Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard in relation to paracetamol – ACMS meeting, November 2022

14 September 2022

TGA Health Safety Regulation

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

Contents

1 About this consultation

Subdivision 3D.2 of the *Therapeutic Goods Regulations 1990* (the **Regulations**) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act 1989* (the **Act**) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals in relation to paracetamol referred to the November 2022 meeting of the Advisory Committees on Medicines Scheduling (**ACMS**). Submissions must be received by close of business **14 October 2022.**

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS).

This consultation closes on 14 October 2022

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

2 Proposed amendments referred for scheduling advice to ACMS meeting #40, November 2022

Paracetamol

Introduction

The TGA is seeking public comment about whether the current scheduling of paracetamol is appropriate considering available data on paracetamol poisoning, including intentional overdose, and associated hospitalisations and deaths. Comment is specifically sought on a variety of options that the delegate of the Secretary of the Department of Health and Aged Care (the Delegate) has proposed for amending the Poisons Standard in relation to paracetamol. These are proposed in view of the findings and recommendations in the independent expert report on intentional paracetamol self-poisoning that was commissioned by the TGA. However it is emphasised that the TGA seeks open feedback on each of these options and does not have a view at this stage on the merits or otherwise of any particular options.

CAS number

103-90-2

Alternative names

Acetaminophen, 4-Acetamidophenol and N-(4-Hydroxyphenyl) acetamide

Applicant

Delegate of the Secretary of the Department of Health and Aged Care (Delegate-initiated proposal).

Current scheduling

Paracetamol is currently listed in Schedules 2, 3 and 4, and Appendix F, Part 3 and H, of the Poisons Standard as follows:

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more thann100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules enclosed in a primary pack containing not more than 100 tablets or capsules; or

d) 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'; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules; or

f) 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'; or

g) in other preparation **except**:

i. when included in Schedule 3 or 4; or

ii. in individually wrapped powders pr sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules,

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(C) not labelled for the treatment of children 6 years or age or less, and

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin; or

iii. in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure,

(B) in a primary pack containing not more than 20 tablets or capsules,

(C) complaint with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, and

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin.

Appendix F, Part 3

97 - Adults: Keep to the recommended dose. Don't take this medicine for longer than a few days at a time unless advised to by a doctor.

and/or

98 - Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor.

99 - If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26; New Zealand 0800 764 766) or go to a hospital straightaway even if you feel well because of the risk of delayed, serious liver damage.

100 - Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

Appendix H

PARACETAMOL.

INDEX

PARACETAMOL
cross reference: ASPIRIN, IBUPROFEN, METOCLOPRAMIDE, SALICYLAMIDE, CAFFEINE

Schedule 4
Schedule 3
Schedule 2
Appendix F, Part 3
Appendix H

Summary and rationale of proposed changes

The Delegate has proposed a number of different options for amending the Poisons Standard that could be made alone or in combination to mitigate the risks of paracetamol poisoning. Following the public consultation and subsequent advice from the ACMS, the Delegate will make an interim decision that may incorporate one or more of these options.

Neither the TGA nor the Delegate have formed a view at this time as to which option(s) should be implemented or are preferred.

- ***Requirement for blister packs***. It is slower to consume paracetamol tablets or capsules that must be individually ejected from blister or strip packs as compared to other packaging (e.g. bottles). Slowing the consumption of multiple tablets or capsules by restricting these dosage forms to being presented in blister or strip packs may reduce the likelihood of overdose and harm from impulsive attempts to self-poison.
- ***Pack size restrictions.*** For example, maximum pack sizes for unscheduled products reduced from 20 to 12 or 16 tabs; S2 pack sizes reduced from 100 to 24 or 32. This would reduce the number of grams of paracetamol held in homes and thus the numbers of very large overdoses taken in impulsive self-poisonings.
- ***Pack number limits***. Most (~95%) sales of paracetamol tablets involve the purchase of 1 or 2 packs. Making this the maximum number of packs that can be purchased in one transaction would reduce home stockpiles, and likely also reduce the number of very large overdoses, which have much higher morbidity and risk of death.
- ***Sale from behind the counter***. The prohibition of display and self-selection of paracetamol in general (non-pharmacy) retail outlets may discourage impulsive purchasing by those vulnerable to overdosing with paracetamol.
- ***Modified Release paracetamol restrictions.*** This product is designed for long-term use (e.g., for osteoarthritis), rather than for acute pain. Prescription only (S4) scheduling would

be expected to reduce inappropriate use of this product which is harder to treat in overdose than immediate release paracetamol.

