

GUIDE TO THE POISONS AND THERAPEUTIC GOODS LEGISLATION FOR GENERAL SELLERS OF POISONS

This Guide is a summary only. Reference should be made to the *Poisons and Therapeutic Goods Act 1966* and the *Poisons and Therapeutic Goods Regulation 2008* for complete details (online publication of legislation available on the Internet at www.legislation.nsw.gov.au).

Further information may be obtained from Pharmaceutical Regulatory Unit – see contact details on the last page of this Guide.

A wide range of substances, medicines and poisons is controlled under the Poisons and Therapeutic Goods Act. Substances such as arsenic, strychnine and cyanide have been recognised as poisons for years, but many other substances of a poisonous nature are not as well recognised. Commonly available items such as kerosene, mineral turpentine and many horticultural and agricultural products can be quite harmful if accidentally swallowed, as can a wide range of medicines. Many children are treated each year for poisoning from swallowing such substances.

THE POISONS LIST

The Poisons List is the list of substances to which the Poisons and Therapeutic Goods Act and its Regulation apply. It is divided into eight schedules (Schedule 1 is empty, so reference to it has been omitted) according to a pattern that is uniform in most respects throughout Australia.

Different conditions apply to the packaging, labelling and sale of poisons depending upon the way they are classified in the Poisons List.

The Poisons Schedules are described in Section 8 of the Act as follows:

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. May be supplied by, for example, medical practitioners, pharmacists or veterinary surgeons, or persons licensed as “Poisons Licence Holders” (see page 3).

Schedule 3

Substances which are for therapeutic use and:

- a) about which personal advice may be required by the purchaser in respect of their dosage, frequency of administration and general toxicity; or
- b) with which excessive unsupervised medication is unlikely; or

- c) which may be required for use urgently so that their supply only on the prescription of a medical practitioner or veterinary surgeon would be likely to cause hardship.

Schedule 3 substances may be supplied by, for example, medical practitioners, pharmacists or veterinary surgeons. Where a pharmacist supplies such substances, they must be personally handed to the patient by the pharmacist and, with certain of these substances, special conditions apply.

Schedule 4 (Restricted Substances)

Substances which in the public interest should be supplied only on prescription.

Schedule 5

Poisonous substances of a dangerous nature commonly used for domestic purposes, such as methylated spirits, kerosene and bleaches which should be readily available to the public but which require caution in their handling, use and storage. Sellers are not required to be licensed under the Poisons and Therapeutic Goods Act.

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. Sellers are not required to be licensed under the Poisons and Therapeutic Goods Act.

Schedule 7

Substances of exceptional danger which require special precautions in their manufacture or use. Sellers in NSW are not generally required to be licensed under the Poisons and Therapeutic Goods Act but in the case of some specified Highly Dangerous substances included in Schedule 7 supply or use must be authorised by the NSW Ministry of Health.

“SPECIFIED” HIGHLY DANGEROUS SCHEDULE 7 SUBSTANCES

These comprise the following substances:

- arsenic
- cyanides
- fluoroacetamide
- fluoroacetic acid
- hydrocyanic acid
- strychnine
- thallium

and those substances included in Appendix C of the Standard for the Uniform Scheduling of Medicines and Poisons, being a range of herbal and other substances

which are extremely dangerous and whose use or supply is prohibited when intended for therapeutic use.

The acquisition or use of any of the above substances without an authority issued by the Ministry of Health is an offence, as is their supply, unless the person being supplied holds an authority to use the substance.

Schedule 8

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

Provision is also made for substances to be completely banned by declaring them as prohibited substances.

POISONS LICENCES

A person may be licensed under the Poisons and Therapeutic Goods Regulation to sell by retail substances in **Schedule 2** of the Poisons List. On application, a licence may be issued by the Ministry of Health to an applicant who owns a shop for the sale of goods by retail situated at least 20 kilometres from the nearest pharmacy.

If you don't have a "poisons licence" you cannot legally sell products in Schedule 2.

It is easy to tell which products are in Schedule 2 as the label on these products is headed "**PHARMACY MEDICINE**" (not "PHARMACIST ONLY MEDICINE", as these are in Schedule 3 and are sold only by pharmacies).

A poisons licence does NOT authorise the procurement or sale of substances in Schedule 3, 4 or 8 of the Poisons List.

