ACMS MEETING #40

16 NOVEMBER 2022

AGENDA PAPER

Paracetamol

Referred scheduling proposal

The delegate[1] of the Secretary of the Department of Health and Aged Care that is responsible for medicines scheduling (the **Delegate**) is seeking advice from the Advisory Committee on Medicines Scheduling (the **Committee**) on scheduling proposals with respect to paracetamol. The Delegate has proposed a number of options for amending the Poisons Standard in relation to paracetamol. These are proposed in view of the findings and recommendations in the expert report on intentional paracetamol self-poisoning that was commissioned by the TGA.[2]

Proposed scheduling

Options 1A-D: Blister packs

Description of options

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)).

Depiction of all options implemented in the Poisons Standard[3]

Schedule 4

PARACETAMOL:

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

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).
[2] Independent expert report on the risks of intentional self-poisoning with paracetamol | Therapeutic Goods Administration (TGA)
[3] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

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 of options

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)).

Depiction of all options implemented in the Poisons Standard

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 5 ~~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 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 of options

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)).

Depiction of all options implemented in the Poisons Standard

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) 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) 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 of options

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

Depiction of all options implemented in the Poisons Standard

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 of options

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)).

Depiction of all options implemented in the Poisons Standard

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) 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) 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 of option

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

Depiction of option implemented in the Poisons Standard

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.

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.

- ***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.

Current scheduling status

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

Scheduling history

Paracetamol has a long and extensive history of scheduling changes and updates. The following is an excerpt of scheduling changes concerning paracetamol from the past twenty years.

- In October 2003, the National Drugs and Poisons Schedule Committee (NDPSC) considered the Medicines Evaluation Committee's (MEC) package of warning statements for OTC paracetamol for inclusion in Appendix F of the Poisons Standard. The Committee agreed to the inclusion of the

MEC's proposed new label warning statements for paracetamol in Appendix F of the Poisons Standard and the consequential amendments to the Schedule 2 entry for paracetamol.

- In February 2007, the NDPSC noted the safety concerns surrounding the potential for overdose and toxicity with immediate release paracetamol over 500 mg. With consideration to these safety concerns and in order to harmonise with New Zealand, the NDPSC agreed that slow-release paracetamol with >665 mg should remain in Schedule 4. The NDPSC also agreed to lower the non-slow-release cut-off for Schedule 4 preparations to >500 mg.
- In February 2012, the Delegate sought advice from the Advisory Committee on Medicines Scheduling (ACMS) to further restrict the pack size requirements for paracetamol to be exempt from scheduling. The ACMS recommended that Australia harmonise with New Zealand and restrict the exempt pack size requirements for paracetamol to a maximum of 20 tablets or capsules, and no more than 10 g of paracetamol per pack.
- In March 2016, the ACMS considered and supported a proposal by TGA OTC Medicines Evaluation to amend the Schedule 2 entry for paracetamol to (a) restrict the pack size requirements to no more than 100 tablets or capsules per pack and no more than 50 wrapped powders or sachets of granules per pack for domestic supply, and (b) specifically limit bulk pack sizes of paracetamol for supply only to hospital, nursing homes and pharmacies for dispensing purposes.
- A proposal to up-schedule modified release (MR) paracetamol from Schedule 2 (Pharmacy Only) to Schedule 3 (Pharmacist Only) was considered and supported at the March 2019 meeting of the ACMS. The decision was based on concerns regarding the potential for harm associated with overdoses (accidental or deliberate) of modified release paracetamol. Arguments regarding the lower rate of overdose in Australia compared to overseas, disadvantages to patients accessing MR paracetamol for relief from osteoarthritis, and the potential for diversion of patients to opioids or other medicines that may be caused by up-scheduling of paracetamol, were all addressed in the interim and final decisions.

Australian regulations

- According to the TGA Ingredient Database,[4] 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 October 2022, there were 655 medicines currently active on the Australian Register of Therapeutic Goods (ARTG)[5] that contain paracetamol as an active ingredient. These include:
  - 86 prescription only medicines;
  - 548 over the counter medicines;
  - 21 export only medicines.

[4] TGA Ingredient Database https://www.ebs.tga.gov.au/
[5] 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[6] No.4 of 2022.
- The TGA prescribing medicines in pregnancy database[7] 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.[8]

Item	Substance	Circumstances	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.
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.

[6] Therapeutic Goods (Permissible Ingredients) Determination https://www.legislation.gov.au/Search/Therapeutic%20Goods%20LBPermissible%20IngredientsRB%20Determination
[7] TGA prescribing medicines in pregnancy database https://www.tga.gov.au/prescribing-medicines-pregnancy-database
[8] Therapeutic Goods (Medicines Advisory Statements) Specification 2021 https://www.legislation.gov.au/Details/F2021L01888

Item	Substance	Circumstances	Required Statements
			• 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. • 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.

- Between January 2012 and October 2022, there were 1,957 reports of adverse events for products containing paracetamol as an active ingredient on the Database of Adverse Event Notifications (DAEN),[9] with 1,158 reports where paracetamol was the single suspected medicine. There were

[9] Database of Adverse Event Notifications (DAEN) www.tga.gov.au/database-adverse-event-notifications-medicines-daen

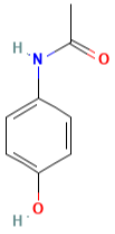
222 reports of deaths associated with paracetamol use. The recorded adverse events were widely varied in nature.

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 of the international regulation of paracetamol.

Substance summary

Table 1: Chemical information for paracetamol

Property	Substance
Chemical structure	
Molecular formula	$C_8H_9NO_2$
CAS numbers	103-90-2
IUPAC and/or common and/or other names	Acetaminophen, 4-Acetamidophenol and N-(4-Hydroxyphenyl) acetamide

Pre-meeting public submissions

Responses have been separated into those submitting on behalf of an organisation (e.g. peak body or industry association) and individuals. To reduce the practice of indiscriminate voting as seen in previous consultations, different voting formats were trialed for individuals and organisations.

Through the consultation portal, respondents submitting on behalf of an organisation were given the choice to indicate their support, partial support, or opposition for all the proposed options. The votes have been summarised in the tables below.

Organisation response summary

Options	Supports	Partially support	Opposes	Total
1A	9 (50%)	4 (22%)	5 (28%)	**18 (100%)**
1B	7 (40%)	5 (30%)	5 (30%)	**17 (100%)**
1C	12 (55%)	4 (18%)	6 (27%)	**22 (100%)**
1D	9 (56%)	1 (6%)	6 (38%)	**16 (100%)**
2A	7 (27%)	6 (26%)	13 (50%)	**26 (100%)**
2B	5 (20%)	8 (32%)	12 (48%)	**25 (100%)**
3A	5 (19%)	7 (26%)	15 (55%)	**27 (100%)**
3B	6 (24%)	7 (28%)	12 (48%)	**25 (100%)**
4	6 (27%)	4 (18%)	12 (55%)	**22 (100%)**
5A	5 (26%)	2 (11%)	12 (63%)	**19 (100%)**
5B	8 (36%)	2 (9%)	12 (55%)	**22 (100%)**
6	9 (34%)	1(4%)	16 (62%)	**26 (100%)**

Individual response summary

Through the consultation portal, individual respondents were given the choice to indicate their support for one of, or none of the proposed options from group 1A-AD, 3A-3B and 5A-5B. Respondents were able to select Option 2A, 2B, both, and neither of the options. As options 4 and 6 were standalone proposals, respondents indicated their support, partial support or opposition of the proposed options.

Option	Support
1A	19 (13%)
1B	19 (13%)
1C	39 (26%)
1D	28 (19%)
None of the above	42 (29%)
Total for Option 1	**147 (100%)**
2A	23 (15%)
2B	23 (15%)
Both	3 (2%)
Neither	102 (68%)
Total for Option 2	**151 (100%)**
3A	23 (15%)
3B	32 (22%)
Neither of the above	95 (63%)
Total for Option 3	**150 (100%)**
5A	41 (28%)
5B	30 (20%)
Neither of the above	76 (52%)
Total for Option 5	**147 (100%)**

Option	Support	Partially support	Opposes	Total
4	32 (21%)	20 (13%)	100 (66%)	**152 (100%)**
6	23 (16%)	12 (8%)	110 (76%)	**145 (100%)**

Main points in support:

- All solid dose paracetamol preparations should be supplied in blister packs only. There is sufficient evidence to show that blister packs reduce the number of tablets ingested by individuals who intentionally overdose, due to the time needed to access each tablet before consumption.
- The proposed options are not unprecedented internationally. Smaller pack sizes in the UK (similar to the proposed Options 2A and 2B) and age restrictions on the purchase of paracetamol in Denmark (similar to the proposed Option 5B) have already been implemented in overseas markets. In addition, paracetamol is a pharmacy-only medicine in several countries, and modified release paracetamol is currently banned in several countries, including throughout the European Union.
- While supportive of many or all of the proposed options, a long transition period should be instituted for all implemented changes to allow retailers, pharmacies, sponsors, and consumers sufficient time to adjust their practices and familiarise themselves with the changes.

Main points in support with caveats:

- Purchase limits should be 2 packs per transaction to be more consistent with therapeutic needs, rather than the proposed 1 pack.

- While supporting purchase limits, concerns regarding adequate access and supply of medicines for consumers in rural and remote communities under any new restrictions were raised.
- Introducing requirements for blister packs (Options 1A-1D) was generally supported, but access to some paracetamol products in bottles is still required to cater for the elderly and consumers with a mobility disability. All solid dose paracetamol products should be supplied in blister packs, except for bottles that may be accessed from behind the counter in a pharmacy but only sold to the cohort who may experience difficulty with blister packs.
- Reducing pack sizes (Options 2A & 2B) has the potential to raise the prices of paracetamol products, due to the corresponding increase in the use of packaging materials in smaller packs.

Main points in opposition:

- Reduced pack sizes may inadvertently lead to the opposite of what is sought to be achieved, causing consumers to 'stockpile' paracetamol and therefore potentially increasing accessibility to large amounts in the home.
- Restrictions on accessibility and pack sizes would impact consumers with chronic pain that rely on large and affordable pack sizes. The reduction in pack sizes and introduction of purchase limits would necessarily increase the frequency of purchasing in these cases, which would be inconvenient and difficult for those with chronic pain and mobility issues.
- Restrictions on purchases of paracetamol may cause consumers to turn to alternative pain relief such as NSAIDs, which may not be the correct therapeutic intervention for their ailment.
- Items sold behind the counter are usually products that are toxic or potentially cause harm (such as cigarettes). Sale of paracetamol products behind the counter in a similar fashion to cigarettes may introduce a stigma of paracetamol being toxic and dangerous, despite having a better safety profile than most oral NSAIDs.
- Rescheduling modified release paracetamol would decrease access for several consumers who require constant use of paracetamol to treat chronic pain. Up-scheduling of these preparations would expose chronic pain sufferers to increased wait times at GP's and increased out of pocket costs and would disproportionately affect those with limited access to medical professionals.
- Enforcement of age restrictions on purchases of paracetamol would require increased resources and place unnecessary burden on both general sales outlets and pharmacies.

Delegate's specific issues and questions to be considered by the Committee

The Medicines Scheduling Delegate seeks advice from the Committee on the following questions:

1. Noting there are multiple options and sub-options, which (if any) are most likely to provide appropriate access to paracetamol through scheduling?
2. Are there any options that should not be considered further at this time given the availability of other more preferable options?
3. Is there one or a particular combination of options/sub-options that is likely to provide the most favourable balance of benefits and risks from their implementation?
4. Should restrictions on pack sizes for paracetamol, as outlined in the Poisons Standard, be changed?
5. If so, is a pack size of 16 or 10 dosage units most appropriate?
6. Is a maximum pack size of 50 dosage units appropriate for Schedule 2 products?

7. Are restrictions on purchasing multiple packs able to be implemented through scheduling?
8. Should any changes be applied to all paracetamol products, or only single-active preparations?
9. Is it appropriate to up-schedule modified release paracetamol to prescription-only?
10. Should consideration also be given to other analgesics (aspirin and ibuprofen) that are available through general sale, although the literature review did not indicate that method substitution is likely?

OPTIONS

OPTION 1
The Committee recommends that the current scheduling of paracetamol remains appropriate.
OPTION 2
The Committee recommends the Delegate further investigate the following options for the scheduling of paracetamol (tick all that apply): ☐ Option 1A ☐ Option 1B ☐ Option 1C ☐ Option 1D ☐ Option 2A ☐ Option 2B ☐ Option 3A ☐ Option 3B ☐ Option 4 ☐ Option 5A ☐ Option 5B ☐ Option 6
IMPLEMENTATION DATE
The Committee is asked to discuss and consider the resolutions with an implementation date of 1 June 2023/1 October 2023/1 February 2024.
RECOMMENDATION FOR OTHER ACTION BY THE DELEGATE

ATTACHMENTS

Attachment A: Pre-meeting public submissions (D22-5987098)

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

Pages 26-338 removed in accordance with section 22 (*irrelevant material)* of the *Freedom of Information Act, 1982.*

Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Record of the 40th meeting of the Advisory Committee on Medicines Scheduling

16 November 2022

TRIM Reference no. D22-6160803

TGA Health Safety Regulation

Contents

1 Preliminary matters

1.1 Opening of the meeting

The 40th meeting of the Advisory Committee on Medicines Scheduling (the **Committee**) was held at the Department of Health and Aged Care's Fairbairn (ACT) office and via video conference on 16 November 2022.

