New Poisons Standard format and structure

Dr Adam Cook

Director, Scheduling Section,
Regulatory Engagement Branch

Ms Navreen Kular

Acting Principal Lawyer, Legal Advisings and
Legislation, Regulatory Legal Services Branch

7 December 2022

Welcome

Housekeeping

- This webinar is being recorded
- This webinar will be made available in the upcoming weeks
- Any relevant links will be broadcasted via the slido app/ or chat
- Q&A session will occur after todays presentation
- Live poll – how did we go, let us know

Difficulties hearing from computer?

Check your settings located under

"**Audio & Video"** tab located top of your screen:

OR

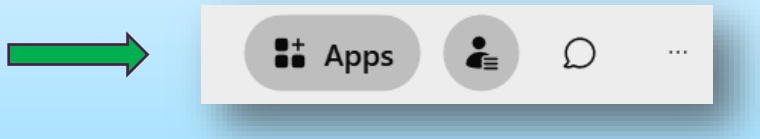
Dial: 02 9338 2221 (+61-2-9338-2221)

Access code: 2654 357 4854

How to ask questions

SLIDO

Slido App



- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device

Overview

- Background
- Key changes to the Poisons Standard
  - Structure
  - Formatting
  - Language and expression
- Implementation timeline
- Questions and answers

Background

What is the Poisons Standard?

- The Poisons Standard is a record of decisions on the classification of medicines and chemicals into Schedules.

- It also includes model provisions for containers and labels, and recommendations about other controls on medicines and chemicals.

- It is a Commonwealth legislative instrument published on the Federal Register of Legislation, which is managed by the Office of Parliamentary Counsel.

Background

How is the Poisons Standard implemented in law?

- The Poisons Standard is implemented through state and territory legislation which refers to different parts and Schedules of the Poisons Standard.

How often is the Poisons Standard updated?

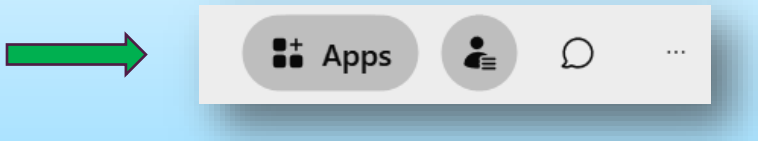
- The Poisons Standard is updated at a minimum of three times a year, which means that past versions are repealed and replaced with a new version.

- These regular updates to include decisions made on changes to the scheduling of substances are not the subject of today's presentation.

Question ‘App’ is now open

SLIDO

Slido App

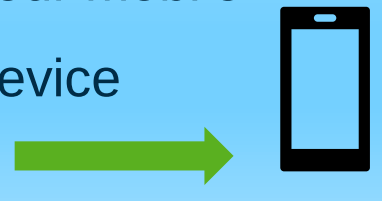


- Click on Apps+ icon
- Select “Slido”
- Open “Q&A” tab to ask questions
- Live Poll (use survey tab when prompted)

