



Frequently Asked Questions about medicine scheduling

In Australia, medicines and poisons are classified into Schedules, a national classification system that controls how they are made available to the public. Schedules have varying levels of restrictions that determine the availability of supply of a medicine or poison, in order to protect public health and safety.

Of the 9 schedule categories, pharmacy is primarily concerned with the following:

- **Schedule 2**

Pharmacy Medicine

Medicines, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy, or where a pharmacy service is not available, from a licence holder.

- **Schedule 3**

Pharmacist Only Medicine

Medicines, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.

- **Schedule 4**

Prescription Only Medicine

Medicines, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.

- **Schedule 8**

Controlled Drug

Medicines which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.



Q: Why are there more restrictions on the supply of certain medicines compared to others?

Varying levels of restrictions are in place because some medicines carry a greater potential to cause harm or to be misused or abused. The primary aim of the Scheduling system is to balance access to medicines and self-management of health conditions with protecting consumers from harm, particularly vulnerable consumer groups such as children.

Q: I regularly buy a certain type of medicine without a prescription, but I always have to ask for it and the pharmacy staff ask me a lot of questions before giving it to me. Why?

By law, Pharmacist Only Medicines (Schedule 3) can only be supplied from a pharmacy by or under direction of a pharmacist and must be stored in an area of the pharmacy that is not accessible to the public. Although these medicines are available without the need of a prescription, every time a Pharmacist Only Medicine is requested or supplied, a pharmacist is required to ensure the medicine is appropriate and will be used safely and correctly. If a pharmacist thinks that a particular medicine is not suitable for the condition, is unsafe for the person or is being misused, they may suggest another treatment, refuse the sale of a product and/or refer you to a doctor or health centre.

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Q: Why is it that some medicines no longer require a prescription?

The Scheduling classification of any medicine can be subject to review and changed if justified. Proposals to change a Scheduling classification can come from any source, but typically come from the sponsor for the supply of the medicine in Australia.

A down-schedule (e.g. prescription medicine being reclassified to non-prescription) may occur when new evidence indicates the medicine's level of risk is not as great as originally perceived and/or the potential health benefits of making the medicine more readily available outweighs any potential increase in risk.

Conversely, a medicine may be up-scheduled if evidence suggests a significant increase in the potential for abuse or misuse or the severity or frequency of adverse effects warrant further restriction. Consideration is given to any potential costs associated with an up-schedule as well as expected individual or public health benefits and risks associated with more restricted access.

Proposed changes are publicised by the Therapeutic Goods Administration (TGA) with an opportunity for comment from interested stakeholders.

The Pharmacy Guild of Australia (Guild) examines all medicines Scheduling proposals and undertakes research to provide submissions commenting on proposals identified to be of significance to community pharmacy, Guild members and/or consumers.

Q: Do the rules regarding the supply of medicines vary between the States and Territories?

Although the Schedule system is nationally based, the States and Territories manage the laws relating to the storage and supply of medicines. While for the main part they are very similar, there are some differences depending on the medicine Schedule. If you are travelling or moving interstate and are concerned about or have problems obtaining medicines, just Ask Your Pharmacist.

Q: Why can I get certain medicines from supermarkets and other outlets but others only from a pharmacy?

Medicines are not treated as normal products of commerce as they have the potential to do significant harm if used incorrectly or inappropriately. Medicines that have a greater risk are scheduled and restricted to supply from a pharmacy so that consumers have access to professional advice from a pharmacist. Medicines with the greatest risk require a prescription to authorise supply.

Community pharmacists provide professional advice about the safe use of medicines for optimal effect and are supported by a team of pharmacy assistants who are trained to ask questions in order to assist the pharmacist and assess if and when the pharmacist should be consulted.

There are some medicines (including complementary medicines such as herbal remedies and vitamins) that are exempt from scheduling which are available through non-pharmacy outlets, such as supermarkets, service stations and health food stores. These medicines have been deemed sufficiently safe to allow consumers to self-select without the need for any pharmacist advice. Risk of misadventure is managed by including cautions and warnings on the medicine pack.

Although a medicine may be exempt from scheduling, it does not indicate it is completely 'safe' or 'risk free'. If you have any concerns regarding a medicine, you should consult your community pharmacist or doctor.

If you are concerned that someone may have taken an overdose or too much of any medicine, call the Poisons Information Line on 13 11 26.

Therapeutic Goods Administration

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