The meeting was chaired by s22 [redacted], who opened the meeting at 10:03 am (AEDT) and welcomed attending members and observers.

Members were informed that the discussions and recommendations of the Committee are confidential until the interim decisions are published.

1.2 Attendance

A quorum was present for all decisions. Those present at the meeting were:

Committee members

Name	Representation
s22 [redacted]	Ministerial appointment
	Ministerial appointment
	Ministerial appointment
	Ministerial appointment
	Ministerial appointment
	Ministerial appointment
	Ministerial appointment
	Commonwealth
	NSW
	VIC
	QLD
	WA
	TAS
	ACT
	NT

Guest speakers

Name	Participation
s22	Presentation on paracetamol (10.21 am to 10.57 am) Presentation on paracetamol (10.21 am to 10.57 am)

Committee Secretariat (Commonwealth Department of Health and Aged Care)

s22	

Observers

Name	Items
Commonwealth Department of Health and Aged Care (Therapeutic Goods Administration)	
s22	All All All All All All
ACT	
s22	All
s22	
s22	Paracetamol presentation from s22 and s22

Apologies

s22 [redacted]

1.3 Conflict of interest

Conflicts of interest declared prior to the meeting by s22 [redacted], and s22 [redacted] were discussed.

s22 [redacted]

1.4 Procedural matters

Members were informed of various housekeeping rules to ensure the smooth running of the meeting via videoconference.

All present were reminded of confidentiality in relation to all matters discussed by the Committee and that all decisions are to remain confidential until they are published along with

the interim decision of the delegate[1] of the Secretary of the Department of Health and Aged Care responsible for medicines scheduling (the **Delegate**).

2 Discussion Item

2.1 Paracetamol

Advice for the Delegate's consideration

The Committee recommended that the scheduling of paracetamol be amended in the Poisons Standard as follows[2]:

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 3 ~~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

[1] For the purposes of s 52D of the *Therapeutic Goods Act 1989* (Cth).

[2] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

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 non-modified release tablets or capsules containing not more than 500 mg paracetamol and in a primary pack containing not more than 100 tablets or capsules; or

e) in individually wrapped powders or sachets of granules enclosed in a primary pack containing more than 16 wrapped powders or sachets of granules; or

f) 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 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 8 ~~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 16 ~~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.

The Committee recommended consultation with relevant stakeholders regarding a possible implementation date.

Committee discussion

- The Committee discussed the options that the Delegate had proposed for amending the Poisons Standard in relation to paracetamol. The TGA sought public comment to determine whether current scheduling of paracetamol is appropriate considering available data on paracetamol poisoning, including intentional overdose, and associated hospitalisations and deaths. The proposed options were presented as a result of the findings and recommendations in the independent expert report on intentional paracetamol self-poisoning (the **Report**).
- The Committee observed a presentation from s22 and the s22 and had the opportunity to ask specific questions to assist with their deliberations.
  - s22 outlined the concerns of chronic pain suffers regarding the proposed changes and the effect possible restrictions on access may have on them. Of Australian adults with chronic pain, 45% experience psychological effects and it was noted that there were anecdotal reports of an increase in suicide following the access restrictions placed on opioids (prescription only). Regarding paracetamol, although larger pack sizes are available in pharmacies, s22 asserted that if the proposed changes were implemented, those living with pain will be disadvantaged. Factors of concern included a lack of availability of pharmacy facilities, especially in some rural and

remote areas, and additional costs, which are aggravated for those households on fixed incomes.

  - s22 had some cautious agreement with some of the proposed options. They were of the view that modified release (MR) paracetamol was overly recommended and used for chronic pain, and that pack size restrictions and supply restrictions to pharmacies would be too restrictive and any restrictions of multiple pack sales would be too difficult to implement. They stated that most people see their general practitioner (GP) at least once a year and have the opportunity to discuss chronic pain relief. Correct usage and storage of medication in the home is an ongoing issue that requires attention to address the trend of young people overdosing impulsively.

- **Blister packs**: The Committee agreed that there was evidence of the effectiveness of this measure and it is likely to reduce the risk of harm from impulsive attempts to self-poison. It was noted that most products are already present as blister packs although there was concern that this option may result in the removal of some cheaper (more cost effective) products and create difficulties for consumers with dexterity issues. It was noted that there was broad support expressed in public submissions for option 1C (blister packaging for pharmacist only, pharmacy and general sale preparations) however most stakeholders supported blister pack restrictions for paracetamol tablet and capsule preparations that are not scheduled or are in Schedule 2.

- **Decrease pack size**: The Committee noted that this option was broadly supported by medical, pharmacy and consumer organisations and some manufacturers. The Committee agreed that it would be counterproductive to make pack sizes so small that it may lead to stockpiling and as such reaching the 10 g threshold (minimum toxic dose) or for consumers to switch to using other OTC products (e.g., ibuprofen). In addition, there would need to be a balance between having a 'safe' pack size in cases of overdose against the ability to purchase a suitable quantity for legitimate use (treating pain and fever). Members agreed that it would be reasonable to create a new Schedule 3 entry for a pack size of 100 tablets or capsules which would require direct interaction with a pharmacist prior to supply, thus enabling adequate provision of advice regarding correct usage and storage.

- **Restrictions of number of packs per sale:** Members agreed with the rationale that this option would enable less paracetamol to be available within the home and it would be harder to purchase large quantities for intentional self-poisoning. More organisations were supportive of this option vs individuals (~50% and 37% respectively). Members observed that a majority of respondents supported a restriction on purchasing to 2 packs rather than 1 pack only and there was significant concern from respondents that restricting packs per sale would impede the self-management of chronic pain, especially for those with mobility issues. It was noted that the Professional Practice Guidelines[3] for pharmacists already recommends supply of 1 or 2 pack only per transaction for products in these schedules unless there are extenuating circumstances. The Committee also noted that this option may not be enforceable outside of supermarkets e.g., convenience stores and petrol stations, and doesn't prevent repeated purchases from multiple locations.

- **MR products to Schedule 4:** The Committee recognised that MR products pose a greater risk for intentional self-poisonings as larger amounts of paracetamol are consumed and there are particular treatment challenges, leading to higher risk of liver toxicity. However, the consensus was that there has only been a short time since the last rescheduling change (June 2020) and as such the impact of those changes are difficult to assess. This option was not supported by the majority of individuals and organisations who made submissions. It

[3] Pharmacy-Board---Guidelines---Guidelines-on-practice-specific-issues (1).PDF (central.health)

should be noted that the demographic of people using MR paracetamol differs to the younger adolescent cohort implicated in intentional self-poisonings.

- **Retail storage of preparations that are not scheduled**: Members raised concerns that there is a risk that this measure would reduce reasonable access for the majority of people who are purchasing for genuine therapeutic use. This would also make it difficult for consumers to make informed decisions as they cannot easily read the label prior to purchase and compare against other products (that would be available in aisles). It was noted that this option was opposed by consumer groups and most organisations with the exception of some larger pharmacy groups. The Committee suggested that the storage of paracetamol out of sight with items such as cigarettes may lead to a perception that paracetamol is not safe for self-selection and as such should not be supplied in supermarkets at all.

- **Limiting sales to those aged 18 years and over:** Members discussed the intention behind this option to reduce purchasing by vulnerable age groups and the expectation that this would reduce poisoning in this age group. However, the impact of this may be limited as most paracetamol used for intentional self-poisoning is already in the home. This would restrict access for vulnerable groups such as under 18 years old who live independently. It was noted that this was an effective measure when regulatory changes were enacted in Denmark to restrict sales to those 18 years of age and older from pharmacies[4]. An option to create a new Schedule 3 entry for sale to those aged under 18 years was also discussed, allowing access without a prescription for individuals that may still require paracetamol but are younger than 18 years old.

- Members agreed that care needs to be taken when comparing Australian data against overseas data as regulatory environments differ. Some jurisdictions do not permit sales of paracetamol outside of pharmacies, and countries like the United States of America (USA) do not have the Australian equivalent of pharmacy (Schedule 2) or pharmacist only (Schedule 3) categories. However, the Committee noted that the introduction of tighter pack size restrictions in the United Kingdom (UK) than Australia was associated with sustained reductions in paracetamol deaths.

- The Committee deliberated on the most viable options in lieu of both the rationale and challenges posed by the different proposed options. Members agreed that scheduling alone would not eradicate the issue of intentional self-poisonings with paracetamol, but that it could minimise harm through limiting what is available in the home and what can be purchased for impulsive acts.

- The Committee agreed that of the options presented for public consultation and recommendations in the expert report a combination of reducing pack sizes and mandating blister packaging was the preferred way forward. The Committee advice to the delegate was as follows:

  - creation of a new Schedule 3 entry for pack sizes of 100 tablets or capsules;
  - amendment to the Schedule 2 entry with a pack size reduction to 32 tablets or capsules in blister packs; and
  - amendment to the exempt products with a reduction in pack size to 16 tablets or capsule in blister packs.

The reasons for the advice

[4] It was noted that paracetamol is not permitted for sale in Danish supermarkets and convenience stores.

Members agreed that the relevant matters under Section 52E(1) of the *Therapeutic Goods Act 1989* included (a) the risks and benefits of the use of a substance; (b) the purpose for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; (e) the potential for abuse of a substance; and (f) any other matters that the Secretary considers necessary to protect public health.

The Committee's reasons were:

a) the risks and benefits of the use of a substance

Risks:

- The size of packs that are currently available mean many households have surplus supply.
- Modified release formulations pose additional challenges in poisoning events.
- Some people, particularly younger people, at risk of harm from intentional overdose.

Benefits:

- Low cost.
- Usually well tolerated with minimal side effects or precautions/contraindications associated with use.

b) the purposes for which a substance is to be used and the extent of use of a substance

- Long history of use as an analgesic for many common pain ailments, including chronic pain.
- Widely available in supermarkets, convenience stores and pharmacies.

c) the toxicity of a substance

- Low toxicity when used in therapeutic doses, significant toxicity when 10 g or more is taken as a single dose for an average sized adult (including when taken as an intentional self-poisoning).
- Untreated overdose can result in acute liver failure and death.

d) the dosage, formulation, labelling, packaging and presentation of a substance

- Many formulations, pack sizes and presentations available at present.
- Evidence that adjustments to packaging (blister packs and reduces pack sizes) may reduce risk of intentional self-poisoning with paracetamol products.

