

GUIDE TO THE REQUIREMENTS OF THE NSW POISONS AND THERAPEUTIC GOODS LEGISLATION FOR THE SUPPLY OF SCHEDULE 3 SUBSTANCES FROM PHARMACIES

1. CONTROLS APPLICABLE TO ALL SCHEDULE 3 SUBSTANCES

1.1 Storage

Schedule 3 substances must be kept in a room or enclosure to which the public do not have access. This means Schedule 3 substances must be kept in a part of the premises partitioned off or otherwise separated from the remainder of the premises. This part of the premises must be apart from food intended for consumption by humans or animals and set up in such a way that, if the container of a stored Schedule 3 substance breaks or leaks, the poison cannot mix with or contaminate any food intended for consumption by humans or animals. For example, Schedule 3 substances may be kept in the dispensary or elsewhere in the pharmacy in lockable cabinets, provided the cabinets are kept locked when not in immediate use, or in sections of the pharmacy where access is impeded by “batwings” or “stable doors”. Consultation areas in forward pharmacy dispensing models or behind the counter are acceptable locations provided the products are genuinely out of public access. Merely “roping off” an area in the pharmacy is not acceptable. The storage of the Schedule 3 substance must facilitate the mandatory intervention by the pharmacist in the sale of the product.

1.2 Labelling

The container containing the Schedule 3 substance must be labelled with the name and address of the supplier. Price stickers, for example, showing the pharmacy name and suburb, are acceptable, if affixed to the immediate container, i.e. bottle, tube, etc. In the case of strip or blister packaged goods, metered dose inhalers or individually wrapped powders, it is sufficient to label the outer container. If the product is supplied other than in the manufacturer's original pack labelled “PHARMACIST ONLY MEDICINE”, it must be labelled as a re-packed or dispensed medicine. See TG79/33, Section 11 (clause 7 and Appendix A, *Poisons & Therapeutic Goods Regulation 2008*).

1.3 Supply

Where a pharmacist supplies a Schedule 3 substance to a person (other than on prescription), the pharmacist must personally hand the product to the person and give the person an opportunity to seek advice as to the use of the substance, including dosage and general toxicity. This means that the pharmacist must be present in a face-to-face situation so that they can satisfy themselves as to the needs of the person, to give whatever advice is deemed necessary, and to answer any questions the person may have regarding the Schedule 3 product. An assistant may complete the sale.

It is illegal for a pharmacist to supply a Schedule 3 substance or any other scheduled substance in a quantity or for a purpose that does not accord with the recognised therapeutic standard of what is appropriate in the circumstances.

1.4 Advertising

Products containing substances in Schedule 3 may not generally be advertised direct to the public. However, some exceptions apply. Appendix H of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) lists medicines included in Schedule 3 that are permitted to be advertised to the public. Advertisements in professional or trade

journals, etc. are exempt from this prohibition, but any other form of public advertising which is designed to promote the sale or use of the goods, including window banners, leaflets, point-of sale material, the conspicuous display of the goods themselves, etc. is illegal. The purpose of this is to ensure that, in general, pharmacists have the principal role in initiating treatment with Schedule 3 substances.

2. ADDITIONAL CONTROLS APPLICABLE TO THE SUPPLY OF PSEUDOEPHEDRINE

Pseudoephedrine, although used therapeutically as a decongestant in sinus and cold & flu preparations, is also a precursor chemical used in the manufacture of crystal methamphetamine in clandestine laboratories.

A pharmacist's role is pivotal in the control of the supply of pseudoephedrine, as the law requires that a pharmacist must not supply a medicine, including pseudoephedrine, in a quantity and for a purpose that does not accord with recognised therapeutic standard of what is appropriate in the circumstances.

Clause 24 of the *Poisons and Therapeutic Goods Regulation 2008* requires that when a pharmacist supplies pseudoephedrine over-the-counter, without a prescription, the sale must be recorded in an electronic form online, in real-time, at the time of supply, in a system that meets specific criteria. The only software program that currently meets these criteria is ProjectSTOP®.

ProjectSTOP® serves as a tool to assist the pharmacist in determining appropriate supply of pseudoephedrine, and in complying with the recording requirements of the legislation. For guidance on the use of ProjectSTOP®, see the Pharmacy Guild of Australia website.

Requirements under the *Poisons and Therapeutic Goods Regulation*

2.1 Records of Pseudoephedrine Supplied On Prescription

A pharmacist who supplies pseudoephedrine on prescription must record details of the supply in accordance with clause 55 of the Regulation as if pseudoephedrine were a Schedule 4 substance, in the same way as other medicines supplied on prescription are recorded.

2.2 Records of Pseudoephedrine Supplied Over-the-Counter

A pharmacist who supplies pseudoephedrine to a person without a prescription must, at the time of the supply, record the following details in an electronic form, online and in real-time, at the time of supply:

- (a) a unique reference number for the supply,
- (b) the name of the person by whom the pseudoephedrine is supplied,
- (c) the name and address of the person to whom the pseudoephedrine is supplied,
- (d) the name, strength (if not readily apparent) and quantity of the pseudoephedrine supplied and the date on which it is supplied,
- (e) if the pharmacist does not know the identity of the person to whom the pseudoephedrine is supplied, the unique reference number of a photo identification of the person and the type of that identification.

The pharmacist is obliged to ensure that the required details are recorded for each supply of pseudoephedrine over-the-counter, including the pharmacist's name and the complete name and current address of the person being supplied. The information recorded is to relate to the person being supplied, this is not necessarily the patient. The name, strength and quantity of the product supplied must be recorded, such that if a product is chosen from a system's dropdown list for example, it must be ensured that the required details are included.

2.3 Identifying the Person Supplied

If the pharmacist, in the course of the pharmacist's practice of the profession, knows the identity of the person being supplied the pseudoephedrine, photo identification of the person need not be recorded. However, the legislation does not preclude the recording of photo identification of a person known to the pharmacist, should the pharmacist choose to do so, for example, if the pharmacy implements a local protocol that requires this. If photo identification is not sought, the pharmacist must be able to demonstrate how they know the identity of the person.

If the pharmacist does not know the identity of the person, the pharmacist is required to sight photo identification of the person being supplied the pseudoephedrine, and record the unique reference number of the photo identification.

Photo identification means any of the following types of identification held by the person being supplied:

- (a) an Australian driver licence that displays a photograph of the person,
- (b) a passport, or
- (c) a NSW Photo Card issued under the *Photo Card Act 2005*, or
- (d) a card issued under a law of the Commonwealth or another State or Territory for the purpose of proving the person's age which contains a photograph of the person in whose name the card is issued.

Pharmacists are reminded that in recording health information, there is an obligation under Privacy laws that the information recorded is accurate, up to date and complete.

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

This guide has been produced by:

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