A poisons licence is not required to sell domestic poisons (Schedule 5), industrial and agricultural poisons (Schedule 6), or agricultural chemicals or animal medicines in Schedule 7 of the Poisons List but some restrictions apply to the latter (see further on in this Guide under Schedule 7).

If you are unsure whether or not you can legally sell a particular product, ask your supplier or contact the Pharmaceutical Regulatory Unit (see contact details at the end of this Guide).

PROCUREMENT OF POISONS

Poisons may be purchased for resale from any bona fide wholesale dealer or distributor. Wholesale dealers in medicines are generally required to hold a licence under Poisons and Therapeutic Goods legislation.

Wholesale dealers in medicines or poisons of any kind must supply an invoice to the purchaser of the goods.

Wholesale dealers of Highly Dangerous Schedule 7 Poisons are required to be authorised by the Ministry of Health to supply Highly Dangerous Schedule 7 Poisons to authorised end-users of Highly Dangerous Schedule 7 Poisons.

STORAGE OF POISONS

General conditions

All poisons should be stored out of the reach of children and should be kept apart from foodstuffs and in such a way that, if its container breaks or leaks, foodstuffs will not be contaminated with the poison. Other conditions of storage of poisons depend upon their schedule classification. The following conditions apply:

Schedule 5

The label on these products is headed “**CAUTION**”.

General conditions of storage apply.

Schedule 6

The label on these products is headed “**POISON**”.

General storage conditions apply. In addition, they must be stored at least 1.2 metres above the floor (out of the reach of young children) unless they are:

- (a) stored in a storeroom or other area to which customers do not have access; or
- (b) packed in containers with child-resistant closures; or
- (c) packed in containers with a capacity of 5 litres (or 5 kilograms) or more; or
- (d) a hair dye contained in a container which has a capacity of 50 millilitres or less; or
- (e) a cockroach bait enclosed in a welded plastics labyrinth; or
- (f) a medicine for internal use in animals.

Schedule 7

The label on these products is headed “**DANGEROUS POISON**”.

Must be stored in a part of the premises to which the public does not have access, for example, in a locked cupboard or storeroom.

Special conditions apply to the supply or use of the poison according to the particular substance or class of substances. Some Schedule 7 poisons may only be supplied or used in accordance with an authority issued under the *Poisons and Therapeutic Goods Regulation 2008* (see above). A list of some of the products included in

Schedule 7 (see TG 207, available at <http://www.health.nsw.gov.au/pharmaceutical>) and restrictions on their sale or use is available from Pharmaceutical Services (see contact details at the end of this Guide). Generally, Schedule 7 Dangerous Poisons are not appropriate for domestic use because of their poisonous nature.

PACKAGING AND REPACKING OF POISONS

Packing and labelling of poisons is a complicated business and can be covered only fairly generally in this Guide. If you want further information on this, especially in relation to a particular product, contact the Pharmaceutical Regulatory Unit (see contact details at the end of this Guide).

Refilling of containers of household poisons such as kerosene, mineral turpentine, methylated spirit, pool chemicals and dry cleaning fluids **should be generally avoided.** However, it can be undertaken provided the container being refilled was originally used for the same material, is still sound and still bears the original label. Some petroleum product manufacturers supply labels for use in refilling containers where the original label has been damaged. Child-resistant closures must be used where required by the Regulation.

Beverage containers such as soft drink, beer or wine bottles or other containers that do not meet the requirements for poisons containers must NEVER be used for or refilled with poisonous substances, even temporarily. This is very dangerous as well as illegal.

Where a poison is specified in Schedule 5, 6 or 7 for a particular use, it cannot be repacked and must be sold only in the manufacturer's original, unopened container. This applies particularly to some stock medicines and agricultural chemicals classified as poisons.

Poisons must be packed in containers which:

- (a) are impervious to their contents;
- (b) are of sufficient strength to prevent leakage arising from the ordinary risks of handling, storage and transport;
- (c) except when intended for use on one occasion only, are capable of effective reclosure.

Bottles or jars having a capacity of **2 litres or less** must be embossed with the word "POISON" or the words "NOT TO BE TAKEN". They must also be embossed with prominent vertical ribs or prominent points or stars sufficient to make them readily distinguishable by sight and touch from containers used for food, drink or medicine for internal use.

