Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation on temporary labelling exemptions for paracetamol

Pharmacy Medicine (S2) and Pharmacist Only (S3) products

Version 1.1, September 2024

Contents

Invitation to comment

In May 2023, a final decision was made to change the scheduling of certain paracetamol products with the aim of minimising the harm from intentional overdose. These changes are due to take effect on 1 February 2025.

The Therapeutic Goods Administration (TGA) is seeking views from interested parties on a proposal for granting temporary labelling exemptions for certain paracetamol products to support the transition. This proposal has been developed with input from state and territory jurisdictions.

The forthcoming scheduling changes for paracetamol will:

- reduce the maximum size of packs available for general sale (e.g. supermarkets and convenience stores) from 20 to 16 tablets or capsules
- reduce the maximum size of packs available in pharmacies **without** the supervision of a pharmacist (i.e. 'Pharmacy Medicine' packs) from 100 to 50 tablets or capsules
- make other pack sizes of up to 100 tablets or capsules available only **under the supervision** of a pharmacist ('Pharmacist Only' medicines).

These changes will apply to products containing paracetamol as the only active ingredient, and also to some that are combination products (such as cold and flu preparations) that contain paracetamol and other ingredients.

Sponsors were provided a 21-month transition period to prepare for these changes. Organisations representing sponsors and retailers have advised that due to the substantial size of the market, wide distribution of products across Australia, and supply logistics, it is anticipated that there will be some product inventory held by wholesalers, dealers and pharmacies that will have non-compliant signal wording after 1 February 2025. These products will still meet requirements for safety, quality and efficacy.

In Australia, signal words are mandatory on medicine packaging to indicate the level of control required for the supply of the medicine. The proposed exemptions will allow pharmacies and wholesalers to store and supply remaining stock with non-compliant signal words on the package after 1 February 2025, without the need for repacking or over-labelling. This will also allow wholesalers to keep accepting stock from sponsors or the return of stock from retailers.

In practice, this means some Pharmacist Only (Schedule 3) products will not have the 'Pharmacist Only Medicine' signal words, but instead have the current 'Pharmacy Medicine' signal words that are on Schedule 2 medicine labels. It also means some Pharmacy Medicine (Schedule 2) products will not have the 'Pharmacy Medicine' signal words, but instead have no signal words as they were unscheduled.

The proposed exemptions will also allow pharmacies to supply newly labelled Pharmacist Only (Schedule 3) products in anticipation of the changes to the Poisons Standard, before 1 February 2025.

The supply of these products will need to be in accordance with their new labels.

Proposed exemptions

Signal word exemptions are proposed to be made through the granting of an exemption from labelling requirements under section 39 of the Poisons Standard (Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024). A labelling exemption granted through the TGA in the Department of Health and Aged Care will automatically apply, or be able to be recognised, through relevant state and territory legislation. The exemptions are proposed to apply to any product affected by the scheduling change (for example, single active products and certain combination products).

The 3 proposed exemptions are as follows:

Proposal 1 – Exemption of certain Schedule 2 products from requiring signal words

This proposal will allow a person licensed or authorised to supply Schedule 2 medicines to store and supply:

a. paracetamol tablets or capsules each containing 500 mg or less of paracetamol in blister or strip packaging enclosed in a primary pack containing not more than 20 tablets or capsules, which have been packed and labelled for general sale (that is, without labelling with signal words) despite being a Schedule 2 substance.

For example, this will allow remaining inventory of 20 tablet or capsule paracetamol packs that had been available for general sale (i.e. with no signal heading) to be sold in pharmacies from 1 February 2025.

Products exempted from this labelling requirement must be sold in accordance with other controls for Schedule 2 medicines, despite the products having no signal words (as they were unscheduled).

Proposal 2 - Exemption of certain Schedule 3 products from requiring signal words

This proposal will allow a person licensed or authorised to supply Schedule 3 medicines to store and supply:

a. Paracetamol tablets or capsules each containing 500 mg or less of paracetamol packed in a container **without** blister or strip packaging in a primary pack containing not more than 20 tablets or capsules, which have been packed and labelled for general sale (that is, without labelling with signal words) or above 20 tablets or capsules, which have been packed and labelled as a Schedule 2 substance, despite being a Schedule 3 substance.

For example, this will allow remaining inventory of 20 tablet or capsule paracetamol bottles that had been sold in general sale to be available from behind the counter in pharmacies after 1 February 2025.

b. Paracetamol tablets or capsules each containing 500 mg or less of paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules, which were packed and labelled as a Schedule 2 substance (that is, labelled 'PHARMACY MEDICINE') despite being a Schedule 3 substance.

For example, this will allow remaining inventory of Schedule 2 labelled packs above 50 tablets or capsules of paracetamol to continue to be sold but under controls required for a Schedule 3 substance after 1 February 2025.

c. Paracetamol in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules, which have been packed and labelled as a Schedule 2 substance (that is, labelled 'PHARMACY MEDICINE') despite being a Schedule 3 substance.

For example, this will allow remaining inventory of packs containing up to 50 wrapped powders or sachets of granules containing paracetamol that had been usually available on the shelf at pharmacies to be available from behind the counter after 1 February 2025.

d. Paracetamol in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine pack and labelled ‘For dispensing only’ and ‘This pack is not to be supplied to a patient’, which have been packed and labelled as a Schedule 2 substance (that is, labelled 'PHARMACY MEDICINE') despite being a Schedule 3 substance.