e) the potential for abuse of a substance

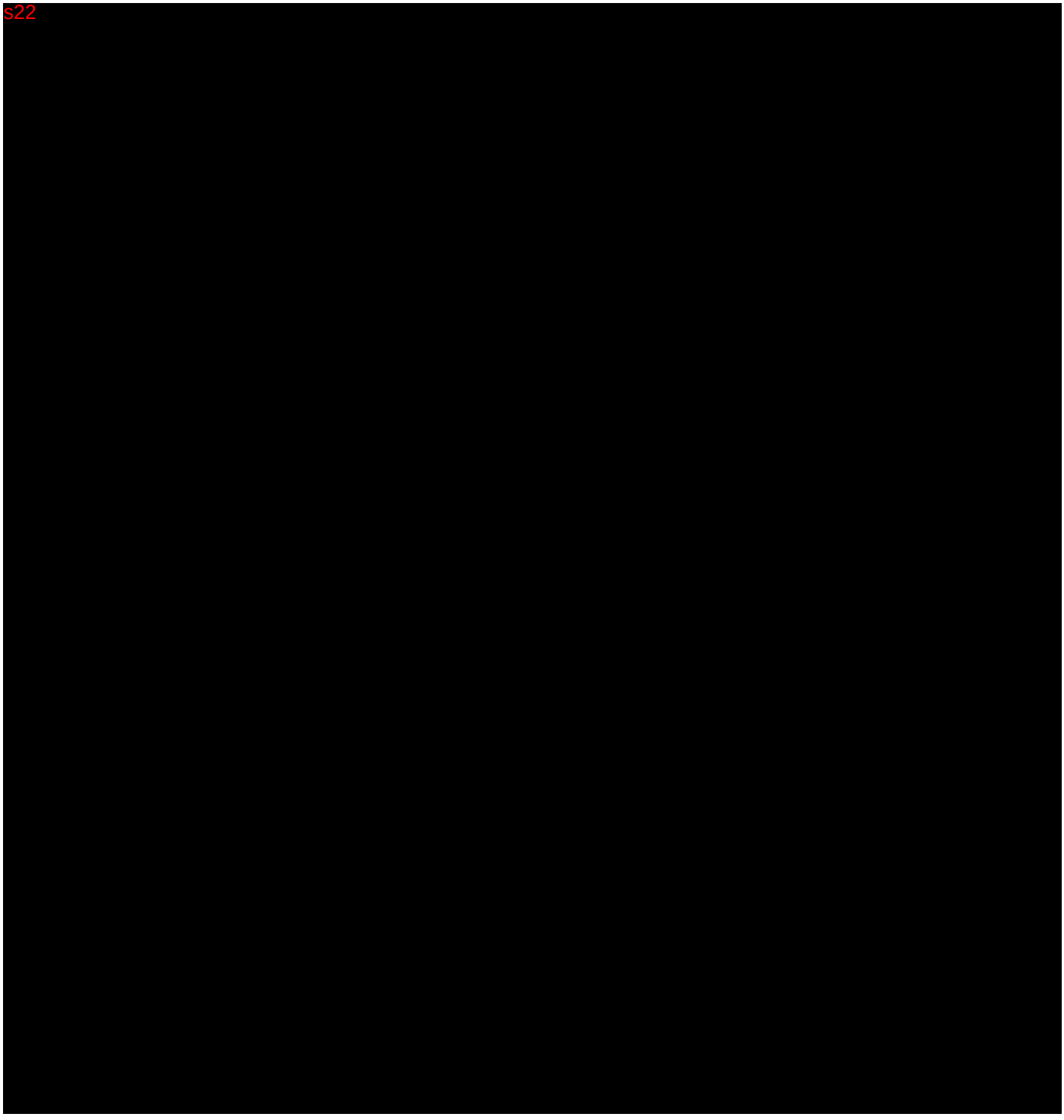
- Low potential for abuse with regards to psychoactive effects, however there is considerable evidence of nonmedical use in the context of intentional poisoning.

f) any other matters that the Secretary considers necessary to protect public health

- Proportion of paracetamol used for intentional self-poisoning out of all paracetamol sold/supplied in Australia to ensure equity of access. However, consequences of intentional self-poisoning can be high morbidity (irreversible liver damage) and even death.

- Pack size ingested in cases of deliberate self-harm are reflective of the pack sizes that are currently available for sale. Smaller pack sizes available for spontaneous purchase should be less than the toxic dose.
- 10% of cases of deliberate self-harm/overdose involved going out to purchase paracetamol, however over all the source of paracetamol was unknown in a large proportion of cases.
- Changing current access controls may have unintended impacts on legitimate use of paracetamol e.g., imposing restrictions that are too severe could result in substitution with other medications as it may be perceived that paracetamol is unsafe/harmful.

s22



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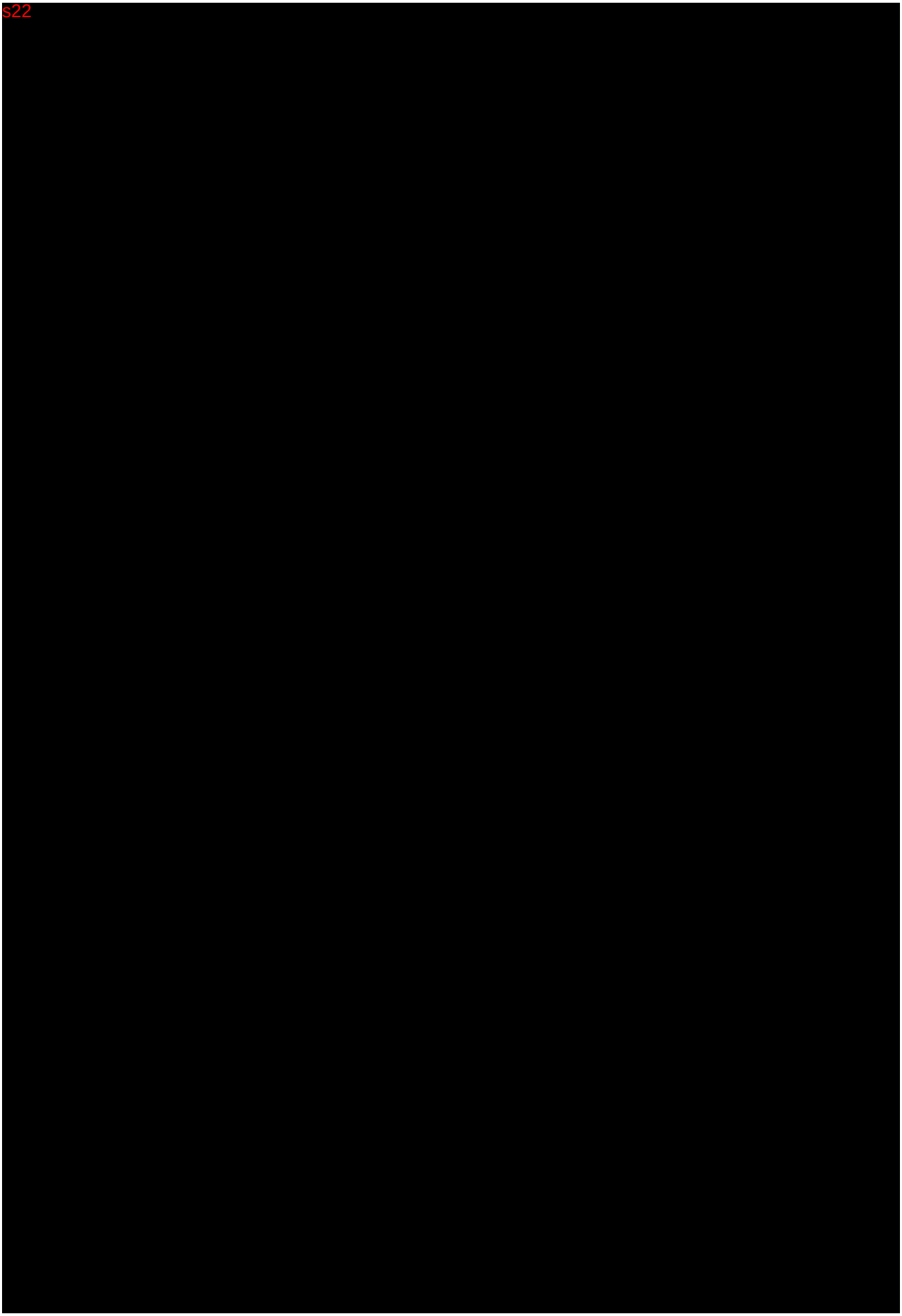

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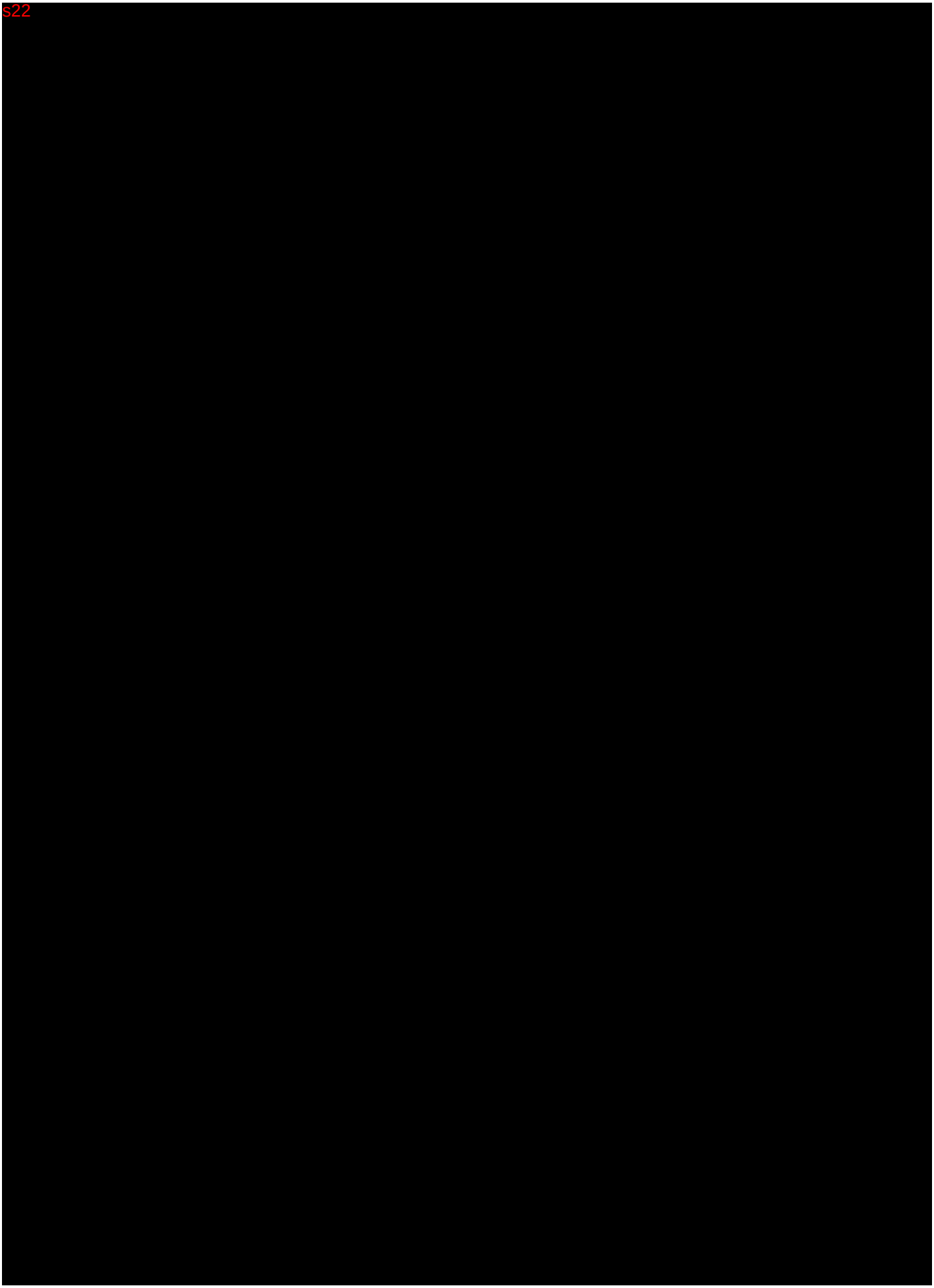

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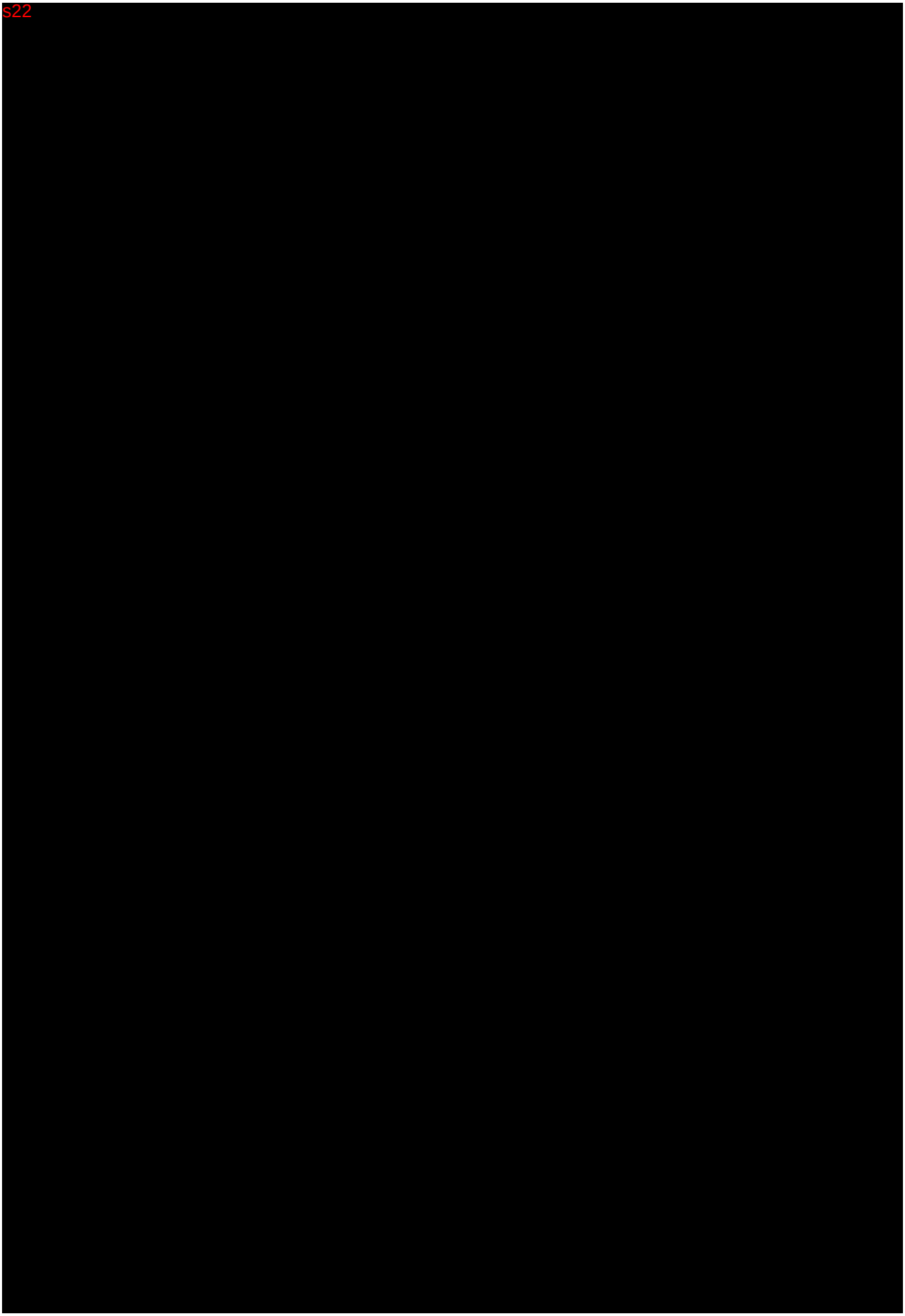