- ***Age restrictions.*** An 18+ age restriction on the purchasing of over-the-counter analgesics would be expected to reduce poisonings among 10-17 year-olds.

Proposed scheduling

Note:

- the proposed options for amending different Schedules of the Poisons Standard are grouped together by type of control (e.g. pack size limits) for simplicity of presentation in this notice. However the individual options (A, B, …) under each parent option (1, 2, ..) could be considered individually or in combination.
- proposed additions to schedule entries are in green text and proposed deletions are in red text.

Options 1A-C: Blister packs

Description

Solid dose paracetamol (tablets/capsules) made available only in blister packs (not loose dose units):

- Option 1A: for general sale preparations only (amendment to Schedule 2 entry, paragraph g);
- Option 1B: for general sale and pharmacy preparations only (amendment to Schedule 2 entry, paragraphs c) and g));
- Option 1C: for pharmacist only, pharmacy and general sale preparations (amendment to Schedule 3 entry, paragraph b) and Schedule 2 entry, paragraphs c) and g)).
- Option 1D: for prescription only, pharmacist only, pharmacy and general sale preparations (amendment to Appendix D, Schedule 3 entry, paragraph b), and Schedule 2 entry, paragraphs c) and g))

Proposed amendments

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules in blister or strip packaging containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules in blister or strip packaging enclosed in a primary pack containing not more than 100 tablets or capsules; or

d) 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’; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules; or

f) 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’; or

g) in other preparations **except**:

i) when included in Schedule 3 or 4; or

ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules,

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(C) not labelled for the treatment of children 6 years of age or less, and

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin; or

iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging ~~or in a container with a child-resistant closure~~,

(B) in a primary pack containing not more than 20 tablets or capsules,

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, and

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin.

Appendix D – new entry

11.	**Poisons which must be packed in blister or strip packaging:**
	PARACETAMOL in tablets or capsules.

Options 2A-B: Pack size

Description

Reductions in the maximum paracetamol pack size sold in Australian retailers:

- Option 2A: for general sale preparations, to be reduced to 10 x 500 mg tablets/capsules or 5 individually wrapped sachets (amendment to Schedule 2 entry, paragraphs g) (ii)(A) and (iii)(B));
- Option 2B: for pharmacy only medicines, to be reduced to 32 x 500 mg tablets/capsules or 16 individually wrapped sachets (amendments to Schedule 2 entry, paragraphs f) and g) and Schedule 2 entry, paragraphs c), g)(ii)(A) and (iii)(B)).

Proposed amendments

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 32 ~~100~~ tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 16 ~~50~~ wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules

intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules enclosed in a primary pack containing not more than 32 ~~100~~ tablets or capsules; or

d) 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'; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 16 ~~50~~ wrapped powders or sachets of granules; or

f) 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'; or

g) in other preparations **except**:

i) when included in Schedule 3 or 4; or

ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than ~~10~~ 5 such powders or sachets of granules,

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(C) not labelled for the treatment of children 6 years of age or less, and

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin; or

iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure,

(B) in a primary pack containing not more than 10 ~~20~~ tablets or capsules,

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, and

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin.

Options 3A-B: Restrictions on the purchasing of multiple packs

Description

Allowing only one pack to be purchased at a time when purchased in the following retail settings:

- Option 3A: without a prescription in pharmacies (amendment to Schedule 2 entry paragraphs c) and e)), or
- Option 3B: in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)).