OR

Slido QR

Scan the QR code to access separately from your mobile device



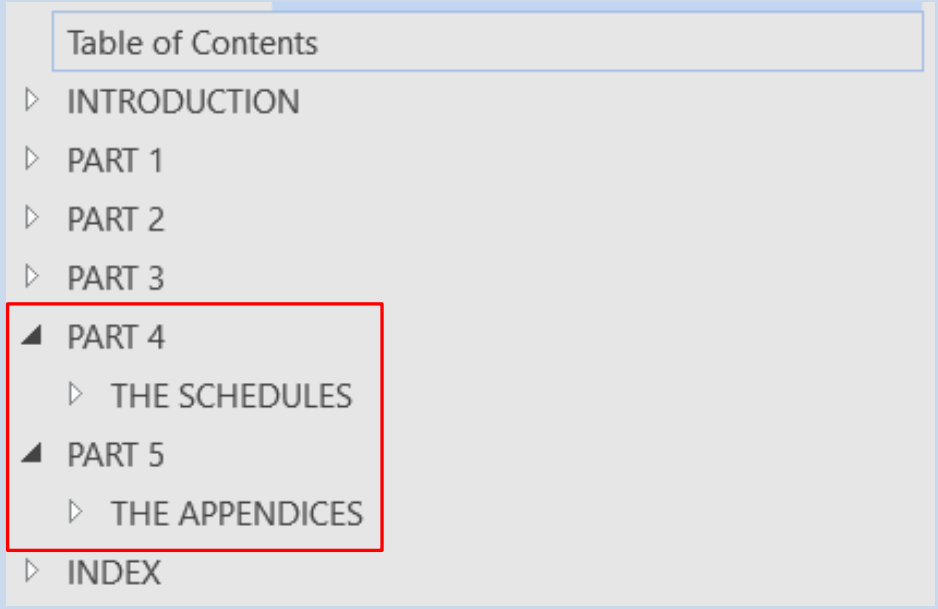
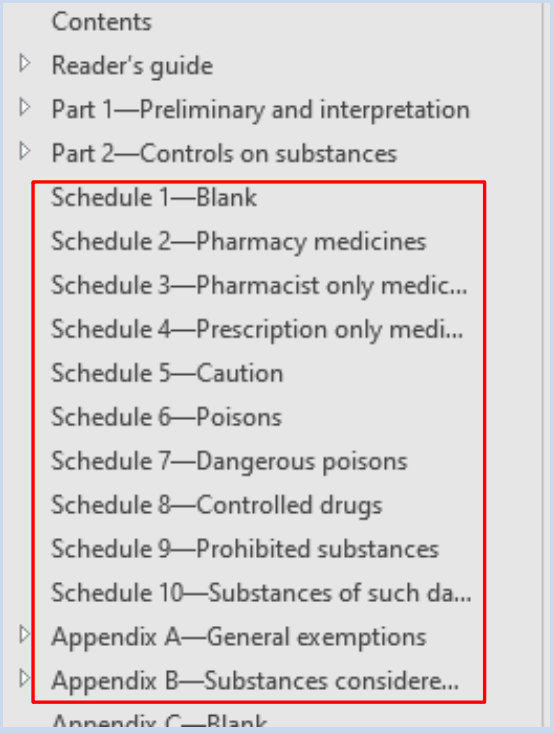
The new formatting and structure

Why change?

- To align the instrument with **modern drafting conventions** and **current rules**
- To make it **clearer** and **easier to understand**
- Legislative instruments normally undergo a process called '**sunsetting**'
- The Poisons Standard has **not** undergone the revision that occurs when a sunsetting instrument is remade because it is regularly revoked and remade

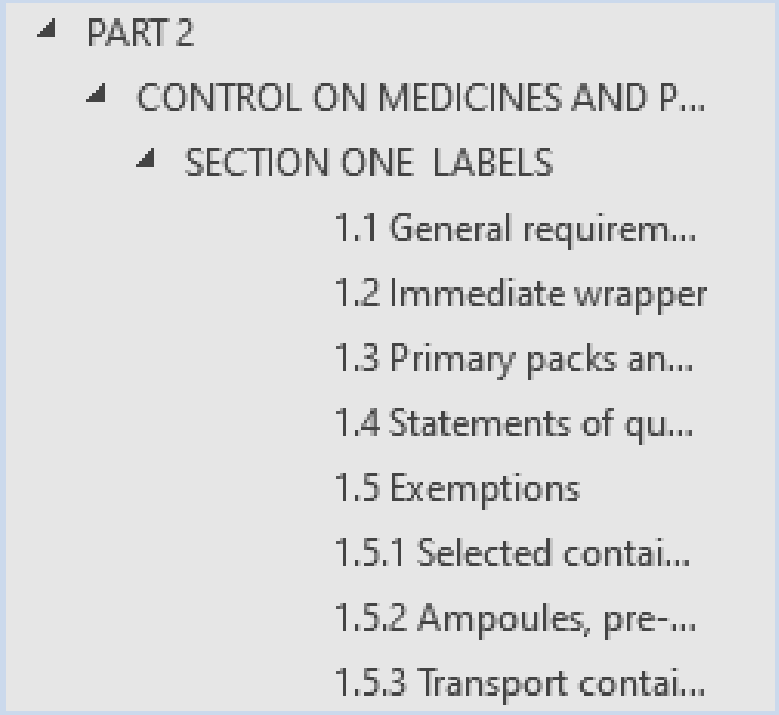
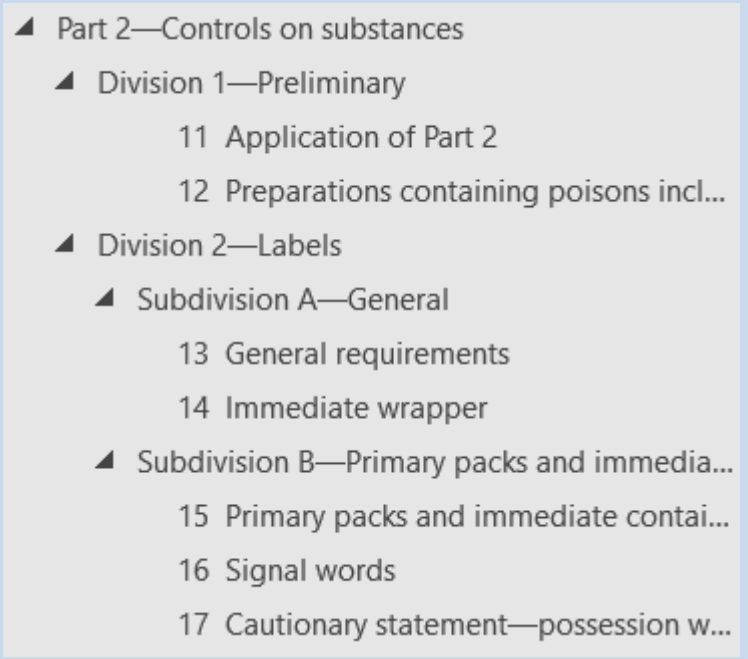
Changes to structure