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[9] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

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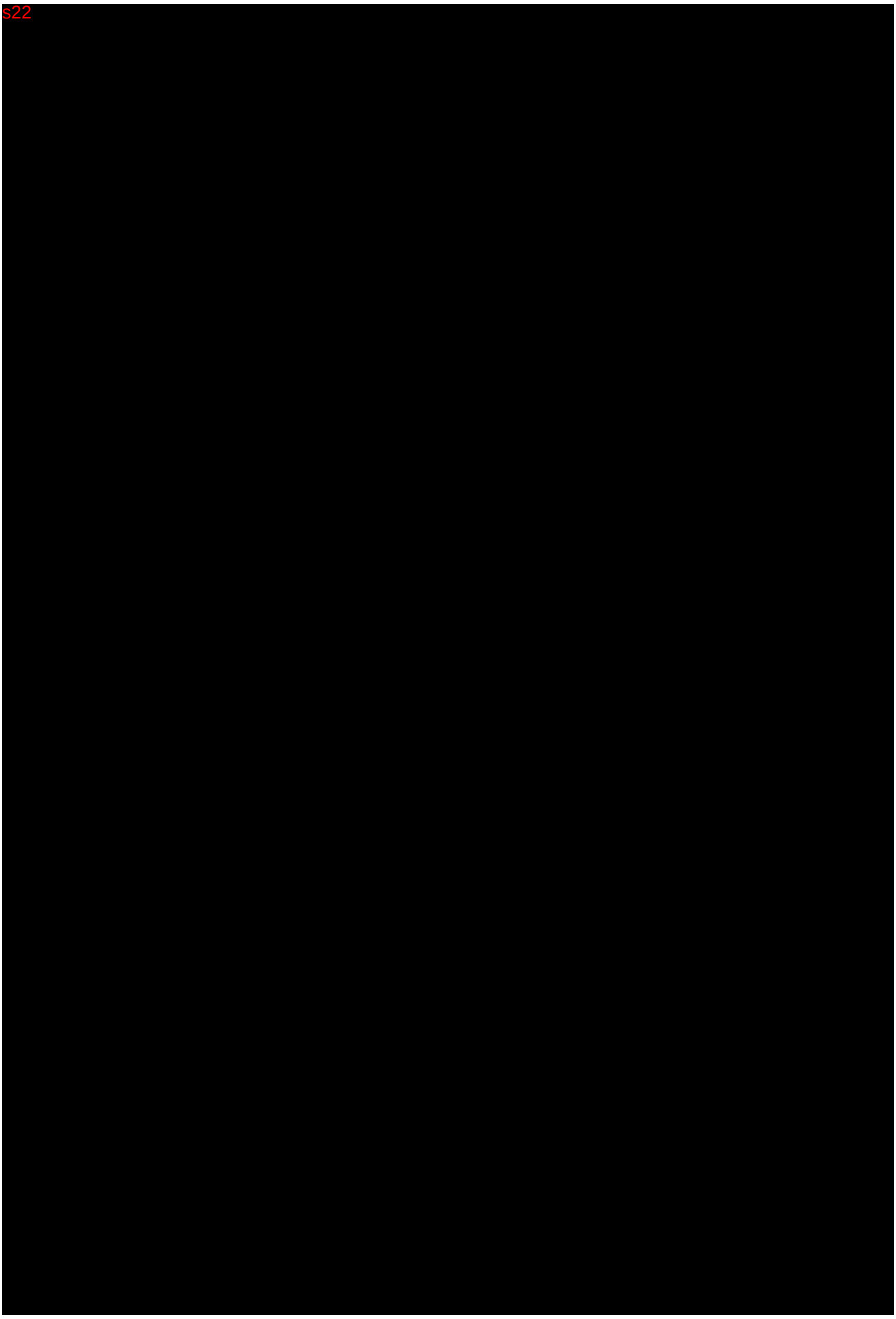

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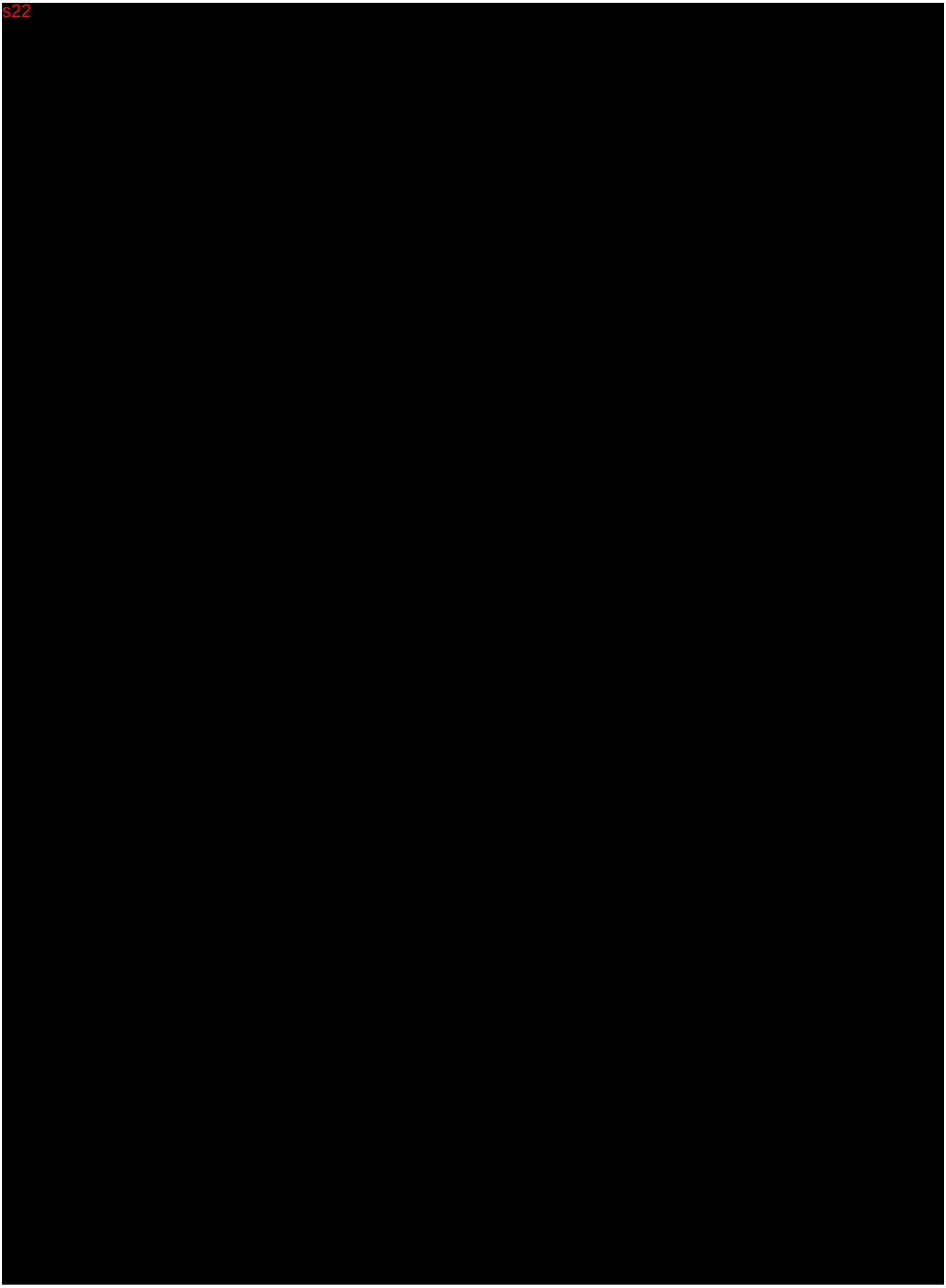

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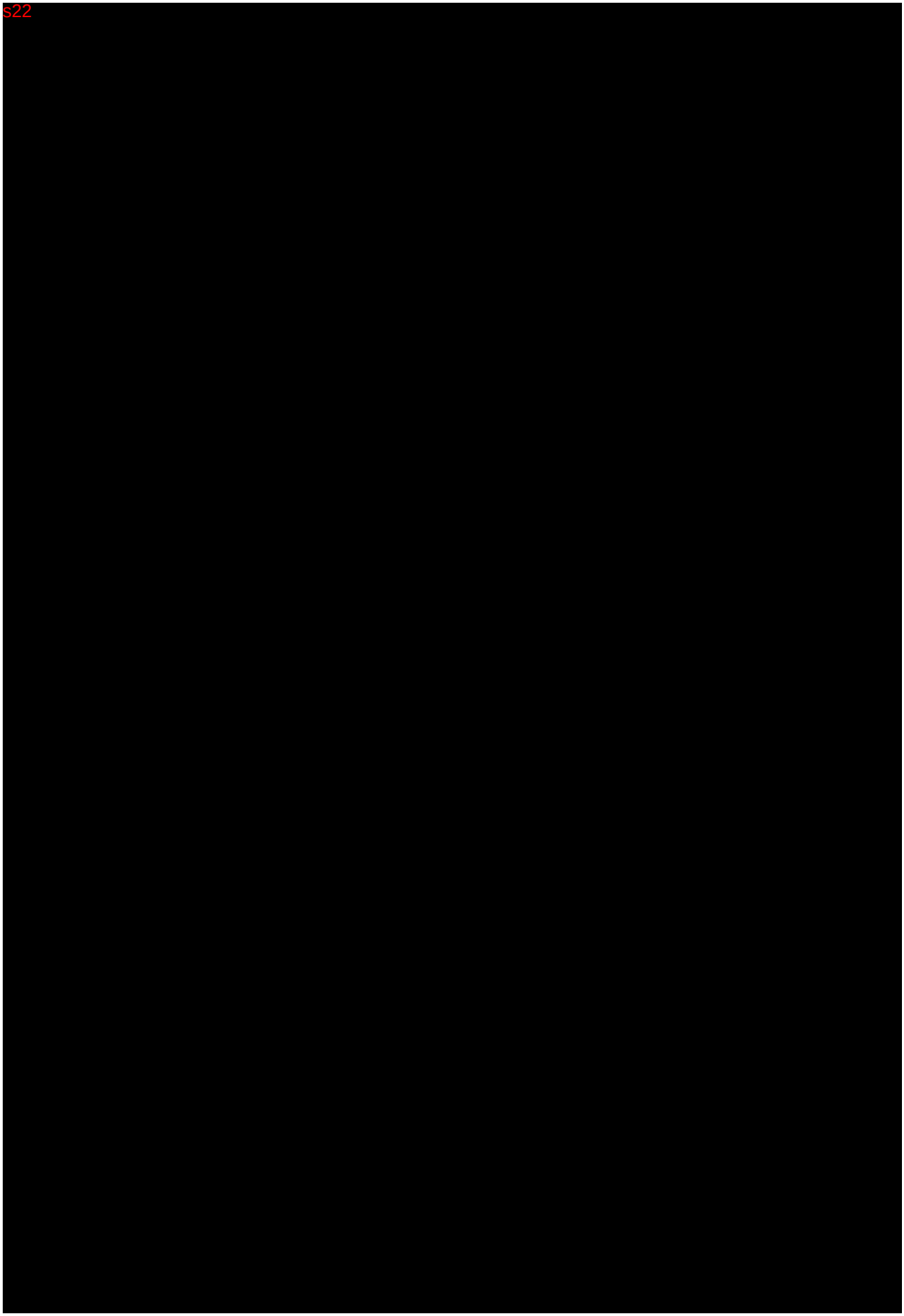

