The Pharmacy Guild of Australia

POSITION STATEMENT

Packaging and Labelling of Medicines

Position

The Pharmacy Guild of Australia (Guild) believes that proper packaging of medicines and labels for dispensed medicines are important for communicating information about medicines to consumers and ensuring effective medicine use. The Guild supports that labels should be easily distinguishable, clear in presentation (including visibility of batch number, expiry date and storage conditions), and suited to the consumer's vision, dexterity, and other characteristics.

The Guild believes that all practitioners should label and package medicines in accordance with Commonwealth, State and Territory legislations, including prescribers supplying starter packs.

Irrespective of the information that is included on a medicine pack or dispensing label, the Guild believes that pharmacists have a responsibility to ensure consumers understand how to use their medicine and that where appropriate, counselling by the pharmacist or other appropriately trained pharmacy staff complements any written instructions.

The Guild supports measures that improve the quality of medicines packaging and minimise the risk of consumer medicines misadventures. The following medicine packaging and labelling issues have significant relevance to community pharmacy practice and patient care:

- Pack size.
- Pharmacist dispensing label space and internal packs.
- Active ingredient prescribing.
- Colour and design of medicine packs (including similarity between packs).
- Child Resistant Packaging.
- Industry-wide use of barcodes.
- Dose Administration Aids.

Pack size

Medicines should ideally be available from a pharmacy in packs of suitable quantities to allow for a single course of treatment. Packs of non-prescription medicines, particularly medicines which are exempt from scheduling should be restricted to the minimum amount required to treat a condition. These medicines should be prevented to be given out in quantities which can result in accidental or deliberate overdose.

Medicine packs should be available in a size, shape and design that allow for the inclusion of essential information in a readable font with specific consideration for the needs of more vulnerable consumer groups, such as visually impaired, the elderly and people of a culturally and linguistically diverse background.

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Pharmacist Dispensing Label Space

Prescription Only Medicines (S4), Controlled Drugs (S8) and all medicines listed on the PBS should be provided in packs that allow adequate space for a pharmacist dispensing label without covering essential information required by the Therapeutic Goods Order No.91 – *Standards for labels of prescription and related medicines*.

The Guild considers that the Therapeutic Goods Administration (TGA) registration process for S4, S8 or other PBS-listed medicines should ensure packaging with adequate space for a dispensing label to be attached to the primary packaging; this is particularly important to reduce the risk of patients discarding dosing instructions where a medicine contains inner and outer packaging. Small containers medicines like eye/nose/ear drops and creams and ointments should be packaged to allow pharmacists to attach as a minimum a 'flagged' dispensing label without obscuring essential information.

Given that the professional recommendation[1] is for pharmacists to attach a dispensing label to primary medicine packs, including each component for multi-therapy packs (e.g., Nexium HP7), the Guild believes:

- The design of inner packaging should enable dispensing labels to be attached without obscuring essential information or compromising storage conditions (e.g., Symbicort inhalers, Duotrav eye drops), and
- The design of outer and inner packaging should allow dispensing labels to be affixed to packaging that is not subsequently discarded by the consumer once opened for use.

Active Ingredient Prescribing

Active Ingredient Prescribing (AIP) means that most medicines will be prescribed by their active ingredient and not brand name. This initiative supports safe prescribing, dispensing and appropriate use of medicines.[2] The Guild believes that the way ingredients are written on a prescription, need to be aligned to the medicine label to reduce ambiguity, especially for medicines which contain more than one active ingredient. This could also extend to dispensing software and how the ingredients are presented for selection.

Colour and design of medicine packs

The Guild's preference is for prescribed medicines to be supplied in cartons rather than bottles with product name, strength and form included on at least 3 of the 4 side panels to enable easy identification on dispensary shelves. Packaging of all medicines should be distinctive so that the potential for confusion in all supply processes is minimised. Distinctive packaging also enables pharmacists to readily distinguish all products with respect to:

- different active ingredients
- the same active ingredient/s, but different strengths, and
- the same active ingredient/s, but different dose forms.