Proposed amendments

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules enclosed in a primary pack containing not more than 100 tablets or capsules and, at the place where primary packs are offered for sale to the public, supply is limited to one primary pack of paracetamol per person; or

d) 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’; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules, and, at the place where primary packs are offered for sale to the public, supply is limited to one primary pack of paracetamol per person; or

f) 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’; or

g) in other preparations **except**:

   i) when included in Schedule 3 or 4; or

   ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules,

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(C) not labelled for the treatment of children 6 years of age or less, ~~and~~

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin, and

(E) and, at the place where primary packs are offered for sale to the public, supply is limited to one primary pack of paracetamol per person; or

iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure,

(B) in a primary pack containing not more than 20 tablets or capsules,

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, ~~and~~

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin~~,~~ and

(F) and, at the place where primary packs are offered for sale to the public, supply is limited to one primary pack of paracetamol per person.

Option 4: Sale from behind the counter

Description

Display and self-selection of paracetamol in non-pharmacy outlets to no longer be permitted.

Proposed amendment

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules enclosed in a primary pack containing not more than 100 tablets or capsules; or

d) 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’; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules; or

f) 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'; or

g) in other preparations **except**:

i) when included in Schedule 3 or 4; or

ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules,

(B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(C) not labelled for the treatment of children 6 years of age or less, ~~and~~

(D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin, and

(E) at the place where primary packs of paracetamol are offered for sale to the public, the primary packs are not visible to the public from inside or outside the place, and are only available on request; or

iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure,

(B) in a primary pack containing not more than 20 tablets or capsules,

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, ~~and~~

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin, and

(F) at the place where primary packs of paracetamol are offered for sale to the public, the primary packs are not visible to the public from inside or outside the place and are only available on request.

Option 5: Age restrictions

Description

The minimum age of purchase to be restricted to those 18 years and over:

- Option 5A: in pharmacies (amendment to Schedule 2 entry paragraphs c) and e)), or
- Option 5B: in outlets other than pharmacies (amendment to Schedule 2 entry paragraph g)).

Proposed amendments

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules containing more than 665 mg paracetamol;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or

c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or

d) in liquid preparations for oral use **except** when in Schedule 2.

Schedule 2

PARACETAMOL for therapeutic use:

a) in liquid preparations for oral use containing a maximum of 10 g of paracetamol per container; or

b) when combined with ibuprofen in preparations for oral use when labelled with a recommended daily dose of 1200 mg or less of ibuprofen in divided doses in a primary pack containing no more than 12 dosage units per pack; or

c) in tablets or capsules enclosed in a primary pack containing not more than 100 tablets or capsules and, at the place where primary packs are offered for sale to the public, supply is limited to persons aged 18 years of age or over; or

d) 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'; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing not more than 50 wrapped powders or sachets of granules, and, at the place where primary packs are offered for sale to the public, supply is limited to persons aged 18 years of age or over; or

f) 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'; or

g) in other preparations **except**:

  i) when included in Schedule 3 or 4; or

  ii) in individually wrapped powders or sachets of granules each containing 1000 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine, phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

    (A) enclosed in a primary pack that contains not more than 10 such powders or sachets of granules,

    (B) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

    (C) not labelled for the treatment of children 6 years of age or less, ~~and~~

    (D) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin, and

    (E) and, at the place where primary packs are offered for sale to the public, supply is limited to persons aged 18 years of age or over; or

  iii) in tablets or capsules each containing 500 mg or less of paracetamol as the only therapeutically active constituent (other than caffeine,

phenylephrine and/or guaifenesin or when combined with effervescent agents) when:

(A) packed in blister or strip packaging or in a container with a child-resistant closure,

(B) in a primary pack containing not more than 20 tablets or capsules,

(C) compliant with the requirements of the Required Advisory Statements for Medicine Labels,

(D) not labelled for the treatment of children 6 years of age or less, ~~and~~

(E) not labelled for the treatment of children under 12 years of age when combined with caffeine, phenylephrine and/or guaifenesin~~.~~ and

(F) and, at the place where primary packs are offered for sale to the public, supply is limited to persons aged 18 years of age or over.

Option 6: Modified release paracetamol

Description

All modified release paracetamol is rescheduled from Schedule 3 to Schedule 4, without change to maximum pack size.