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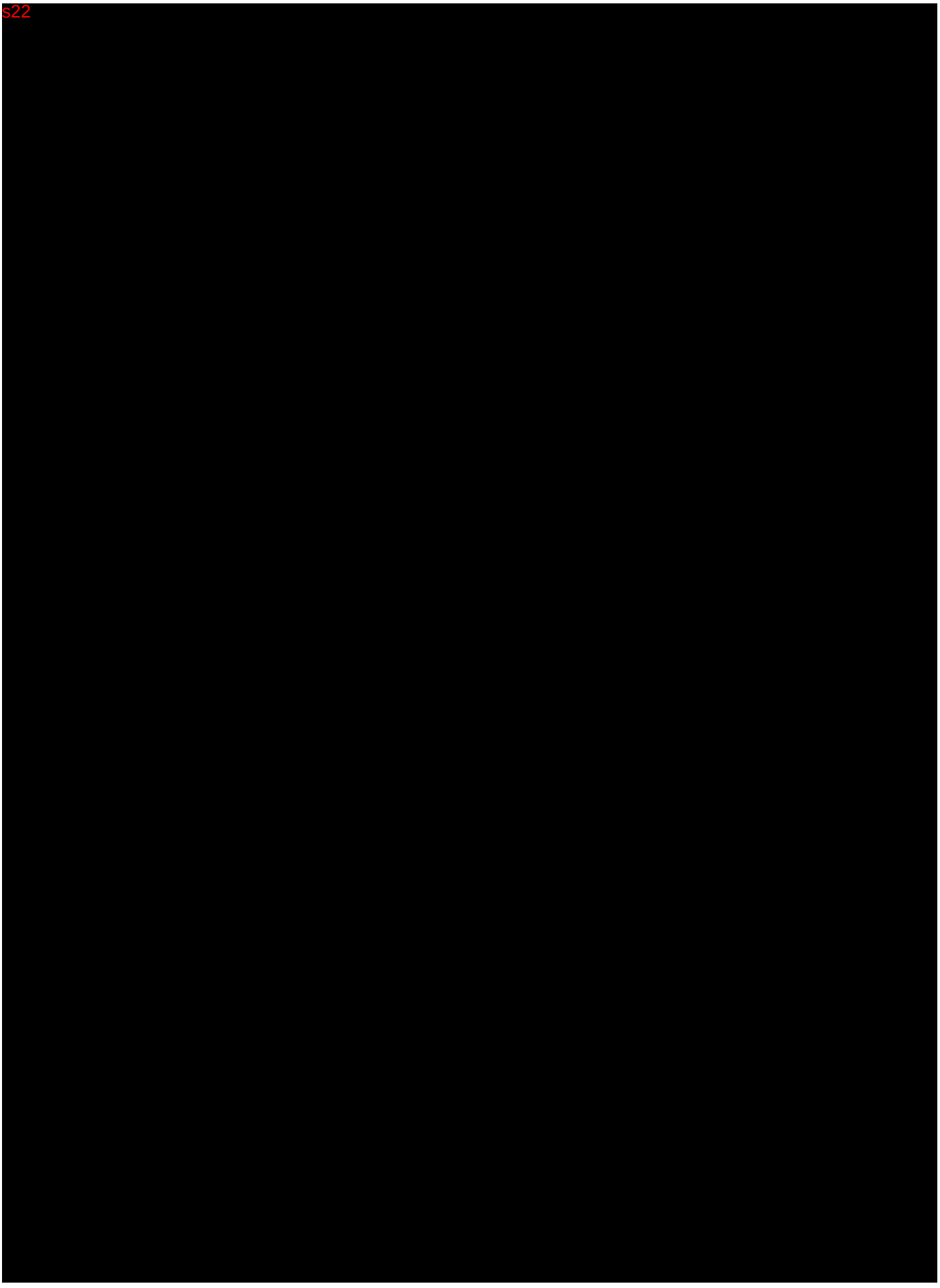

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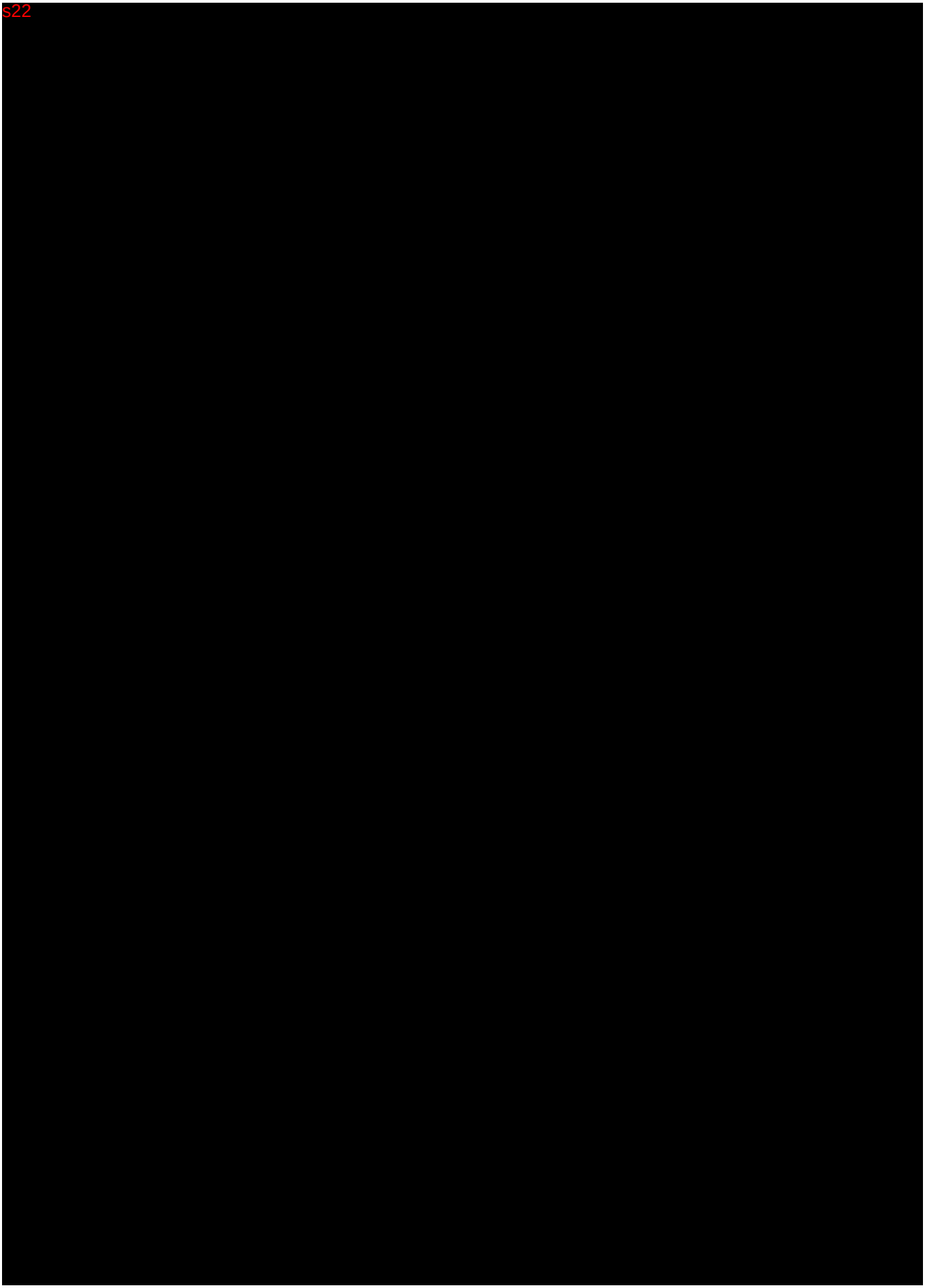

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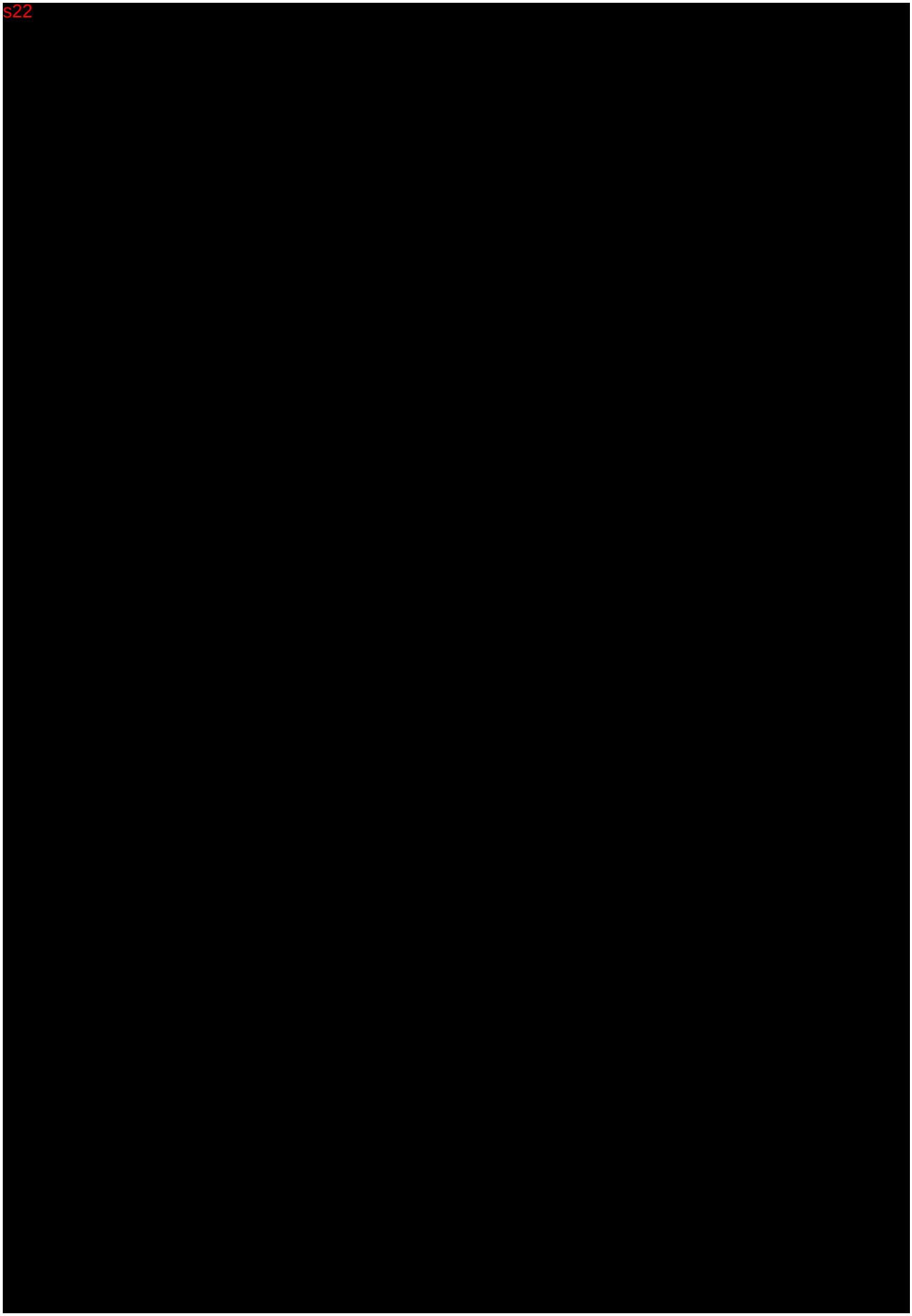

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3 Next meeting

The members noted that the next meeting of the Committee is scheduled for 14-16 March 2023.

4 Closure

The Chair closed the meeting at 5:30 pm, 16 November 2022.

s22 [redacted]

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s22 [redacted] Date 27 January 2023

s22 [redacted]

40th meeting of the Advisory Committee on Medicines Scheduling

DECISION MINUTE

The medicines scheduling delegate's interim decisions on proposed amendments to the current Poisons Standard and the public notice of those decisions

To: s22 [redacted]
Advanced Biological and Therapeutics Section
Prescription Medicines Authorisation Branch
Medicines Regulation Division
Health Products Regulation Group

From: s22 [redacted]
Scheduling Section
Regulatory Engagement Branch
Regulatory Practice and Support Division
Health Products Regulation Group

_____Signed in TRIM_____
01 / 02 / 2023

Purpose

Interim Decisions

For you to approve the scheduling interim decisions, including the reasons for those decisions, in the *November 2022 Notice of the interim decision to amend (or not amend) the current Poisons Standard* (the **Notice**) **(Attachment A)** in relation to

- substances referred to the November 2022 meetings of the:
  - Advisory Committee on Medicines Scheduling (ACMS #40);
    - Paracetamol;

s22 [redacted]

  - Advisory Committees on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #32)

s22 [redacted]

Scheduling interim decisions public notice

Per regulation 42ZCZP of the *Therapeutic Goods Regulations 1990* (the **Regulations**), the Notice will inform the public of the interim scheduling decisions, the reasons for the decisions, and the proposed dates of effect. It will also invite interested persons to make submissions in relation to this interim decision by the closing date (at least 10 business days after publication of the notice).

