

GUIDE TO THE POISONS AND THERAPEUTIC GOODS LEGISLATION FOR POISONS LICENCE HOLDERS

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 Services – 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, methylated spirits 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 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. For example, some medicines (Schedule 2) may be sold only by pharmacies and persons licensed under the Regulation to sell them; other medicines (Schedule 3) may be sold only by pharmacists **personally** (other shops are not licensed to sell them); and yet other medicines (Schedules 4) may only be supplied on prescription.

It is easy to tell which group a medicine belongs to by the wording at the top of the label, as follows:

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|-----------------------------------|-------------------------------------|
| Schedule 2 medicines are labelled | “PHARMACY MEDICINE” |
| Schedule 3 medicines are labelled | “PHARMACIST ONLY MEDICINE” |
| Schedule 4 medicines are labelled | “PRESCRIPTION ONLY MEDICINE” |

Schedules 5, 6 and 7 are taken up by domestic, industrial and agricultural poisons that are all labelled to indicate their poisonous nature, such as “CAUTION”, “POISON” or “DANGEROUS POISON” and are packed in special bottles which are sometimes required to be fitted with child-resistant closures.

POISONS LICENCES

A person may be licensed under the Poisons and Therapeutic Goods Regulation to sell by retail medicines 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.

A poisons licence applies only to Schedule 2 medicines and does NOT authorise the procurement or sale of substances in Schedule 3, 4 or 8 of the Poisons List, nor the procurement or sale of Highly Dangerous Substances in Schedule 7 of the Poisons List (eg cyanides).

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, but special conditions apply to the storage and supply of Schedule 7 poisons.

If you are unsure whether or not you can legally sell a particular product or need advice as to any conditions applying to its storage or sale, ask your supplier or contact Pharmaceutical Services (see contact details at the end of this Guide).

Note: A licence, when issued, may impose conditions and/or restrictions on the sale of a particular medicine or class of medicines in Schedule 2.

PROCUREMENT OF POISONS

Poisons may be purchased for resale from any bona fide wholesale dealer. Wholesale dealers in medicines are required to hold a licence under the Poisons and Therapeutic Goods Act. A list of licensed manufacturers and wholesale distributors of medicines will be supplied by Pharmaceutical Services to any poisons licence holder on request.

Wholesale dealers in poisons, both medicinal and non-medicinal, must supply an invoice to the purchaser of any poison. Poisons licence holders should retain their copy of any invoice for Schedule 2 products for not less than 2 years.

STORAGE OF POISONS

General conditions

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

Schedule 2

As stated earlier, the label on these products is headed “**PHARMACY MEDICINE**”.

The general conditions (above) for the storage of poisons apply, although it is suggested they should be stored in an area to which customers do not have direct access, for example, behind a counter, as some of these substances are subject to misuse or abuse.

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 conditions of storage 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 which is contained in a container which has a capacity of 50 millilitres or less; or
- (e) a cockroach bait which is 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**”.

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

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.

PACKAGING AND LABELLING OF POISONS

Packing and labelling of poisons is a complicated business and should be avoided. If, however, you want further information on this, contact Pharmaceutical Services (see contact details at the end of this Guide).

Refilling of containers of household poisons such as kerosene, mineral turpentine, methylated spirits, pool chemicals and dry cleaning fluids can be undertaken provided the container being refilled was originally used for the same material, is still sound and still bears the original label. Child-resistant closures must be used where required by the Regulation.

It is very dangerous and against the law to supply a poison in a container or package that is not clearly and correctly labelled. Beverage containers such as soft drink, beer or wine bottles or other containers that do not meet the requirements for poison containers must NEVER be refilled with poisonous substances, even temporarily.

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 stock medicines and agricultural chemicals.

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.

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 the expiry date set by the manufacturer.

VENDING MACHINES

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

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 Services, during office hours on (02) 9391 9944.

This guide has been produced by:

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