Schedules and Appendices no longer within Parts

Current Poisons Standard	New Poisons Standard
	

Changes to structure

Provision numbering

Current Poisons Standard	New Poisons Standard
	

Changes to structure

All non-substantive parts moved to Reader's guide

Current Poisons Standard

APPENDIX J – SCHEDULE 7 POISONS REQUIRING ADDITIONAL CONTROLS ON AVAILABILITY AND USE

PART 1 – AUTHORISATION CONSIDERATIONS FOR AVAILABILITY AND USE

All poisons included in this Appendix are not to be available except to authorised or licensed persons.

The use of a poison may be restricted for a particular purpose. Controls recommended for the Schedule 7 poisons listed in the table below may be implemented through poisons controls or other State or Territory legislation.

Authorisation considerations

a	Poisons marked with 'a' are restricted to analytical or research purposes only.
p	Poisons marked with 'p' have been identified as representing a significant risk to public health. Additional restrictions on their possession and use must be applied through an authorisation or licensing process which includes a case by case assessment of risks to public health.

PART 2

A poison listed in this Appendix is to be available in accordance with the authorisations considerations specified beside it in the "Authorisation Considerations" column.

POISONS	AUTHORISATION CONSIDERATIONS
ABAMECTIN	

New Poisons Standard

Appendix H (Schedule 3 medicines permitted to be advertised)
Appendix H lists medicines included in Schedule 3 that are permitted to be advertised to the public.

Appendix I (blank)
Appendix I is intentionally blank.

Appendix J (Conditions for availability and use of certain poisons included in Schedule 7)
All poisons included in Appendix J are not to be available except to authorised or licensed persons.

The use of a poison may be restricted for a particular purpose. Controls recommended for the Schedule 7 poisons included in Appendix J may be implemented through poisons controls or other State or Territory legislation.

Appendix K (Human medicines required to be labelled with a sedation warning)
Medicines for human use that contain a poison included in Appendix K are required to be labelled with a warning regarding their sedation potential.

Changes to formatting

Table Styles

Current Poisons Standard

APPENDIX D – ADDITIONAL CONTROLS ON POSSESSION OR SUPPLY OF POISONS INCLUDED IN SCHEDULE 4 OR 8

(The following controls apply to the substances listed only when included in Schedule 4 or Schedule 8.)

1.	**Poisons available only from or on the prescription or order of an authorised medical practitioner:**
	CANNABIS for human use.
	CLOMIFENE for human use.
	CLOZAPINE for human use.
	CORIFOLLITROPIN ALFA (recombinant follicle stimulant) for human use.
	CYCLOFENIL for human use.
	DINOPROST for human use.