For example, this will allow remaining inventory of bulk medicine paracetamol packs that had been dispensed with Schedule 2 signal words to continue to be available from behind the counter after 1 February 2025.

e. Paracetamol in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules intended only as a bulk medicine pack and labelled ‘For dispensing only’ and ‘This pack is not to be supplied to a patient’,

which have been packed and labelled as a Schedule 2 substance (that is, labelled 'PHARMACY MEDICINE') despite being a Schedule 3 substance.

For example, this will allow remaining inventory of bulk medicine packs of wrapped powders or sachets of granules paracetamol that had been dispensed with Schedule 2 signal words to continue to be available from behind the counter after 1 February 2025.

Products exempted for these labelling requirements must be sold in accordance with other controls for Schedule 3 medicines (including the requirements for a Product Information (PI) and Consumer Medicines Information (CMI) to be available), despite the product being labelled as unscheduled or as a Schedule 2 medicine.

Proposal 3 – Early introduction of products that will be Schedule 3 from 1 February 2025

This proposal will allow a person licensed or authorised to store and supply Pharmacist Only (Schedule 3) medicines to supply products that will be Schedule 3 after 1 February 2025 but are currently Pharmacy Medicine (Schedule 2) products, before the changes are made in the Poisons Standard.

A condition of registration would be imposed under section 28(2B) of the Therapeutic Goods Regulations 1990, that sale of these products before 1 February 2025 would need to comply with controls for a Schedule 3 medicine to align with the signal words on the package.

It is expected that sponsors will have submitted the Product Information (PI) and Consumer Medicines Information (PMI) for these products as part of the registration process.

Exemption period

The exemption period available for Proposals 1 and 2 is 12 months (that is until 31 January 2026).

The exemption period for Proposal 3 would be from the date of commencement until 31 January 2025 (after which the new scheduling changes will occur and affected products will become compliant with labelling requirements).

State and Territory legislation

ACT	Under section 193 of the *Medicines, Poisons and Therapeutic Goods Act 2008*, the Australian Capital Territory can approve non-standard packaging and labelling. In addition, regulation 502(b) of the Medicines, Poisons and Therapeutic Goods Regulations 2008 provides for supply of a medicine labelled in accordance with a corresponding law.
NSW	A labelling exemption issued by the Commonwealth (through section 39 of Part 2 of the Poisons Standard) applies automatically in New South Wales law through subclauses 10(3) and 28(3) of the NSW Poisons and Therapeutic Goods Regulation 2008 (as well as through subclauses 7 (1) (a) and 26 (1)(a) of the Regulation and through Section 31 of the NSW *Poisons and Therapeutic Goods Act 1966*).
NT	Under the *Medicines, Poisons and Therapeutic Goods Act 2012*, and regulation 34 of the Medicines, Poisons and Therapeutic Goods Regulations 2014, the Northern Territory recognises exemptions from labelling requirements that exist under another corresponding law.
QLD	Subregulation 237(4) and 237(5) of the Medicines and Poisons (Medicines) Regulation 2021 allows an appropriate authority which has approved an alternate way of labelling or packaging of medicines to be taken as an approved alternate way in Queensland (unless it is published that the other exemption is not approved).

SA	Under section 26(7) and 26(8) of the South Australian Controlled Substances (Poisons) Regulations 2011, the Minister for Health and Wellbeing (or delegate) may grant an exemption from requirements of section 24 (b) or (c) of the *Controlled Substances Act 1984* which detail the packaging and labelling requirements for scheduled medicines in South Australia. Exemptions can be granted directly or by reference. In addition, if one jurisdiction grants a labelling exemption, the other jurisdictions will recognise the exemption provided it is granted for less than 12 months.
TAS	Tasmania adopts the Part 2 of the Poisons Standard with respect to packaging and labelling requirements (Regulation 109 - Application of provisions of Uniform Standard of the Poisons Regulations 2018). A label exemption granted to a sponsor by the relevant appropriate authority in the sponsor's jurisdiction or by the TGA in accordance with Part 2, section 39 of the Poisons Standard would also apply in Tasmania.
VIC	Any labelling exemption for Victoria could be granted while considering the *Victorian Drugs, Poisons and Controlled Substances Act 1981.* After a labelling exemption is issued under section 39 of the Commonwealth Poisons Standard and sent to each jurisdiction, the Victorian Department of Health can then endorse/approve and implement the labelling exemption.
WA	Western Australia adopts Part 2 of the national Poisons Standard with respect to packaging and labelling requirements (Regulation 82 of the Medicines and Poisons Regulations 2016). A label exemption issued in accordance with part 2, section 39 of the Poisons Standard would automatically apply in WA.

Consultation timetable

Consultation commences on **Monday, 16 September 2024**

Interested parties should respond by close of business **Monday, 30 September 2024.**

Submissions

While the consultation is open you can make a submission at our consultation hub.

We review the submissions. After that the submissions and our decision will be available on the same consultation page.

Privacy information

The TGA collects your personal information in this submission to:

- contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available.
- help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).

The TGA will disclose your name and (if applicable) your designation/work title publicly on the consultation hub if you consent to publication.

Any text within the body of your submission that is to remain confidential should be marked ‘IN CONFIDENCE'.

Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

Enquiries

Any questions relating to submissions should be directed by email to medicines.scheduling@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Scheduling and Chemicals Policy Section	September 2024
V1.1	Update to publication of submissions from TGA website to consultation hub.	Scheduling and Chemicals Policy Section	September 2024

Therapeutic Goods Administration

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