The container of a Schedule 5 poison other than:

liquid hydrocarbons when packed as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit or dry cleaning fluid;

methylated spirit;

petrol;

toluene; or

xylene,

is exempted from the foregoing requirements, provided it is embossed or indelibly printed with the words “POISON”, “NOT TO BE TAKEN” or “NOT TO BE USED AS A FOOD CONTAINER”.

Other containers must have the word “POISON” embossed or indelibly printed on the side of the container.

In addition to the above container requirements, some poisons may be supplied only in containers fitted with approved child-resistant closures; for example, bottles or jars having a capacity of 5 litres or less when used for such poisons as kerosene, lamp oil, mineral turpentine, thinners, reducers, white petroleum spirit, dry cleaning fluid, methylated spirit, ethylene glycol, hydrochloric acid, alkaline salts when packed and labelled as dishwashing machine liquids, gels or tablets and most potassium hydroxide and sodium hydroxide preparations. These are general examples only as the requirements are quite complicated. For specific advice contact the Pharmaceutical Regulatory Unit (see contact details at the end of this Guide).

Medicines for internal use and solid or semi-solid medicines for external use are not required to be packed in poison containers.

Eye, ear and nose drops or sprays in packs of 15mL or less are also exempt from container requirements.

LABELLING OF POISONS

Adequate labelling is one of the most important measures to protect users from accidental poisoning or injury. All poisons have a signal warning at the top of the main label, as follows:

SCHEDULE	PURPOSE	LABELLING REQUIRED
5	All	CAUTION -[the principal hazard(s) consistent with safety directions may be inserted] KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS (BEFORE OPENING OR USING)
6	All	POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS (BEFORE OPENING OR USING)
7	All	DANGEROUS POISON KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS (BEFORE OPENING OR USING)

Note: (i) The signal heading “READ SAFETY DIRECTIONS (BEFORE OPENING OR USING)” is to be used only if safety directions appear on the label.

(ii) The print colour is not specified but printing must be bold-face sanserif capitals of uniform thickness in a colour which affords a contrast to the background.

In addition, the label must include:

- (a) the common name and the quantity or proportion of the poison;
- (b) the name and address of the manufacturer or distributor;
- (c) when prepared for a specific purpose, clear and adequate directions for use;
- (d) for most Schedule 5, 6 and 7 poisons, directions for first aid attention in case of poisoning; and
- (e) specified statements warning of particular hazards.

DISPOSAL AND USE OF POISONS

Poisons must not be disposed of or used in any place or manner likely to constitute a risk to the public. Advice on the disposal of poisons can be obtained from your local council health department, the NSW Department of Environment, Climate Change and Water (Contact telephone number: 131-555) or a licensed waste disposal company.

HAWKING

It is unlawful to sell poisons by hawking or peddling, or to sell poisons in the street or from door to door. Free sampling of poisons from door to door or in the street or any public place is also prohibited.

VENDING MACHINES

The use of automatic vending machines to sell poisons is generally prohibited.

SUPPLY OF OUT-OF-DATE STOCK

It is illegal under the Poisons and Therapeutic Goods Act to supply any medicine, including those for veterinary use, after the expiry (“use by”) 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.

IMPROPER SUPPLY

It is an offence under the Poisons and Therapeutic Goods Regulation for any person to sell a scheduled poison classified as:

- (a) a medicine, in a quantity or for a purpose, that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances, or
- (b) other than a medicine, for a purpose other than that stated on the container or for a purpose other than that for which it is normally used.

This means that every person who sells scheduled poisons has an obligation to ensure that they do not sell a product or a quantity of a product to a person, knowing that the person intends or is likely to use it other than for a purpose or in a way that it is meant to be used or is normally used. If a doubt exists, the seller has the right and an obligation to refuse to sell the product(s) in those circumstances. Particular examples might be selling pain killers, methylated spirits, paint thinners etc, knowing that they are going to be misused or abused.

PENALTIES

The maximum penalty for most offences arising from the packaging, labelling or sale of poisons is a fine of \$1,100. However, some penalties, such as inappropriate supply or disposal of poisons may attract a fine of up to \$2,200 or imprisonment for 3 months or both a fine and imprisonment for each offence.

FURTHER INFORMATION

Further information may be obtained from the Duty Pharmaceutical Officer, Pharmaceutical Regulatory Unit, during office hours on (02) 9391 9944.

This guide has been produced by:

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