Proposed amendment

Schedule 4

PARACETAMOL:

a) when combined with aspirin or salicylamide or any derivative of these substances **except** when separately specified in these Schedules;

b) when combined with ibuprofen in a primary pack containing more than 30 dosage units;

c) in modified release tablets or capsules ~~containing more than 665 mg paracetamol~~;

d) in non-modified release tablets or capsules containing more than 500 mg paracetamol;

e) in individually wrapped powders or sachets of granules each containing more than 1000 mg paracetamol;

f) in tablets or capsules enclosed in a primary pack containing more than 100 tablets or capsules except in Schedule 2 or Schedule 3;

g) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 50 wrapped powders or sachets of granules except when included in Schedule 2;

h) for injection;

i) for the treatment of animals.

Schedule 3

PARACETAMOL:

a) when combined with ibuprofen in a primary pack containing 30 dosage units or less **except** when included in Schedule 2; or

~~b) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing not more than 100 tablets or capsules; or~~

~~c) in modified release tablets or capsules containing 665 mg or less paracetamol enclosed in a primary pack containing more than 100 tablets or capsules intended only as a bulk medicine and labelled 'For dispensing only' and 'This pack is not to be supplied to a patient'; or~~

in liquid preparations for oral use **except** when in Schedule 2.

Background

- Paracetamol is the most widely used over the counter (OTC) analgesic agent in the world. While paracetamol has well established favourable safety and toxicity profiles, the wide use is paralleled by a high prevalence of accidental paracetamol poisoning in the community in both adults and children.
- The TGA has been aware of concerns, particularly of families of affected consumers of paracetamol, regarding the number of poisonings and deliberate overdoses from paracetamol obtained from general retail outlets without restrictions to children and adolescents.

Paracetamol scheduling history

- In 2012, pack sizes of paracetamol that could be sold in retail outlets other than pharmacies were restricted through the Poisons Standard to a maximum of 20 tablets or capsules, and no more than 10 g of paracetamol per pack.
- In 2016, the pack size of paracetamol available from pharmacy outlets was restricted to no more than 100 tablets or capsules per pack.
- Limits have been placed, through the Poisons Standard, on the pack size and strengths of paracetamol and ibuprofen allowed for general retail sale. These restrictions aim to minimise the risks to public health; however, the Poisons Standard does not currently specify limits on the number of packs sold by general retail outlets nor does it place any controls on display for sale. Any additional restrictions needs to be balanced with whether there would be a broader impact on consumer access.
- Modified release (MR) paracetamol was previously up-scheduled from Schedule 2 (Pharmacy Only) to Schedule 3 (Pharmacist Only), effective from 1 June 2020. MR paracetamol supply is therefore only available with pharmacist approval, a necessary oversight given that antidotes for MR paracetamol poisoning are not as effective as for immediate release (IR) paracetamol.

Comparison with other OTC analgesics on general sale

- Although considered relatively benign at normal therapeutic doses, the toxic (and fatal) doses of paracetamol are considerably lower than the other two main OTC analgesics,

ibuprofen and aspirin. A 2019 Australian – NZ study[1] found that about one-quarter of paracetamol overdose patients died in hospital after a median ingested dose of 30 g (which is only 10 times the maximum daily recommended dose of IR paracetamol), and the equivalent of three packs available in supermarkets or convenience stores.

- In contrast, a review of aspirin toxicity indicated that reports of lethal doses of aspirin ranges from 480 to 800 mg/kg.[2] In a 70 kg adult this equates to 34-56 g, the equivalent of 5-8 packs available in supermarkets or convenience stores.
- Ibuprofen is also rarely fatal in overdose, with a small number of reports of fatalities after ingestion of 36 -105 g in adults, the equivalent of 7.5-22 packs available in supermarkets or convenience stores.[3]
- The differences between the three analgesics are reflected in fatality data. For example, in the July 2021 Coroners Court of Victoria report on Victorian overdose deaths 2011-20, there was an average of 36 paracetamol overdose deaths annually reported in Victoria alone, compared to 4 ibuprofen overdose deaths per year and no reports for aspirin. In addition, 52 % of admissions to liver transplant centres in Australia are attributed to paracetamol overdoses.[4]

Independent expert report on the risks of intentional self-poisoning with paracetamol