Background

The Secretary of the Department of Health and Aged Care is granted powers concerning the making of interim decisions to amend the current Poisons Standard under regulation 42ZCZN of the Regulations.

Where the Secretary exercises the powers granted under regulation 42ZCZN of the Regulations, regulation 42ZCZP of the Regulations requires that the Secretary publish, in a manner that the Secretary considers appropriate, the decision, the reasons for the decision, and the proposed date of effect of the decision (in circumstances where the interim decision proposes an amendment to the current Poisons Standard). Regulation 42ZCZP further requires that the notice invite interested persons to make submissions to the Secretary in relation to the interim decision by a date mentioned in the notice as the closing date for submissions (being a date at least 10 business days after the publication of the notice).

As an s22 in the Medicines Regulation Division, you have been delegated the powers of the Secretary under regulation 42ZCZN of the Regulations (**Attachment B**).

Timing

As the Minister has been briefed that the Notice will be published on 3 February 2023, it must be finalised and provided to the TGA website by 1 February 2023. Therefore, this minute is requested to be actioned before **1 February 2023**.

Scheduling amendments referred to expert advisory committee

Before making an interim decision in relation to a proposed amendment to the current Poisons Standard under regulation 42ZCZN of the Regulations, you must have regard to any recommendations or advice of the following expert advisory committees:

- The advice received from the meeting of the Advisory Committee on Medicines Scheduling (ACMS #40), available at D23-5069580;
- The advice received from the joint meeting of the Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #32), available at D23-5052518.

Consultation

Consultations occurred in accordance with regulation 42ZCZK of the Regulations. A notice inviting public submissions on proposed amendments to the Poisons Standard referred to the November 2022 meetings of the ACMS #40 and Joint ACMS-ACCS #32 was made available on the TGA website on 1 September 2022 (closed on 29 September 2022).

The public submissions received in response to the pre-meeting consultation under regulation 42ZCZK of the Regulations are available at D22-5986882 and D22-5941859.

After considering the advice or recommendation of the ACMS and Joint ACMS-ACCS, you must, subject to regulation 42ZCZO (see below), make an interim decision in relation to the proposed amendments.

In accordance with regulation 42ZCZO of the Regulations, you may make a final decision without making an interim decision if no public submissions are received in response to the pre-meeting consultation.

Medicines Scheduling Delegate's Decision

I am a delegate of the Secretary for the purpose of regulation 42ZCZN of the Regulations. After considering all relevant submissions and advice received from the ACMS #40, I have made an interim decision under regulation 42ZCZK with respect to the following substances:

- Paracetamol;

s22 [redacted]

I **approve** the scheduling interim decisions in the Notice **(Attachment A)**, and I confirm it correctly reflects my interim decisions for the above named substances.

I **approve** the publication of the Notice **(Attachment A)** on the TGA website.

I note that the publication of the Notice **(Attachment A)** is in compliance with regulations 42ZCZP of the Regulations.

Signed in TRIM

_____

s22 [redacted]

s22 [redacted]

01 / 02 / 2023

Resigned in TRIM 2/2/23

Attachments:

Attachment A *Notice of the interim decisions to amend (or not amend) the current Poisons Standard* for publication on the TGA website (D22-6198608).

Attachment B Therapeutic Goods (Secretary) (No. 2) Delegation 2022 Instrument – dated 9 November 2022 (D22-6079964).

Contact officer:	s22
Phone:	s22

DECISION MINUTE

The medicines scheduling delegate's final decisions on proposed amendments to the current Poisons Standard and the public notice of those decisions

To: s22 [redacted]
Advanced Biological and Therapeutics Section
Prescription Medicines Authorisation Branch
Medicines Regulation Division
Health Products Regulation Group

From: s22 [redacted]
Scheduling and Chemicals Policy Section
Regulatory Engagement Branch
Regulatory Practice and Support Division
Health Products Regulation Group

Signed in TRIM

1 / 05 / 2023

Purpose

Final Decisions

For you to approve the scheduling final decisions in the *Notice of the final decisions to amend (or not amend) the current Poisons Standard* (the **Notice**) **(Attachment A)**, and confirm that Attachment A correctly reflects your final decisions for those decisions, in relation to the below substances:

- Substances referred to the November 2022 meeting of the Advisory Committee on Medicines Scheduling (ACMS #40);
    - paracetamol;

s22 [redacted]

- Medicines that are new chemical entities (NCEs):

s22 [redacted]

s22 [redacted]

Scheduling final decisions public notice

For you to note that, as per regulation 42ZCZS of the *Therapeutic Goods Regulations 1990* (the **Regulations**), the Notice will inform the public of the final scheduling decisions, the reasons for those decisions and the proposed dates of effect.

Background

The Secretary of the Department of Health and Aged Care is granted powers concerning the making of final decisions to amend the current Poisons Standard under regulation 42ZCZR of the Regulations.

Where the Secretary exercises the powers granted under regulation 42ZCZR, regulation 42ZCZS of the Regulations requires that the Secretary publish, in a manner that the Secretary considers appropriate, the decision, the reasons for the decision, and the date of effect of the decision.

The powers of the Secretary under regulations 42ZCZR, 42ZCZS, 42ZCZU and 42ZCZX are delegated to you, as an s22 [redacted] in the Medicines Regulation Division (**Attachment B**).

Timing

We are seeking to publish the Notice on the TGA website no later than 3 May 2023. As such, we request that the Notice be finalised and this Minute actioned by COB **2 May 2023**.

Scheduling amendments referred to expert advisory committee

In exercising a power under subsection 52D(2) of the *Therapeutic Goods Act 1989* (Act), you must have regard to any recommendations or advice of the Advisory Committee on Medicines Scheduling:

- The advice received from the Meeting of the Advisory Committee on Medicines Scheduling (ACMS #40) is available at D23-5069580.

Consultation

Consultations occurred in accordance with regulations 42ZCZK and 42ZCZP of the Regulations. Notices inviting public submissions on proposed amendments to the Poisons Standard referred to the November 2022 meetings of the ACMS #40 and Joint ACMS-ACCS #32 were made available on the TGA website on 14 September 2022 (closed on 14 October 2022) and 3 February 2023 (closed on 3 March 2023).

- The public submissions received in response to an invitation published under regulation 42ZCZK of the Regulations are available at D22-5986882 (paracetamol submissions) and D22-5941859 (submissions relating to all other substances).

- The public submissions received in response to the call for further submissions under regulation 42ZCZP of the Regulations are available at D23-5184793 (paracetamol submissions) and D23-5184797 (submissions relating to all other substances).

In reconsidering an interim decision under regulations 42ZCZQ you must:

- consider all public submissions (the relevant submissions) made by the second closing date that:
  - address a matter mentioned in section 52E of the Act; and
  - are relevant to the Secretary's interim decision.

Medicines Scheduling Delegate's Decision

I am a delegate of the Secretary for the purpose of regulation 42ZCZR of the Regulations. After considering all relevant submissions and advice received from the Advisory Committee on Medicines Scheduling (ACMS #40), I have made final decisions under regulation 42ZCZR with respect to the following substances:

- paracetamol;

s22 [redacted]

I **approve** the scheduling final decisions for these substances in the Notice **(Attachment A)**, and I confirm it correctly reflects my reasons for those decisions.

I **approve** the publication of the Notice **(Attachment A)** on the TGA website.

I note that the publication of the Notice **(Attachment A)** is in compliance with regulations 42ZCZS and 42ZCZX of the Regulations.

Electronically signed in TRIM

_____

s22 [redacted]

s22 [redacted]

01 / 05 / 2023

Attachments:

Attachment A *Notice of the final decisions to amend (or not amend) the current Poisons Standard* for publication on the TGA website (D23-5097707)

Attachment B Therapeutic Goods (Secretary) Delegation (No. 2) 2023 instrument - dated 6 April 2023 (D23-5282035).

Contact officer: Phone:	s22 [redacted]

Australian Government
Department of the Prime Minister and Cabinet
Office of Best Practice Regulation

GUIDANCE NOTE

Australian Government Regulation Impact Statement Preliminary Assessment Form: Is a RIS required?

March 2020

The Government has introduced the *Australian Government Guide to Regulatory Impact Analysis* (the Guide), which outlines the process for developing a regulatory proposal, including a Regulation Impact Statement (RIS).

All Cabinet submissions require a RIS. RISs are also required for all decisions made by the Australian Government and its agencies[1] that are likely to have a positive or negative impact on businesses, community organisations or individuals, unless the proposed change is a minor or machinery change.

It is your responsibility to contact OBPR for advice on whether a RIS is required for your proposal. OBPR conducts a Preliminary Assessment to determine whether one is needed, based on the information that you provide in the form discussed in this guidance note.

Contacting OBPR early during policy development will help you to:

- progress the proposal through decision making forums, such as Cabinet, in a timely manner
- ensure full compliance with the Government's requirements.

The Preliminary Assessment form

When you have a rudimentary set of answers to the seven RIS questions listed in the Guide, give a written summary to OBPR in the form shown on the following page. If you provide enough information to help OBPR understand the nature of the proposal, you should receive a response within five working days confirming whether or not a RIS is required and, if so, the depth of analysis required. This is known as a Preliminary Assessment.

Of course, OBPR's advice on whether a RIS is required may be revised in light of additional or updated information – such as from stakeholders – indicating the impacts are likely to be more significant than first envisaged.

While filling in this form is not compulsory, it will help you identify the key features of your regulatory proposal. This will allow OBPR to quickly assess whether a RIS is required.

If you have any questions about completing the form, contact OBPR at Helpdesk-OBPR@pmc.gov.au or call (02) 6271 6270.

A different Preliminary Assessment form is required for decisions taken by intergovernmental decision-making bodies.

[1] Such as decisions arising through correspondence with the Prime Minister, decisions made by departmental heads, and those made by statutory agencies and boards.

Preliminary Assessment Form

Overview

Name of department/agency

Department of Health and Aged Care – Therapeutic Goods Administration (TGA)

Name of proposal

Proposed amendments to the Poisons Standard in relation to paracetamol

Description of the problem

Each year in Australia around 225 people are hospitalised and 50 Australians die from intentional paracetamol overdose, involving products that are self-selected by the consumer in general retail sale and in pharmacies. There has been an increase in the incidence of intentional paracetamol overdoses in the last decade in Australia, with the greatest proportion of cases in adolescents and young adults, and females are significantly over-represented. The steepest increases in young people have been between 2019 to 2021. The age of persons overdosing has also been lowering. The mortality and morbidity has lasting impacts for individuals, families, and communities, as well as the healthcare system and the economy.

Outline of the objectives of government action

Reduce the incidence and harm from intentional paracetamol overdose. The recommended dosage for people over the age of 12 years is 500 to 1000 mg every four to six hours as necessary, with a maximum of 4000 mg in any 24 hour period. Government action is focussed on limiting access to paracetamol in amounts corresponding to the minimum toxic dose of 10 grams (10 times the upper limit of the recommended four to six hourly dosage), and giving regard to 25 grams or higher of paracetamol that disproportionately causes harm.

Background

Scheduling is a national classification system that allows restrictions to be placed on how medicines and poisons are made available to the public in order to protect public health. Medicines and poisons are classified into Schedules within the Poisons Standard according to the level of regulatory control required over the availability of the medicine or poison. This is aimed at minimising the risks of poisoning from, and the misuse and abuse of, scheduled substances. The current version of the Poisons Standard is available at https://www.legislation.gov.au/Details/F2023L00067.

Scheduling is a scheme agreed to by all states and territories and legislated in the *Therapeutic Goods Act 1989* (Cth) ('the Act') by the Commonwealth Parliament, which has intended that access restrictions on medicines may be (and regularly are) imposed from time to time through scheduling to protect public health. The Poisons Standard is given legal effect through state and territory legislation. This is different to policy decisions made by government.

Scheduling decisions are made by a delegate of the Secretary of the Department of Health and Aged Care ('the Delegate') according to subsection 52D(2) of the the Act and take into account relevant matters of public health as set out under section 52E of the Act. These matters include the risks and benefits of the use of a substance, the purposes for which a substance is to be used, the substance's toxicity, dosage, formulation, labelling, packaging, presentation, any potential for abuse, and the Scheduling Policy Framework (SPF). The SPF sets out the national policy for applying access restrictions on medicines and chemicals, including the factors to be considered for including substances in particular Schedules of the Poisons Standard. Decision makers have a measure of discretion particularly in relation to the timeframe for the implementation of any changes to access controls on poisons.

