug of addiction that
could be regarded as being dangerous or unusual by underlining the dose and initialling in the margin.

Each time a medical practitioner or dentist prescribes a drug of addiction, they must make a record (in the patient’s file kept at the surgery, office or hospital) of:

- date of the prescription
- patient’s name and address
- drug name, strength and quantity
- number of repeats (if any) and intervals, and
- directions for use, as written on the prescription

Where, in the case of an emergency, a medical practitioner or dentist directs the supply of a drug of addiction either by telephone, electronic mail message or facsimile, a prescription, endorsed to show that it is issued as confirmation of such a direction, must be written forthwith and forwarded to the pharmacist within 24 hours. (Note: A facsimile or electronic mail message still has to be followed up by a written prescription).

It should be noted that prescriptions for which repeats are ordered must be retained at the pharmacy dispensing the original prescription. Patients who require repeat dispensing, where ordered, will therefore be required to return to the pharmacy at which the prescription was originally dispensed.

PRESCRIPTION PADS AND STATIONERY FOR COMPUTER GENERATED PRESCRIPTIONS ARE FREQUENTLY STOLEN. It is wise to have only one pad and limited stationery in use at any time and to keep the remainder in a locked cupboard. If a loss is discovered or forgeries are detected, the police should be notified immediately. Arrangements can be made to alert pharmacists by contacting the Duty Pharmaceutical Officer, Pharmaceutical Services (Tel: 02 9391 9944).

NOTE: It is obligatory under the Poisons and Therapeutic Goods Regulation 2008 for a pharmacist to contact the prescriber to confirm the validity of a prescription for any drug of addiction unless the pharmacist knows the patient or is familiar with the prescriber’s handwriting. Prescribers may therefore expect phone calls from pharmacists carrying out their obligations in this regard or in relation to prescriptions whose validity is otherwise doubtful. This is designed to help prevent illegal access to drugs by forgeries.

C5. Prescribing and Supply to be within Therapeutic Standards. A medical practitioner or dentist must not issue a prescription for, or supply, a drug of addiction in a quantity, or for a purpose, that does not accord with recognised therapeutic standards of what is appropriate in the circumstances.

C6 Authority Requirements. An authority that is required under the provisions of the Poisons and Therapeutic Goods Act is distinct from, and independent of, any authority under the Pharmaceutical Benefits Scheme which is only for the subsidy of the cost of the medication to the patient.
An authority is required to prescribe or supply a drug of addiction under the NSW Poisons and Therapeutic Goods legislation, only in the circumstances described below.

(i) **The Treatment of Drug Dependent Persons**

*A drug dependent person* may not be supplied with any drug of addiction or a prescription for a drug of addiction without the **prior written authority** of the NSW Ministry of Health, except for treatment of the person as an in-patient in a hospital for a period not exceeding 14 consecutive days following admission. See “Forms” below.

**NOTE:** Drug dependent persons frequently attempt to persuade medical practitioners to write prescriptions for drugs of addiction, often for the treatment of non-existent conditions. Medical practitioners should be particularly alert to the possibility of a deception, especially if confronted with a person who has not previously attended the practice and who nominates the drug for which they want a prescription, directly or by inference. A guide to the tactics used by drug dependent persons to persuade practitioners to write prescriptions for drugs of addiction is available from Pharmaceutical Services (Tel: 02 9391 9944) – “Recognising and Handling Drug Dependent Persons - Notes for Medical Practitioners”.

(ii) **The Treatment of other than Drug Dependent Persons**

This applies to the following drugs of addiction:
- any injectible drug of addiction
- buprenorphine (except transdermal patches)
- alprazolam (expected to be in force from 1 February 2014)
- flunitrazepam
- hydromorphone
- methadone

Where a medical practitioner elects to continue treatment of a patient with any of the above drugs of addiction for more than two months, an authority must be obtained from the NSW Ministry of Health. (Refer C4 for restrictions applying to prescribing by dentists).

**Forms**

Forms to be used to apply for an authority to prescribe drugs of addiction are available from the Internet at:


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*A drug dependent person means a person who has acquired, as a result of repeated administration of:

(a) a drug of addiction, or

(b) a prohibited drug within the meaning of the Drug Misuse and Trafficking Act 1985, an overpowering desire for the continued administration of such a drug.*
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.

(iii) Psychostimulants (dexamphetamine, lisdexamfetamine and methylphenidate)

The psychostimulants dexamphetamine, lisdexamfetamine (Vyvanse®), and methylphenidate (Concerta®, Ritalin®, Ritalin LA®) may be prescribed only:

(1) with the prior written authority of the NSW Ministry of Health, issued following receipt of a written application. (Special application forms are available for authority to prescribe stimulants for the treatment of Attention Deficit Hyperactivity Disorder – See “Forms” in (ii) above), or

(2) by prescribers approved by the NSW Ministry of Health for the management of Attention Deficit Hyperactivity Disorder, provided that criteria and conditions are met as described below:

(a) in order to prescribe psychostimulants for children and adolescents for Attention Deficit Hyperactivity Disorder, the criteria set down in the latest version of “Criteria for the Diagnosis and Management of Attention Deficit Hyperactivity Disorder in Children and Adolescents” (TG181) must be met.