- An independent report was commissioned by the TGA in May 2022. The review was led by a panel comprised of Professors Nicholas Buckley (University of Sydney and NSW Poisons Information Centre), Alison Calear (Centre for Mental Health Research, Australian National University) and Helen Christensen (Black Dog Institute, University of New South Wales), with expertise in pharmacology, toxicology and mental health.
- The report was commissioned to examine the rate of serious injury and death from intentional paracetamol overdose and to understand whether the current access controls for purchasing paracetamol products are appropriate, particularly in younger more vulnerable groups in the community.
- In addition, the panel assessed whether stricter controls on access to paracetamol were implemented, individuals would likely seek other means for self-harm. However, assessment of the international literature and experience of the authors suggested that this was not likely.
- The panel found that the rates of intentional paracetamol overdose were highest among adolescents and young adults, and more common among females, further highlighting the need to develop targeted interventions to help younger people. Survival rates from paracetamol overdose are excellent, but only where medical treatment is sought within 2-6 hours after ingestion. If treatment is delayed after ingesting high doses of paracetamol, there is a risk of serious liver injury, and sometimes death. Treatment of overdose is also more challenging following ingestion of modified release paracetamol than immediate release paracetamol.

[1] Warrillow, S, *et al.* (2019). Characteristics, management and outcomes of patients with acute liver failure admitted to Australian intensive care units. Critical Care and Resuscitation. 21(3): 188-199

[2] Chyka, P.A, *et al.* (2007). Salicylate poisoning: An evidence-based consensus guideline for out-of-hospital management. Clinical Toxicology. 45(2), 95-131. DOI: http://dx.doi.org/10.1080/15563650600907140

[3] Hunter, L.J, Wood, D.M, and Dargan P.I. (2011). The patterns of toxicity and management of acute nonsteroidal anti-inflammatory drug (NSAID) overdose. Open Access Emerg Med, 3, 39-48. DOI: https://dx.doi.org/10.2147/OAEM.S22795

[4] Warrillow, S, *et al.* (2019). Characteristics, management and outcomes of patients with acute liver failure admitted to Australian intensive care units. Critical Care and Resuscitation. 21(3): 188-199

- Recent data show that each year in Australia, paracetamol overdose leads to around nine people per million hospitalised with liver injury and two deaths per million – or about 50 Australian lives lost. While hospitalisation and death rates have not increased in recent years, there is a concerning increase of misuse in the community.
- The panel also found that both impulsive and planned paracetamol overdose occur at similar rates, with impulsive acts often using paracetamol already present in the home. They found that while most overdose attempts used paracetamol from large (96 unit) packs present in the home, a proportion of individuals overdosed immediately after purchase of several packs from a supermarket or convenience store. Contributing to the high number of doses available in the home, it was found that when purchasing paracetamol, consumers generally favour the largest pack size available, and that these larger pack sizes are more frequently used in overdose cases.
- Few poisonings were noted with ibuprofen or aspirin (10-15 % of the total for paracetamol, and very few of these were fatal) so there was not considered to be a case to change scheduling controls on these substances. However, if access to paracetamol is restricted there may a flow-on increase in usage of ibuprofen in particular.
- In this case it will be important to emphasise that alternatives such as OTC non-steroidal anti-inflammatory medicines, such as ibuprofen, are only recommended for short-term use as they can cause adverse effects, such as intestinal bleeding, cardiac disorders, kidney and heart failure, or liver damage. In addition, some people are also allergic to ibuprofen and aspirin. Aspirin can cause gastro-intestinal irritations and is contraindicated in those with bleeding disorders.

Key uses / expected use

Medicines

Australian regulations

- According to the TGA Ingredient Database,[5] paracetamol is:
  - available for use as an Active Ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines;
  - available for use as an Excipient Ingredient in: Biologicals, Devices and Prescription Medicines;
  - available as an equivalent ingredient in: Export Only, Over the Counter and Prescription Medicines.
- As of September 2022, there were 655 medicines currently active on the Australian Register of Therapeutic Goods (ARTG)[6] that contain paracetamol as an active ingredient. These include:
  - 86 prescription only medicines;
  - 548 over the counter medicines;
  - 21 export only medicines.