The Guild supports the use of colour and design that does not unnecessarily clutter or obscure the information on the labels but makes it clear and distinguishable. The Guild also supports relevant user testing tailored to the needs of the particular user group before extensive changes to presentation are introduced.

To avoid the registration of medicine packs with similar designs, the Guild believes that all packaging and labelling applications submitted to the TGA should be reviewed by a practising community pharmacist in order to identify potential safety issues.

Child Resistant Packaging

The Guild recognises the importance of appropriate packaging to restrict access to medicines by children in order to minimise the risk of paediatric poisoning. The Guild supports relevant regulatory instruments for child resistant packaging of medicines[3]. The Guild notes that child resistant packaging may present problems to consumers with dexterity issues, therefore pharmacists should have the professional discretion to supply medicines in containers that allow easy access if needed.

Industry-wide use of barcodes

The Guild supports the industry-wide use of barcodes as a quality assurance mechanism within the dispensing process to minimise the risk of dispensing errors which could compromise patient safety and to facilitate faster identification and resolution of manufacturing quality assurance issues. The Guild supports the use of two-dimensional barcodes, also known as a Quick Response or QR code, as a means to provide information to patients about their medicines e.g. Consumer Medicines Information (CMI). Inclusion of QR codes linking to CMIs on medicine packages will also make information more accessible for consumers. The QR codes can also help pharmacies with stock management if it contains information such as expiry date and batch number and can improve processes and efficiency with stock recalls and returns.

Dose Administration Aids (DAAs)

The Guild recognises that DAAs are an effective medicine packaging device that assists at-risk community-based consumers to manage their medicines and avoid medication mismanagement. The Guild supports the exemption of DAAs from packaging and labelling regulations as it is more appropriately managed by the profession.

Regulatory considerations of Labelling

The Guild supports the existing system of mandatory labelling of medicines. In general, the Guild supports the development of the 'performance-based labelling alternative'. However, mandatory labelling is required as a minimum standard to ensure that consumers can read and understand the information on medicine labels.

The Guild is aware that health literacy is a general population concern and that some medicine labels require a level of literacy above the population average in order to be understood. The Guild supports regulatory processes that ensure that medicine labels are able to be read and understood by Australian consumers with an average reading age, which at present is equivalent to that of 12 years of age.

The Guild endorses the use of medicine packaging of sufficient size to accommodate all the information required by legislation (including any dispensing label) in a print size that all consumers can read and understand.

The clear communication of batch numbers and expiry dates on medicine packaging is essential to ensure safe pharmacy practice. The Guild believes that all embossed expiry dates and batch numbers should be inked to facilitate ease of reading.

Many scheduled medicines have the potential to cause harm and where this poses a risk to consumers through incorrect use or interaction with other substances, or accidental poisoning in children, the consumer is entitled to be alerted to the hazard through label information and/or education campaigns. Indicating potential harm due to toxicity also reinforces the public safety concept that medicines are not normal items of trade, and should be regarded with caution, stored safely, and used appropriately.
The Guild believes that labels of medicines considered of greater risk of accidental or deliberate misuse should carry a reference to the national '13 11 26' Help number of the Poisons Information Centre[4].

Pharmacy practice considerations

When dispensing, pharmacists should label dispensed medicines in accordance with relevant State/Territory and Commonwealth legislation as well as relevant professional practice and quality standards and guidelines, including:

- the latest edition of the *Australian Pharmaceutical Formulary and Handbook* (APF)[5],
- the Pharmaceutical Society of Australia (PSA) Professional Practice Standards[6], and
- the Quality Care Pharmacy Program (QCPP)[7] Standard.

The pharmacy dispensing label should be affixed so that generic and brand names, batch number, strength, expiry date, storage requirements, product advice, bactericides/preservatives are left visible where possible. Ideally, dispensing labels should be affixed to dedicated blank label spaces when available.

The pharmacy label should not contain 'use as directed' or equivalent instructions. The label should reiterate the prescriber's instructions in clear and easy-to-understand English.

