The Pharmacy Guild of Australia

POSITION STATEMENT

Patient Access to Medicines Information

Position

The Pharmacy Guild of Australia (Guild) believes that patients should have reliable access to accurate information about their medicines and how to use them safely and effectively. Patients should also have a choice in the type of advice they receive (oral, written and/or digital), and when and how they receive it. Community pharmacies are the most appropriate location for patients to be provided with reliable information to:

- Improve patients' understanding of their medicines,
- Enhance the quality use of their medicines,
- Increase patients' adherence to their medicines,
- Inform patients of the out of pocket cost of the medicineDispel misinformation about their medicines,
- Reduce medicine misadventure (e.g., taking the wrong dose, not taking it correctly or taking it with incompatible medicines), and
- Optimise patient health outcomes relating to their medicines.

Any health professional involved in prescribing, supplying, administering or reviewing medicines should be able to provide their patients with general information about their medicines, and can refer patients to their local community pharmacist as the medicines expert for any medicine-specific information.

The Guild supports the medicines scheduling system in Australia, which promotes access to information and professional advice from a pharmacist based on the specific risk category of a medicine. Medicine Schedules are published in the Poisons Standard and are given legal effect through state and territory legislation, and medicines are classified according to the level of control over their availability that is needed to protect public health and safety.[1]

Technology

The Guild supports efforts to better use technology to help patients access information about their medicines, and we recommend the use of digital versions where possible, with consideration of the patient's preference. The use of QR codes or similar technology on medicine packaging, dispensing or ancillary labels allows patients to access medicine-related information as a digital version, including in their own language where available.

Consumer Medicines Information

The Guild believes the responsibility for developing and ensuring access to formal patient-focused medicines information such as Consumer Medicines Information (CMI)[2] lies with medicine companies, including through the use of technology.

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CMI is one useful tool for providing patients with medicine-related information but it is not an alternative or replacement for face-to-face counselling. The Guild believes that access to CMI is best guaranteed by the mandatory inclusion of QR codes or similar on medicine packs for patients to scan and access at their convenience.

Providing a CMI at the time of dispensing is at the professional discretion of the pharmacist. The Guild recognises the guidance provided by the Pharmacy Board of Australia[3], Pharmaceutical Defence Limited (PDL)[4] and the Pharmaceutical Society of Australia (PSA)[5] on when it may be appropriate to provide a CMI.

The availability of CMI in formats such as Braille, spoken audio or different languages may be of value to some patients. It is the responsibility of medicine companies to determine the need for these resources and to facilitate access.

The general format and contents of CMI should be regularly reviewed by companies and regulators with input from researchers, clinicians and patient groups to ensure they remain useful, relevant and accessible, especially for patients with a lower level of health literacy. As the representative body for community pharmacy, the Guild would welcome inclusion in such reviews. The Guild believes that user testing or similar activities should be a mandatory requirement for companies to improve and test the effectiveness of their CMI. Currently, it is only an option that is encouraged by the Therapeutic Goods Administration (TGA).[6]

Pharmacy owners have obligations as part of clinical governance to support the safe and effective use of medicines to improve the quality of patient care and ensure their pharmacy is meeting the needs of patients. There should be regular assessment and evaluation of processes within a pharmacy for providing medicines information to patients, including the provision of CMI.

Community Safety

All prescribers and dispensers have a responsibility to raise awareness with their patients if a medicine they are taking could affect their behaviour and put themselves or others at risk, including when a medicine may affect a person's capacity to drive or use machinery. The Guild supports the mandatory inclusion of this information at the time of dispensing or supply via ancillary cautionary advisory labels (CALs) and/or as part of the information on manufacturer packs, including for non-prescription medicines. Pharmacists should also highlight this information when counselling patients using these medicines.

Help Centres

Patients should be able to reliably access government-funded helplines for poisons information and general queries about medicines, and the Guild believes that such helplines are best managed by pharmacists as the medicines experts. Patients accessing helplines with questions about medicines should also be referred to their regular clinician for follow up wherever possible.

Background

There are multiple ways that patients have access to medicine-related information from their community pharmacy, such as:

- Cautions and advice on a manufacturer's pack consistent with regulatory requirements, including for non-prescription medicines[7],
- Clear, concise directions as part of the dispensing label,
- Use of cautionary and advisory labels (CALs) to advise of warnings and risks, such as drowsiness, interactions with alcohol or other medicines, avoiding sun exposure or certain food types,

- When counselling patients at the time of dispensing and/or supplying a medicine,
- When counselling patients during a medicines review such as a MedsCheck or Home Medicines Review, and
- Use of, or referral to, a CMI as part of the counselling process.

Patients have a right to refuse counselling, however pharmacists are legally required to ensure that patients can access written information about their medicine packs through dispensary labels, and ancillary labels where appropriate, that contain sufficient information about how to take the medicine and any risks associated with it.

Labelling Requirements

The Poisons Standard[8] and the state and territory Drugs and Poisons legislation regulate medicine labelling requirements, including the mandatory use of relevant CALs for medicines that can affect a person's ability to drive and operate machinery. Pharmacists are expected to meet legislative labelling requirements and exercise professional judgement when using CALs, including whether to omit a CAL for a particular patient.

Consumer Medicines Information

CMI is the written medicine information for patients that is prepared by the company responsible for the medicine in accordance with requirements set out in the *Therapeutic Goods Regulations 1990*. Regulation requires that CMI is available to patients for Pharmacist Only Medicines (Schedule 3), Prescription Only Medicines (Schedule 4) and Controlled Drugs (Schedule 8).

CMI are one method for pharmacists to provide medicines information to their patients. While it is neither required nor recommended for a CMI to be provided every time a medicine is dispensed, pharmacists should ensure that patients can access CMI, noting that CMI is now digitally available from multiple online sources.

The Pharmaceutical Society of Australia's (PSA) Professional Practice Guidelines[9] and Dispensing Practice Guidelines[10] advise pharmacists on counselling and the provision of medicines information, including CMI. The TGA maintains a searchable online database of CMI for patients and Product Information (PI) for healthcare practitioners.[11]

Related Statements

Packaging and Labelling of Medicines

Authority

Endorsed

National Council – December 2024
National Council – March 2011
National Council – July 2004

Reviewed

Policy and Regulation Sub-Committee – October 2024
Government Relations and GRP Committee, Health Economics Committee – February 2011
Strategic Policy / Rural and Professional Services Committee, Health Economics Committee – June 2004

References

[1] Therapeutic Goods Administration, Scheduling basics of medicines and chemicals in Australia
[2] Consumer Medicines Information (CMI) | Therapeutic Goods Administration (TGA)
[3] Guidelines for dispensing of medicines 2015; www.pharmacyboard.gov.au
[4] Guide to Good Dispensing 2023; www.pdl.org.au
[5] Dispensing Practice Guidelines 2019; www.psa.org.au
[6] Therapeutic Goods Administration, Using the TGA CMI template: Guidance for sponsors
[7] Required Advisory Statements for Medicine Labels (RASML) | Therapeutic Goods Administration (TGA)
[8] Therapeutic Goods Administration, Poisons Standard, Appendix K: Human medicines required to be labelled with a sedation warning
[9] PSA: Professional Practice Guidelines Version 6, 2023
[10] PSA: Dispensing Practice Guidelines 2019
[11] Therapeutic Goods Administration, Information about therapeutic goods in Australia