Paracetamol is currently included in Schedules 4 ('Prescription Only'), 3 ('Pharmacist Only') and 2 ('Pharmacy Only') of the Poisons Standard. The types of products containing paracetamol in each schedule differ and are ultimately based on the level of risk and need for health professional involvement. The level of risk varies between products containing paracetamol and depend on factors such as quantity, dosage form and strength. For example:

Preliminary Assessment Form

- Some products are not scheduled and are thus available by general retail sale. This includes, for example, small quantities of instant release paracetamol (≤ 20 tablets) that are very low risk and used for minor, self-resolving ailments.
- Products available over the counter in pharmacies are included in Schedule 2 or 3. Higher quantities of immediate release paracetamol (≤ 100 tablets) are available for self-selection as Schedule 2 medicine but may require pharmacist intervention so are only available from a pharmacy. Modified release paracetamol products are Schedule 3 and are only available behind the counter with pharmacist oversight as they are intended for chronic conditions and pose a greater overdosing risk.
- Products only available by prescription are at least Schedule 4 and require oversight from a doctor, such as very high strength tablets (>665 mg) and preparations for injection.

The TGA, is considering whether the current scheduling of paracetamol is appropriate. This is in response to concerns raised by members of the public around its misuse. The TGA commissioned, on the advice of the Advisory Committee on Medicines Scheduling (ACMS), an independent expert report ('the Report') on the risks of paracetamol overdose. The ACMS is an independent advisory committee made up of medical and pharmacist experts from across Australia as well as nominees of each state and territory.

The Report identified an increasing incidence of intentional overdoses, particularly among adolescents and young adult females, and documented findings on the significant risks of acute paracetamol toxicity and its potential to cause liver failure and death in severe overdoses. Paracetamol is involved in around 50% of all cases of intentional overdose, the incidence of which is increasing. The Report showed that severe paracetamol overdoses of 25 g or higher disproportionately cause severe liver toxicity. Concerningly, this threshold is less than 10 times the recommended maximum daily dose of paracetamol. The nature of intentional paracetamol overdose is impulsive and mostly involves the consumption of paracetamol already in the home. The Report included seven (7) recommendations to reduce the risks associated with this medicine.

Three of these recommendations were not specific to reducing self-poisoning with paracetamol, and included communicating harms, after care services and safer storage messaging. These are outlined further in option 4 below. The Report noted there was little data on the role of education and that public health sites already provide messaging around safe storage. While post care and treatment has been shown to be highly effective, however, the Report highlighted tightening access to paracetamol through the amendment of the Poisons Standard is likely to have the greatest impact in adolescents, especially in the short term (Options 2 and 3, below).

It is accepted that paracetamol has a well-established safety profile at therapeutic doses, which has contributed heavily to its widespread use for acute and chronic pain and to reduce fever. The introduction or tightening of any restrictions on access to paracetamol through scheduling has the potential to interfere with the significant benefit individuals and public health from the legitimate use of paracetamol. Unintended consequences of tightened restrictions could include: stock-piling in response to restrictions, resorting to inappropriate use of anti-inflammatories, and damaging the public's perception of paracetamol as being safe for use in accordance with instructions, as highlighted in the interim decision (see below). Although appropriate access to paracetamol remains essential, intervention is needed to address the devastating consequences of paracetamol overdose among our vulnerable adolescent population.

The Report highlighted several phenomena that suggest such means restrictions should involve reducing the amount of paracetamol available within the home, thereby reducing the likelihood that impulsive self-poisoning leads to severe toxicity:

- over half the time people who overdose with paracetamol, particularly young people, use what is readily available in the home, as they do not have access to other medications, such as prescription drugs.
- the most ingested pack size was 96/100 tablets.
- the majority of people who intentionally overdosed had suicidal intent and did so impulsively.

Preliminary Assessment Form

- overdosing with greater than 25 grams disproportionately causes significant harm. Overdoses of 25 grams or lower are easier to treat.

Currently, pack size limits exist for paracetamol that can be self-selected in general retail sale and in pharmacies. However, the maximum pack size for self selection in pharmacies is 100 tablets (of 500 mg), which exceeds the threshold of 25 g above which liver failure and death is most likely to occur. Additionally, the maximum pack size in general retail sale for self-selection is 20 tablets, which is equal to the minimum toxic dose of paracetamol of 10 grams.

On the advice of the Advisory Committee on Medicines Scheduling (ACMS) in September 2022, the TGA consulted publicly on a variety of possible options to change the scheduling of paracetamol in the Poisons Standard to address the risks of paracetamol overdose in response to the Report. Stakeholders were provided one month to make submissions. 190 submissions were received. There was a broad spectrum of views, however, over 50% of peak body respondents either partially supported or fully supported some form of pack size reduction and blister pack mandate. These two options were also among the most supported of the proposed restrictions (see outline of the options available).

In February 2023, the TGA published the Delegate's interim decision to change the scheduling of paracetamol. The Delegate considered the concerns raised by the ACMS, peak bodies (30+ submissions) and members of the public before making the interim decision. The proposed changes, that are intended to occur in conjunction with public health initiatives (e.g., TGA education campaign about paracetamol), are:

- 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 supervision of a pharmacist (i.e., 'Pharmacy Only' packs) from 100 to 32 tablets or capsules
- make other pack sizes of up to 100 tablets or capsules only available under the supervision of a pharmacist ('Pharmacist Only' medicines).
- Packs of paracetamol on General Sale and Pharmacy Only sale would also be required to be in blister packaging to deter overdose from ingesting large numbers of tablets or capsules.

The interim decision intends to narrow existing limits rather than introduce new limits. The interim decision addresses the nature of the problem, and represents the options that were consulted on that were the most favoured by consultation respondents. The Delegate considered that it provides the most balanced and proportionate response to minimise harm from intentional self-poisoning with paracetamol without compromising essential access. Taking into account consultation submissions, the Delegate decided that the other options that were consulted that do not form part of the interim decision were unsuitable because they will be unlikely to address the problem and/or represent an undesirable risk-benefit balance.

Public consultation was opened on the interim decision from 3 February 2023 to 3 March 2023. There were 15 peak bodies that provided a response with 14 partially or fully supporting the interim decision, including peak bodies with divergent views such as those representing suicide prevention and those representing people with pain. There were ongoing concerns expressed by representatives of industry and the Delegate will consider these along with the timeframe for implementation. However, a number of health professional peak bodies considered that the interim decision achieves an appropriate balance. A final decision has not been made and would only occur after consideration of all public submissions from the second consultation, and any Regulatory Impact Statement (if required).

Outline of the options available

1. Status Quo

2. Tightening access to paracetamol through the amendment of the Poisons Standard as proposed in the **interim decision** (along with public education initiatives):

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a. Requirement for blister packs.
Rationale: 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.

b. Pack size restrictions.
Maximum pack sizes for unscheduled products reduced from 20 to 12 or 16 tabs; S2 pack sizes reduced from 100 to 24 or 32. Rationale: 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.

3. Non-regulatory public health initiatives:
   a. Use safe reporting guidelines for any communication around the harms associated with paracetamol (or any other) overdose. Any communication around the potential harms of paracetamol must comply with safe reporting guidelines and be rigorously evaluated prior to implementation.
   b. Maintain and expand support for aftercare services. All intentional self-poisonings should be offered appropriate care and Australian recommendations for aftercare (follow-up care and support after self-harm) implemented.
   c. Inform safer storage of medicines and reduced stockpiling of unwanted medicines. Generic messages around keeping medications and chemicals out of harm's way might reduce intentional poisoning risks for children and adults.

4. Self regulatory controls: the market providing self-regulatory controls to reduce the amount of paracetamol sold (e.g., pack limits).

The TGA consulted on other options involving amendment of the Poisons Standard before the Delegate made their interim decision. Based on the Report's findings these options are either considered unlikely to address the problem and/or public consultation responses highlighted unfavourable impacts and attracted a low level of support. The options were: limiting the maximum number of packs that can be purchased in one transaction to 1 or 2 packs to reduce home stockpiles; prohibiting display and self-selection of paracetamol in general (non-pharmacy) retail outlets; making Modified Release paracetamol that is for long-term use (e.g., for osteoarthritis) prescription-only (S4), and; restricting sales to adults.

The following questions will be answered in relation to the interim decision.

Other elements of your proposal (including consultation undertaken or proposed)

There is a precedent for addressing the risks from paracetamol use by its rescheduling in the Poisons Standard. A final decision was made on 26 August 2019 to up schedule modified release (MR) paracetamol from Schedule 2 to Schedule 3 in response to intentional MR paracetamol overdose. The date of effect was 1 June 2020. The rescheduling proposal was assessed in June 2019 as having no more than minor impacts and a Regulatory Impact Statement was not required OBPR ref: 25216.

A final decision to amend the Poisons Standard in relation to paracetamol restrictions will follow the two rounds of public consultation—with each round open for one month—that have been undertaken. In the first round of consultation that informed the interim decision there were 190 submissions received including over 30 from peak bodies. From the second round of consultation in response to the interim decision there were 200 submissions received with 15 from peak bodies. Initially, submissions expressed a

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variety of divergent views and have come from individuals, businesses, and peak bodies representing consumers, health professionals and industry. Responses to the interim decisions were less polarised than in the first round of consultation, with increased support from peak healthcare and consumer bodies, and general opposition from industry.

Who will the decision maker be?

Not Cabinet or the Minister for Health and Aged Care.

A senior medical officer employed by TGA as delegate of the Secretary of the Department of Health and Aged Care will be the decision maker.

Likely impact on businesses, community organisations and individuals

Is your proposal likely to have any regulatory impacts? If so, please specify. (Further advice on regulatory impacts, can be found at the end of this document.)

The responses to the changes proposed in the interim decision are anticipated to be:

- Actions by manufacturers/pharmaceutical companies to change the primary and secondary packaging of affected paracetamol containing products, mostly depending on whether the sponsor of the product elects to either (a) change the number of tablets or capsules in their product to maintain its current scheduling status or (b) present the product with a different scheduling status (e.g. from general sale to Pharmacy Only). (See below for information about sponsors).

  There are 350 non-prescription paracetamol products on the ARTG from 40 sponsors. These are general retail (approx. 20%), Pharmacy Only (approx. 60%) or Pharmacist Only (approx. 20%) medicines. The number of these products that are actually marketed is not known but is likely to be less than the total on the ARTG.

  Manufacturers might be required to change blister packaging, reduce pack sizes, or update labelling or a combination of these. However, mandating blister packaging is expected to affect a small proportion of sponsors and products since most tablet or capsule products are already in blister packaging; consultation with industry revealed that bottled products represent only 8% of the market share in general retail and are expected to be similar in a pharmacy setting. This aligns with the small number of bottled paracetamol products on the register. Thus most changes will relate to pack size changes (e.g. changing from 20 (2 x strips of 10) to 16 (2 x strips of 8).

  We estimate that roughly half of the non-prescription paracetamol products that are marketed will be affected in some way by the interim decision to reduce pack sizes.

  Numerous aspects of the manufacturing changes will likely be of relatively low burden. The relabelling of the outer carton (secondary packaging), such as signal headings, should not require any mechanical changes to manufacturing lines. Implementation of the interim decision could be timed so that manufacturers can make the label changes in line with their usual printing cycles (approximately 18 months).

  If the sponsor has elected to change the pack size of their product, this will require redesign and reconfiguration of blister strips (primary packaging). For example, from 10 to 8 tablets per blister strip. Manufacturers could 1) use the existing mould but trim the strip 2) use the existing mould but only punch 8 of the 10 slots, or 3) create and order a new mould specifically for an 8-blister strip. The pack size restrictions of the interim decision allow for the 8-tablet blister strip to be used in both settings for products, such as Panadol, that exist in multiple schedules. For example, 8 blister strip x 2 = product of 16 tablets for general retail and 8 blister strip x 4 = product of 32 tablets for schedule 2 ('Pharmacy Only').

  Higher burden will be placed on manufacturers that opt to create and order a new mould specifically for an 8-blister strip. In a sponsor's response to the interim decision, they highlighted a longer implementation date would be required for redesign, lead-time for new moulds and carton

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size parts along with commissioning the new line and then supplying to retailers. s22 [redacted]

However, sponsors may instead elect to have their reduced pack size product manufactured by a different manufacturer that is already equipped to produce 8-blister strips. There are paracetamol products already marketed abroad (e.g. in the United Kingdom) that are manufactured with 8-blister strips, including Panadol Extra and Panadol Advance

Increased manufacturing costs due to blister pack mandates and reduced pack sizes that may be passed on to consumers. However, paracetamol is generally a low-cost medication, and the proposed changes will principally impact products purchased for the management of short-term pain where purchases are relatively infrequent. The higher pack sizes for chronic pain and loose pack paracetamol for those with dexterity issues should remain at a similar price and will still be available in a pharmacy setting

- Applications to the TGA by sponsors of paracetamol medicines to vary the registration of their products on the Australian Registration of Therapeutic Goods (ARTG) as a result of alterations to packaging (if applicable) and labelling.

