

GUIDELINES FOR THE SUPPLY BY WHOLESALERS OF SUBSTANCES IN SCHEDULE 2, 3 OR 4 OF THE POISONS LIST

A person or company located in New South Wales **may not supply by wholesale** any substance which is for therapeutic use in humans or animals and which is included in Schedule 2, 3 or 4 of the Poisons List made under the *Poisons and Therapeutic Goods Act 1966*, **unless they are licensed or authorised** to do so under the *Poisons and Therapeutic Goods Regulation 2008*.

Additionally, wholesalers have an obligation to ensure that the persons or companies they supply are licensed or authorised, as applicable, to obtain, use, supply or be in possession of the substance, as the case may be.

Any such substance may be supplied only in the **unopened registered pack** as received from the supplier and in accordance with any conditions specified in the licence.

Generally, the above substances **can only be supplied to the following**:

1. a medical practitioner, dentist, veterinary practitioner, pharmacist, authorised nurse practitioner, authorised midwife practitioner or authorised optometrist for use by them in connection with their profession;
2. public institutions (including public hospitals), government departments or universities;
3. a person or company who, if located in NSW, is **licensed as a wholesaler** to obtain or supply the therapeutic substances or, if located elsewhere in Australia, is licensed or authorised under a law of that State or Territory or of the Commonwealth;
4. a person or company who, if located in NSW, is **licensed as a private hospital or day procedure centre** under the provisions of the *Poisons and Therapeutic Goods Regulation* to supply drugs of addiction or, if located elsewhere in Australia, is similarly licensed or authorised under a law of that particular State or Territory;
5. a person or company who, if located in NSW, is otherwise **licensed or authorised** to obtain or supply that substance or, if not located in NSW, is licensed or authorised under an equivalent law of the Commonwealth, State or Territory in which they are located;
6. persons who are carrying on a business, profession, trade or industry listed below, for use in connection with their business etc, but not for resale as such. **In this case the wholesaler must be satisfied that the person genuinely requires that substance for their business, profession, etc.**

- Substances in **Schedule 2 or 3** can be supplied to, for example, a jewellery manufacturer, electroplater, paint manufacturer, commercial pest-control operator, gold-miner or non-ferrous metal refiner.
- Certain specific therapeutic substances in **Schedule 2, 3 or 4** can be supplied, subject to specified conditions, to, for example, masters of ships, optometrists, podiatrists, dental therapists, registered nurses carrying out vaccination campaigns, animal feedstuff producers or persons in charge of industrial first aid posts. Reference should be made to Appendix C of the *Poisons and Therapeutic Goods Regulation* to determine which substances may be supplied to which category of persons and under what conditions.
- Additionally, substances in **Schedule 2, 3 or 4** can be supplied to a qualified person in charge of a research, teaching or quality control laboratory or the holder of a licence to manufacture or supply drugs of addiction *for use in accordance with that licence*.

7. persons outside the Commonwealth of Australia, by way of export.

Wholesalers should ensure that the substances they supply are not supplied contrary to the terms and conditions of their own or their client's licence or authority. For example, if a wholesaler's client is only licensed or authorised to sell substances in Schedule 2 or 3 then they should not be supplied with a substance in Schedule 4.

Conversely, poisons and restricted substances for therapeutic use may be obtained only (i) from a distributor licensed or authorised to supply those goods by wholesale under the law of a State, Territory or the Commonwealth or, (ii) by import approved by the Commonwealth. The export of any therapeutic substance must comply with Commonwealth law.

An exception to the above is a manufacturer, licensed by the Commonwealth to manufacture products that are in Schedule 2 or 3, who may obtain a raw material that is in Schedule 4 for the purpose of manufacturing a product that, once manufactured, falls within Schedule 2 or 3 or is exempt from scheduling.

Consequently, wholesalers should either obtain a copy of their client's licence or authority, or consult the lists of licence and authority holders available from the NSW Ministry of Health (see below) before they supply a scheduled substance.

In order to minimise the risk of impositions or the diversion of drugs:-

- accounts should be opened only in the name of the licensed or authorised person/company. Invoices must reflect supply only to the licensed or authorised person/company at the address shown on the licence or authority. S2, 3 or 4 substances must not be sent to any other address.
- adequate screening processes are essential in order to prevent the illegal

supply or diversion for illicit purposes of substances in Schedule 2, 3 or 4 especially with “cash sale” transactions or where the goods are supplied over the counter.

The above information is by way of a guide to the provisions of Poisons and Therapeutic Goods legislation. For complete information you should consult the Act and its Regulation and/or your legal adviser.

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:

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