The Pharmacy Guild of Australia

# POSITION STATEMENT

## Regulation and Scheduling of Medicines and Poisons

### Position

The Pharmacy Guild of Australia (Guild) supports a regulatory system which ensures that medicines supplied in Australia conform to recognised standards of quality, safety and efficacy, and supports the Quality Use of Medicines (QUM).

The Guild believes that QUM is best supported by the supply of medicines through pharmacy where there is access to professional support and advice from a pharmacist, with assistance provided from trained pharmacy assistants, within a quality-assured framework.

The Guild believes that legislation should ensure a nationally consistent approach to the regulation of medicines and poisons, and we support uniform medicines and poisons standards applying throughout Australia. This includes conditions relating to access, sale, supply, recording, labelling, packaging, advertising and promotion.

The Guild believes that the current scheduling classification system for medicines with two non-prescription categories (Schedule 2 and Schedule 3) and two prescription categories (Schedule 4 and Schedule 8) effectively balances convenience and accessibility with public safety.

The Guild supports the Therapeutic Goods Administration's (TGA) continued focus on the protection of public health, the QUM and the goal of working cooperatively with other public health authorities and stakeholders to develop a comprehensive pharmacovigilance system.

The Guild also supports robust and objective risk management processes to determine the most appropriate schedule for medicines, and the development of pharmacovigilance systems with the requisite sensitivity to allow data collection for decision-making and evaluation purposes.

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## Background

The regulation of medicines in Australia is a joint effort between the Commonwealth and the States and Territories. The Commonwealth is responsible for regulating the supply, manufacturing, and advertising of therapeutic goods in Australia, including medicines. The States and Territories regulate access to medicines, including possession, storage, prescribing, dispensing, supply and administration requirements.

### Quality Use of Medicines

The National Strategy for Quality Use of Medicines defines QUM as:

- selecting management options wisely
- choosing suitable medicines if a medicine is considered necessary so that the best available option is selected
- using medicines safely and effectively to get the best possible results

QUM principles inform professional standards, guidelines and protocols for pharmacists and prescribers involved in the prescribing, recommendation and supply of medicines.

### The TGA and Therapeutic Goods Act

The TGA is part of the Australian Government Department of Health and Aged Care and is responsible for administering the provisions of the legislation contained in the *Therapeutic Goods Act 1989* *(Act)*. The objective of the Act, is to provide a national framework for the regulation of therapeutic goods in Australia, to ensure the quality, safety and efficacy of medicines and medical devices.

### Scheduling Classification and Poisons Standard

The scheduling classification of “poisons” determines the level of public access to these substances. Poisons are defined by the Poisons Standards as medicines for human therapeutic use, veterinary medicines, agricultural, domestic and industrial chemicals. The schedule for a medicine or chemical is decided according to the degree of risk to public health and safety, and consequently determines the level of restriction applied to their availability to the public. In the case of medicines, the classification also incorporates the commensurate level of professional support and intervention across the various schedules.

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), or ‘Poisons Standard’, is the legislative instrument that lists medicines and poisons according to their schedule classification. The implementation of the SUSMP, as it affects access to and supply of medicines and poisons, is given legal effect through related state and territory legislation. The SUSMP constitutes a recommendation to the states and territories however, each jurisdiction reserves the right to implement a different scheduling classification, to take into account local circumstances. The SUSMP also includes provisions about containers and labels, and recommendations about other controls on medicines and poisons. Progression through the schedules signifies increasingly restrictive regulatory controls.

Of the 9 schedule categories within the SUSMP, pharmacy is primarily concerned with those containing poisons for therapeutic use (medicines):

- Schedule 2 – Pharmacy Medicines
- Schedule 3 – Pharmacist Only Medicines
- Schedule 4 – Prescription Only Medicines
- Schedule 8 – Controlled Drugs

While prescribers may supply scheduled medicines according to state or territory legislative requirements, medicines listed in the above schedules are primarily available from pharmacies. In the absence of a pharmacy non-pharmacy retail outlets in remote locations may be licensed to supply Schedule 2 medicines.