  Based on the interim decision, sponsors have a number of options regarding their products, all of which would require some change to their registration in the ARTG through an application to the TGA: 1) reduce the number of tablets/capsules in a pack and adjust labelling to continue to present it under its current scheduling status, 2) present their product as being in a higher schedule of the Poisons Standard (e.g. Pharmacist Only instead of general sale), or 3) withdraw their product.

  Sponsors that elect to keep their product on the market will need to pay a small fee between $1744 and $6053 with processing timeframes between 20 and 64 working days. A significant proportion of these applications—for those Schedule 2 products that will move to be Schedule 3 products—will also need to be accompanied by a product information (PI) and consumer medicine information (CMI) document for their product that is prepared by the sponsor and reviewed by the TGA. The time and effort to develop PI and CMI documents for schedule 3 paracetamol products are expected to be minimal and the TGA are able to provide PI and CMI templates to facilitate this transition.

  If the significant minority of products that currently exist as loose fill are moved to blister packaging, the sponsors will be required to submit a new product application. However, it is likely they will be eligible for reduced data requirements and fees.

  Finally, if a pharmaceutical company decides to withdraw their product, they can formally notify the TGA via an online form on the TGA website and it will be processed within 5 business days.

- Pharmacy staff will need to adjust their arrangements for paracetamol products that vary their registration and move to schedule 3. These adjustments include labelling the products with the name and address of the pharmacy before it is given to the consumer to comply with labelling requirements of schedule 3and changing the location from an area of self-selection to behind the counter.

- Additional time for consumers who will need to personally engage with pharmacists. The consumer will need to consult with a pharmacist but will not be confronted with additional costs such as visiting a GP as a prescription will not be required.

s22 [redacted] is yet to conduct a full review of the interim decision, they have stated it is a detailed

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and well considered response to balance community access to everyday pain relief, alongside the potential for intentional misuse.

In relation to those options that were consulted on in the first round but not included in the interim decision, factors deemed to create an unfavourable risk-benefit balance included:

- increased costs for consumers;
- impacts on chronic pain management in the community;
- impaired timely access for acute management of pain, and;
- disadvantages to certain population groups, such as those in rural and remote areas, those with hand dexterity and mobility issues, and those under the age of 18 living independently.

The changes included in the interim decision are considered to avoid the unintentional consequences of over restriction, such as inadvertent increases in stockpiling in response to restrictions, consumers resorting to inappropriate use of anti-inflammatories, and damaging the public's perception of paracetamol as being safe for use in accordance with instructions.

If the delegate determines that a change is required, the currently proposed implementation for the final decision is 1 June 2024 so the availability of any over-the-counter products containing paracetamol will not change before then. The delegate will announce an implementation date that will allow time for industry, consumers, pharmacists and doctors to manage any change.

What is your assessment of the significance of the likely impacts of the proposed regulation? Why?

The measures in the interim decision, if implemented by a final decision, are likely to meaningfully minimise harm and reduce the severity of intentional paracetamol overdoses, which has been effectively demonstrated by the implementation of similar measures overseas according to the Report.

The interim decision carefully considers the need to ensure adequate access to paracetamol is retained for acute and chronic pain and to reduce fever as well as avoiding unintended consequences, which are detailed in the interim decision.

The Delegate has the power to control the timing of the implementation date and can therefore balance the urgency of the change to protect public health with the impacts it will have on industry. There is opportunity for the Delegate to align an implementation date with manufacturers packaging cycles to integrate the changes and facilitate the transition for industry.

Have you considered whether small businesses should have different obligations from larger businesses in relation to the operation of the possible regulation? ☒ Yes ☐ No

Have you designed the operation of the possible regulation taking into account the impact on small businesses?

☒ Yes ☐No N/A. The size of the business is not a factor. It was considered that there cannot be different regulatory obligations.

The Australian Small Business and Family Enterprise Ombudsman's (ASBFEO) office should be contacted to help assess this (contact: regulation@asbfeo.gov.au)

If you answered yes above:	1. Have you contacted the ASBFEO's office? ☐ Yes ■ No
	2. How does the design of the proposed regulation take into account the impact on small businesses? All businesses, small and large, were able to make submissions in the 1st round of consultation and these were taken into account in developing the possible regulation.

Is your proposal likely to have any international trade and investment law impacts? ☐ Yes ■ No

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The Trade and Investment Law Branch at the Department of Foreign Affairs & Trade (trade.law@dfat.gov.au) can help you assess these impacts.
Timing
Key dates and timeline: • **May 2022:** Independent expert report commissioned by the TGA • **August 2022:** ACMS considered paracetamol and advised to consult widely • **14 September 2022:** Independent expert report published • **14 September 2022 – 14 October 2022:** first round of public consultations • **November 2022:** ACMS meeting where paracetamol restriction recommendations were made • **3 February 2023:** interim decision published • **3 February 2023 – 3 March 2023:** second round of public consultations • **April 2023:** final decision to be published • **June 2024:** proposed date of effect (subject to feedback in second round public consultation closing 3 March 2023)
Contact information (Please enter your contact information below)
Name: s22 [redacted]
Email and Phone: s22 [redacted]
Date: March 2023
Please forward the completed form to OBPR at Helpdesk-OBPR@pmc.gov.au or call (02) 6271 6270 to discuss your proposal with an OBPR officer.

From: Helpdesk-OIA
To: s22
Cc: Regulatory Impact Analysis; s22 s22 Medicines Scheduling; s22
Subject: RE: Update: Paracetamol Preliminary Assessment [SEC=OFFICIAL:Sensitive] - OBPR22-03793 [SEC=OFFICIAL]
Date: Thursday, 6 April 2023 4:28:36 PM
Attachments: image.png
image002.png
image003.jpg
image005.jpg
image009.gif
image008.png
image004.jpg
image010.png
image006.png
image001.png

Dear s22,

Regarding: OBPR22-03793 - Paracetamol reforms

Thank you for submitting your proposal to the Office of Impact Analysis (OIA) for our consideration and advice. Based on the information provided, the OIA considers the proposal is unlikely to have a more than minor regulatory impact, as the proposed changes will not limit the amount of paracetamol available for purchase by consumers who wish to purchase multiple packs, and the impact on pharmaceutical companies can be mitigated by seeking alternative manufacturing arrangements. As such, the preparation of an Impact Analysis (IA) is not required.

If any of the above is inconsistent with your proposal, or should your proposal change significantly from the details provided, please contact us again to ensure our advice remains current. Please quote your reference number (OBPR22-03793) to ensure we can assist you promptly.

Kind regards,
s22

s22
Department of the Prime Minister and Cabinet
p. s22 | m s22 | e. s22 @pmc.gov.au| www.pmc.gov.au
Help Desk: Helpdesk-OIA@pmc.gov.au
1 National Circuit Barton ACT 2600| PO Box 6500 CANBERRA ACT 2600

---------- Original Message ----------
From: s22 @health.gov.au>;

Received: Wed Apr 05 2023 16:06:00 GMT+1000 (Australian Eastern Standard
s22
@pmc.gov.au>; OIA Help Desk helpdesk-oia
<helpdesk-oia@pmc.gov.au>; s22 @pmc.gov.au>;
OBPR Mailbox <helpdesk-oia@pmc.gov.au>;
Cc: Regulatory Impact Analysis s22 ; s22
@pmc.gov.au>; s22 @health.gov.au>; s22
@pmc.gov.au>; s22 @health.gov.au>;
s22 @pmc.gov.au>; s22
@health.gov.au>; Medicines Scheduling
<medicines.scheduling@health.gov.au>; s22 @pmc.gov.au>; s22
@pmc.gov.au>; s22
@pmc.gov.au>;
RE: Update: Paracetamol Preliminary Assessment [OBPR22-03793]
[SEC=OFFICIAL:Sensitive]

Hi s22

Thank you for your time yesterday.

I am following up on your question regarding the s22
s22

s22

If you would like further information, including calculations, we can provide this to you.

Kind regards,
s22

s22
Regulatory Engagement Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
E: s22 @health.gov.au
Location: s22
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Thursday, 30 March 2023 3:50 PM
To: s22 @pmc.gov.au>; s22 @pmc.gov.au>; Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Cc: s22 @Health.gov.au>; Regulatory Impact Analysis s22 ; Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @pmc.gov.au>; s22 @pmc.gov.au>
Subject: RE: Update: Paracetamol Preliminary Assessment [OBPR22-03793] [SEC=OFFICIAL:Sensitive]

Hi s22 ,

Thanks for getting back to us. I can propose 11 am or 1 pm, if either of those would suit on Tuesday? If you let me know I can send you an invite with connection details.

s22

From: s22 @pmc.gov.au>
Sent: Thursday, 30 March 2023 3:41 PM
To: s22 @health.gov.au>; s22 @pmc.gov.au>; Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Cc: s22 @Health.gov.au>; Regulatory Impact Analysis s22 ; Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @pmc.gov.au>; s22 @pmc.gov.au>
Subject: RE: Update: Paracetamol Preliminary Assessment [OBPR22-03793] [SEC=OFFICIAL:Sensitive]

OFFICIAL: Sensitive

Hi s22

Thanks for your email. I'm looking after TGA matters for OIA these days, so I'll take point on this proposal for s22 from here.

It would be good to set up a time to talk through these materials and the Impact Analysis process. Do you have any space in your calendar on Tuesday? We should have time from 10am onwards.

I note that the PA says your final decision point will occur in April 2023, and this proposal is likely to have Impact Analysis requirements, so it would be good to get moving on this as quickly as we can.

Kind regards,

s22

s22

Department of the Prime Minister and Cabinet
p. s22 | e. s22 @pmc.gov.au| www.pmc.gov.au
Help Desk: Helpdesk-OIA@pmc.gov.au
1 National Circuit Barton ACT 2600| PO Box 6500 CANBERRA ACT 2600

From: s22 @health.gov.au>
Sent: Thursday, 30 March 2023 3:12 PM
To: s22 @pmc.gov.au>; Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Cc: s22 @Health.gov.au>; Regulatory Impact Analysis s22 ; Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 @pmc.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: RE: Update: Paracetamol Preliminary Assessment [OBPR22-03793] [SEC=OFFICIAL]

Dear s22 and OIA team,

I pleased to provide you with our preliminary assessment form (***attached***) regarding proposed regulatory changes concerning paracetamol.

If it might assist you, we can propose a short meeting next week to answer any questions particularly in regard to the existing regulatory framework under which changes are

proposed to be made.

Please let us know if you require something further, including additional detail in any part of the form.

Kind regards,
s22

s22

Regulatory Engagement Branch
Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: s22
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @pmc.gov.au>
Sent: Monday, 13 February 2023 10:46 AM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; Regulatory Impact Analysis s22 ; Medicines Scheduling <Medicines.Scheduling@health.gov.au>; s22 @pmc.gov.au>; Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Subject: RE: Update: Paracetamol Preliminary Assessment [OBPR22-03793] [SEC=OFFICIAL]

OFFICIAL

Hi s22

Thanks for the update, much appreciated.

We look forward to receiving the preliminary assessment.

Kind regards,

s22

s22
Department of the Prime Minister and Cabinet
p. s22 | m. s22

Ngunnawal Country, One National Circuit Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600
e. s22 @pmc.gov.au w. pmc.gov.au

The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

From: s22 @Health.gov.au>
Sent: Monday, 13 February 2023 10:27 AM
To: s22 @pmc.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; Regulatory Impact Analysis s22 ; Medicines Scheduling <Medicines.Scheduling@health.gov.au>
Subject: Update: Paracetamol Preliminary Assessment [OBPR22-03793] [SEC=OFFICIAL]

Dear s22

My apologies for a delayed reply, I wanted to provide an update regarding the proposed amendments to the Poisons Standard in relation to paracetamol.

On 3 February 2023, an interim decision was published and proposed the following:

- 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 supervision of a pharmacist (i.e., "Pharmacy Only" packs) from 100 to 32 tablets or capsules
- make other pack sizes of up to 100 tablets or capsules only available under the supervision of a pharmacist ('Pharmacist Only' medicines).
- packs of paracetamol on General Sale and Pharmacy Only sale would also be required to be in blister packaging to deter overdose from ingesting large numbers of tablets or capsules.

A final decision has not yet been made and a second round of consultation are now open until 3 March 2023.

We are in the final stages of drafting the preliminary assessment. Our s22 and we endeavour to provide a draft the following week.

Kind regards,

s22 [redacted]

Regulatory Engagement Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
E: s22 [redacted] @health.gov.au
Location: s22 [redacted]
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

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