(b) in order to prescribe psychostimulants for adults for Attention Deficit Hyperactivity Disorder, the criteria set down in the latest version of “Criteria for the Diagnosis and Management of Attention Deficit Hyperactivity Disorder in Adults” (TG190) must be met.

All prescriptions for psychostimulants must be endorsed with one of the following:

(a) in the case of individual patient authorities as in (1) above- “Ref. No. xxxxxxx-xx-xxxx” (i.e. unique number-month-year)

(b) in the case of dexamphetamine or methylphenidate prescribed by approved prescribers as in (2) above- "CNS xxxxxxxxx” (i.e. unique number), or "S28c xxxxxxxxx” (unique number), as advised in approval letter.

NOTE: Prescribers are reminded that a prescription for the above drugs cannot be dispensed by a pharmacist unless the prescription is endorsed with one of these numbers. These requirements apply to all prescriptions for psychostimulants irrespective of whether they are PBS or non-PBS (private) prescriptions.

Please contact the Monitoring and Compliance Section, Pharmaceutical Services on (02) 9424 5921 (for methadone or buprenorphine for the treatment of opiate dependence) or (02) 9424 5923 (for other drugs of
C7. **Possession. Unauthorised possession of a drug of addiction is an offence.**
Medical practitioners and dentists are authorised to be in possession of drugs of addiction for the purpose of their occupation.

A person for whom a prescription for a drug of addiction has been issued by a medical practitioner or dentist is also authorised to have possession to the extent covered by the prescription(s).

C8. **Destruction.** A drug of addiction in the possession of a medical practitioner or dentist for use in connection with their profession and which has become unusable, may legally be destroyed:

(i) by a community (retail) pharmacist (in the presence of the medical practitioner or dentist (“practitioner”), either at the pharmacy or the practitioner’s practice premises) who must record the destruction in the practitioner’s drug register. The entry must show the date, the name, professional registration number and signature of the pharmacist and the name and signature of the practitioner, if the drug was obtained under emergency supply from a community pharmacist, or

(ii) by or under the direct personal supervision of a police officer, or by a person authorised by the NSW Ministry of Health to do so, by contacting the Duty Pharmaceutical Officer at Pharmaceutical Services on (02) 9391 9944 if the drug was obtained by wholesale.

C9. **Self-Administration of Drugs of Addiction.** A medical practitioner or dentist may not self-administer a drug of addiction other than for the purpose of medical or dental treatment, respectively and only for a period of not more than 7 days (unless they hold an authority to do so from the NSW Ministry of Health or it is prescribed for them by another practitioner).

**FURTHER INFORMATION**

Further information and copies of the latest versions of the following brochures may be obtained by contacting the Duty Pharmaceutical Officer during office hours on (02) 9391 9944 or visiting the Pharmaceutical Services website at:

<table>
<thead>
<tr>
<th>Title</th>
<th>Document No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria for the Diagnosis and Management of Attention Deficit</td>
<td>TG 190</td>
</tr>
<tr>
<td>Hyperactivity Disorder in Adults</td>
<td></td>
</tr>
<tr>
<td>Criteria for the Diagnosis and Management of Attention Deficit</td>
<td>TG 181</td>
</tr>
<tr>
<td>Hyperactivity Disorder in Children and Adolescents</td>
<td></td>
</tr>
<tr>
<td>Prescribing of Benzodiazepines Alprazolam and Flunitrazepam</td>
<td>TG 204</td>
</tr>
<tr>
<td>* Recognising and Handling Patients Liable to Abuse Benzodiazepines</td>
<td>TG 199</td>
</tr>
<tr>
<td>Anabolic/Androgenic Steroids - Information for Medical Practitioners</td>
<td>TG 197</td>
</tr>
<tr>
<td>Guidelines for the Management of Patients with Chronic Non-Cancer</td>
<td>TG 202</td>
</tr>
<tr>
<td>Pain</td>
<td></td>
</tr>
<tr>
<td>Requirements for an Authority to Prescribe Drugs of Addiction under</td>
<td>TG 212</td>
</tr>
<tr>
<td>Section 28 of the Poisons and Therapeutic Goods Act</td>
<td></td>
</tr>
<tr>
<td>Drugs of Addiction (Schedule 8)</td>
<td>TG 13</td>
</tr>
<tr>
<td>Summary of Controls on the Prescribing and Handling of Drugs of</td>
<td>TG 135</td>
</tr>
<tr>
<td>Dependence by Medical, Nurse and Midwife Practitioners</td>
<td></td>
</tr>
<tr>
<td>Schedule 4 Appendix D Drugs (“Prescribed restricted substances”)</td>
<td>TG 14</td>
</tr>
<tr>
<td>* Recognising and Handling Drug Dependent Persons - Notes for</td>
<td>TG 116A</td>
</tr>
<tr>
<td>Medical Practitioners</td>
<td></td>
</tr>
<tr>
<td>Criteria for Issuing Non-Handwritten (Computer Generated) Prescriptions</td>
<td>TG 184</td>
</tr>
</tbody>
</table>

* These guides are not published on the Internet. Contact Pharmaceutical Services for a copy.

This guide has been produced by:
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