Medicines that are exempt from scheduling are available through non-health sector outlets, such as supermarkets and service stations. Although a substance may not be scheduled, it does not indicate that it is 'safe'. Many substances are not scheduled because they have not been referred for consideration.[1]

## Scheduling and Rescheduling Process

Final decisions on scheduling matters lie with the Secretary of the Department of Health and Aged Care (or delegate), with two separate expert scheduling advisory committees to advise the decision-maker/s – one for medicines and the other for chemicals. These committees are:

the Advisory Committee on Medicines Scheduling (ACMS)
the Advisory Committee on Chemicals Scheduling (ACCS)

Applications for the rescheduling of all poisons are subject to a public consultation process, and Commercial-in-Confidence considerations. The Guild examines all proposals to reschedule medicines, and compiles submissions where these proposals are deemed to affect the interests of community pharmacy and public health.

When responding to proposed scheduling amendments, the Guild takes the following approach:

- Medicines within an existing schedule should only be reviewed in light of new evidence relating to the quality use of that medicine.
- Entries in the SUSMP should be unambiguous, ideally with clear limitations to pack size and/or strength rather than therapeutic indication.
- Proposals for scheduling exemptions are not supported, as the availability of medicines through non-pharmacy sectors such as supermarkets and service stations has commoditised the supply of medicines. There are no controls or quality assurance processes in place for the supply of medicines through the non-pharmacy sector.

## Quality Assurance and Staff Training

The *Australian Standard AS85000:2017 – Quality Care Community Pharmacy Standard* is a quality management system to support the provision of consistently high quality health services within community pharmacy. The Quality Care Pharmacy Program (QCPP) is a quality assurance program that accredits community pharmacies against the Australian Standard. More than 94% of Australian pharmacies have achieved quality accreditation with QCPP.[2] QCPP accreditation has been shown to support continuous improvement in the supply of medicines. Additionally, QCPP incorporates a clinical governance framework for implementation by accredited community pharmacies.

As part of QCPP, it is a requirement that all pharmacy assistants involved in the supply of non-prescription medicines must be appropriately trained by an external training provider. This training includes initial and refresher training in supplying non-prescription medicines and teaches the use of protocols such as 'Ask, Assess, Advise' in order to triage patient requests and refer to the pharmacist when appropriate.

### Retaining Schedule 2 and Schedule 3

In 2001, one of the recommendations from the review of Australian medicines regulations against national competition principles (the Galbally Review) was to determine whether the two non-prescription schedules, Schedule 2 and Schedule 3, should be retained.[3]

For many years, the Guild worked with the National Coordinating Committee on Therapeutic Goods (NCCTG) to evaluate the value of having the two non-prescription schedules, utilising collated, de-identified data from the QCPP Mystery Shopper Program as well as data from relevant research projects. The NCCTG, then a sub-committee of the Australian Health Ministers' Advisory Committee (AHMAC), was responsible for the development of a Scheduling Policy Framework for Medicines and Chemicals.

In December 2010, the Guild received official notification from the NCCTG that both Schedule 2 and Schedule 3 would be retained until 2015 while further assessments would be made. The NCCTG acknowledged the changes occurring within community pharmacy since the Galbally Review including the widespread adoption of QCPP and the launch of QCPP 2nd Edition in 2006. It also noted the continuous development of self-care concepts in the primary health care sector and ongoing health workforce reforms such as the establishment of the Pharmacy Board of Australia and its new national standards and guidelines for pharmacists.

The decision to retain the schedules came with a number of recommendations, including:

- ongoing annual reports of Mystery Shopper data
- additional training by 2014 for pharmacy assistants involved in the supply of Schedule 2 medicines

The intention was that these and other considerations would inform NCCTG recommendations to the Australian Health Ministers' Advisory Committee for the ongoing structure of the non-prescription medicine schedules from 2015 onwards. The NCCTG has since been abolished.

## Related Statements

Labelling of Medicines
Supply and Storage of Medicines
Use of Barcode Technology to Assist with Dispensing
Counterfeit Medicines

## Authority

#### Endorsed

National Council – August 2022
National Council – November 2012
National Council – November 2003

#### Reviewed

Policy and Regulation Sub-committee – August 2022
Policy and Regulatory Affairs Committee – October 2012
Government Relations and Policy Committee – February 2010
Strategic Policy/Rural and Professional Services Committee - November 2003