[5] TGA Ingredient Database https://www.ebs.tga.gov.au/
[6] ARTG database https://compliance.health.gov.au/artg/

- Paracetamol is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination[7] No.4 of 2022.
- The TGA prescribing medicines in pregnancy database[8] classifies paracetamol as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Paracetamol	A	Central Nervous System	Analgesics and Antipyretics (see also non-steroidal anti-inflammatory agents)	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.				

- There are three warning statements pertaining to paracetamol in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.[9]

Column 1 Item	Column 2 Substance	Column 3 Circumstances	Column 4 Required Statements
191	Paracetamol *(Entry 1 of 3)*	For the purpose of exclusion from the schedules to the current Poisons Standard	• Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage. • Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

[7] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination

[8] TGA prescribing medicines in pregnancy database https://www.tga.gov.au/prescribing-medicines-pregnancy-database

[9] Therapeutic Goods (Medicines Advisory Statements) Specification 2021 https://www.legislation.gov.au/Details/F2021L01888

Column 1 Item	Column 2 Substance	Column 3 Circumstances	Column 4 Required Statements
192	Paracetamol *(Entry 2 of 3)*	In Schedule 2 or 3 to the current Poisons Standard	• either or both - Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. - Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage. • Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.
193	Paracetamol *(Entry 3 of 3)*	In combination with ibuprofen, in medicines for oral use	• Do not give to children under 12 years of age. • Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if pregnant or trying to become pregnant. • Do not use if you have a stomach ulcer.

Column 1 Item	Column 2 Substance	Column 3 Circumstances	Column 4 Required Statements
			• Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use if you are aged 65 years or over. • Do not take with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly, unless advised to do so by a doctor or pharmacist. If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.

- As of September 2022, there were 5,135 reports of adverse events for products containing paracetamol as an active ingredient on the Database of Adverse Event Notifications (DAEN).[10] with 2,318 reports where paracetamol was the single suspected medicine. There were 311 reports of deaths associated with paracetamol use. The recorded adverse events were widely varied in nature.

[10] Database of Adverse Event Notifications (DAEN) https://daen..tga.gov.au/medicines-search/

International regulations

- The scheduling of paracetamol varies considerably within the Organisation for Economic Co-operation and Development (OECD) countries, with respect to immediate release and modified release formulations, sales outside of pharmacies and the maximum pack sizes available.
- Many European countries do not allow any sales outside of pharmacies and also have lower limits on pharmacy pack sizes. In addition, MR paracetamol is not available in most European countries. Some countries have implemented restrictions while others have no limits on the quantities per pack or number of packs that can be purchased (predominantly in Eastern Europe and Russia). Fourteen countries have implemented pack size restrictions within pharmacies in the last two decades ranging from 8-30 g (which are lower than in Australia).
- Furthermore, in twelve countries paracetamol-containing analgesics are not available outside of pharmacies, with larger quantities only available with a valid prescription from a doctor. Only seven countries allow sales of paracetamol from outside of pharmacies, with six of them having a range between 5-8 g and Russia allowing unlimited quantities for sale. Sweden now only markets effervescent tablets for sale from general sale. Indicating that apart from Russia all remaining countries have tighter restrictions on access outside of pharmacies compared to Australia (either through smaller quantities or no access at all).
- The UK has tighter scheduling of paracetamol compared to Australia, which it enacted in 1998 as a response to self-poisoning. They now have low pack limits (16 tablets), purchase limits (2 packs) from general sale and 32 tablet packs from pharmacies, and do not allow the supply of MR paracetamol.
- The US, Canada and Singapore do not have significant limits placed on the pack sizes of standard paracetamol products.
- Refer to *Chapter 3: International comparisons of scheduling and paracetamol poisoning* in the independent expert report on the risks of intentional self-poisoning with paracetamol for a comprehensive overview.

3 How to respond

Submissions must be provided by the closing date of **14 October 2022** through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS).

4 What will happen

All public submissions will be published on the TGA website at Public submissions on scheduling matters, unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website: Scheduling delegate's interim decisions & invitations for further comment in February 2023.