Cautionary Advisory Labels should be affixed to labels of dispensed medicines in accordance with APF recommendations and The Poisons Standard (SUSMP)[8]. Affixing such labels does not absolve the pharmacist from counselling the consumer on the proper use of the medicine and of other relevant information. Pharmacist should ensure that patients can access *Consumer Medicines Information* (CMI) about their medicine in hard-copy or digital form depending on the patient's wishes. The Guild supports the TGA eBusiness Service CMI database[9] being the single source of truth for up to date CMIs.

Social Position

The Guild supports responsible packaging of medicines. The Guild recognises that medicines must be packed to ensure the integrity of the medicine by protection from environmental factors such as moisture, oxidation and UV exposure, as well as preventing access by children. However, we believe companies should use fully recyclable packaging materials to reduce any unnecessary waste (e.g. a bottle of tablets inside a carton) and be environmentally responsible through initiatives like the Forest Stewardship Council (FSC) certification.[10] The Guild also supports the responsible and preferably recyclable disposal of medicine packaging. The Guild believes there is a need for a service that compliments the role of Return of Unwanted Medicines (RUM)[11] to enable recycling of medicine packaging in an efficient way.

Background

Packaging and labelling of medicines should be in accordance with the Commonwealth and State and Territory legislation as it has evolved with consideration of consumer safety. The regulations for the labelling and packaging of medicines are expressed in relevant Commonwealth instruments that support the *Therapeutic Goods Act 1989* including[12]:

- The Poisons Standard (SUSMP).[13]
- Therapeutic Goods Orders (TGO 91[14], 92[15] and 95[3]).
- Therapeutic Goods (Medicines Advisory Statements) Specification 2021.[16]

Mandatory labelling

The current SUSMP has some mandatory provisions on labelling requirements which are prescriptive (for example, print size) and a small number which are 'performance based' (for example, the colour of signal headings should be in distinct contrast to the background colour). Such requirements are readily understood by industry and can be readily upheld in a court of law if the need arises. A 'plain English' review of the SUSMP mandated label statements also indicates that most SUSMP statements should be understood by 12-year-olds.

Performance based labelling

There is, however, a movement towards another form of performance labelling which involves each medicinal product having its label designed by communication experts, then 'market-tested' using accepted protocols for consumer comprehension before final approval by an expert panel. This would replace mandatory requirements and would be a very time-consuming and costly method. Any change will require consultation with the industry, health professionals and consumers.

Incidents that occur as a result of different medicines or different forms or strengths of the same medicine having similar packaging, is of great concern to practising pharmacists. The Guild participates in and responds to reviews of any legislative requirements, advisories, standards or guidelines that impact on medicine packaging.

DAA Labelling

DAA must be labelled in accordance with the Pharmacy Board of Australia's guidelines.[17] The DAA as a minimum must have the patient's name, address of the pharmacy, name, strength and dose of medicines, any required cautionary and advisory labels, packing and expiry dates, storage instructions and the words "Keep out of reach of children".

Authority

Endorsed

National Council – July 2024
National Council – March 2010
National Council – March 2005

Reviewed

February 2024 – Practice, Policy and Regulations Sub-Committee
February 2010 – Government Relations and Policy Committee
February 2005 – Strategic Policy/Rural and Professional Services Committee

References

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[6] Professional Practice Standards | Pharmaceutical Society of Australia (psa.org.au)
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[8] Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023 (legislation.gov.au)
[9] TGA eBusiness Services
[10] What the FSC Labels Mean | Forest Stewardship Council
[11] About the RUM Project | Return of Unwanted Medicine (returnmed.com.au)
[12] Labelling & packaging | Therapeutic Goods Administration (TGA)
[13] Therapeutic Goods (Poisons Standard—July 2023) Instrument 2023 (legislation.gov.au)
[14] Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines (legislation.gov.au)
[15] Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (legislation.gov.au)
[16] Federal Register of Legislation - Australian Government
[17] Pharmacy Board of Australia, Guidelines on Dose Administration Aids and Staged Supply of Dispensed Medicines, September 2015