New Poisons Standard

Appendix D—Additional controls on possession or supply of poisons included in Schedule 4 or 8

Note: See section 64.

1 Poisons available for human use only from or on the prescription or order of an authorised medical practitioner

A poison specified in the following table may be supplied for human use only by, on the prescription or order of, an authorised medical practitioner.

Item	Poison
1	CANNABIS for human use
2	CLOMIFENE for human use
3	CLOZAPINE for human use
4	CORIFOLLITROPIN ALFA (recombinant follicle stimulant) for human use
5	CYCLOFENIL for human use
6	DINOPROST for human use

Changes to formatting

Other changes

BENZYDAMINE **except**:

(a) when included in Schedule 2; or

(b) in preparations for dermal use; or

(c) in divided topical oral preparations containing 3 mg or less of benzydamine; or

(d) in undivided topical oral preparations containing 0.3 ~~per cent~~% or less of benzydamine in a primary pack containing not more than 50 mL.

2,~~2'~~2',6,~~6'~~6'-TETRAISOPROPYL-DIPHENYL-CARBODIIMIDE in amitraz formulations containing 2 ~~per cent~~% or less of 2,~~2'~~2',6,~~6'~~6'-tetraisopropyl-diphenyl-carbodiimide.

Changes to language and expression

Providing clarity

Current Poisons Standard	New Poisons Standard
"**Authorised prescriber**" means a registered medical, dental or veterinary practitioner or such other person authorised by the appropriate authority.	***authorised prescriber*** means any of the following: (a) a dental practitioner; (b) a medical practitioner; (c) a veterinarian; (d) a person for whom an authorisation, given for the purposes of this paragraph by an appropriate authority, is in effect.

Changes to language and expression

Naming of heads and organisations

Current Poisons Standard

"**Appropriate authority**" means:

a) in the Australian Capital Territory, ACT Government Health Directorate;

b) for the purpose of providing an exemption from all or part of Section 1.1 to Section 1.5.3 in Part 2 of this Standard by the Australian Pesticides and Veterinary Medicines Authority, the Chief Executive Officer or their delegate;

c) in New South Wales, the Director-General of the NSW Ministry of Health;

d) in the Northern Territory, the Chief Health Officer of the Department of Health;

e) in Queensland, the Chief Executive of Queensland Health;

f) in South Australia, the Chief Executive of the Department for Health and Ageing;

g) in Tasmania, the Secretary of the Department of Health and Human Services;

h) for the purpose of providing an exemption from all or part of Section 1.1 to Section 1.5.3 of this Standard, the Deputy Secretary of the Australian Government Department of Health with responsibility for the Therapeutic Goods Administration, or their delegate;

i) in Victoria, the Secretary to the Department of Health;

j) in Western Australia, the Chief Executive Officer of the Department of Health.

New Poisons Standard

appropriate authority: each of the following is an ***appropriate authority***:

(a) each person who is the head of the body (however described) in a State or Territory that is responsible for the administration of matters relating to health in that State or Territory;

(b) the Deputy Secretary of the Department with responsibility for the part of the Department known as the Therapeutic Goods Administration, or their delegate;

(c) the Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, or their delegate.

Changes to language and expression

Requirements imposed on products, not persons

Current Poisons Standard

6.2 Schedule 7 Poisons

(1) A person must not possess or use a Schedule 7 poison for domestic or domestic garden purposes.

(2) A person must not sell or supply:

a) a Schedule 7 poison for domestic or domestic garden purposes; or

b) a Schedule 7 poison being a liquid preparation containing paraquat unless it is coloured blue or green and contains sufficient stenching agent to produce an offensive smell; or

c) a Schedule 7 poison for which an authorisation to purchase, possess or use is required by the appropriate authority unless the purchaser produces his or her authorisation.

(3) A person must not sell, supply or distribute free product samples containing Schedule 7 poisons.

New Poisons Standard

62 Poisons included in Schedule 7

Possession or use for domestic or domestic garden purposes prohibited

(1) A poison included in Schedule 7 must not be possessed or used for domestic or domestic garden purposes.

Supply for domestic or domestic garden purposes prohibited

(2) A poison included in Schedule 7 must not be supplied for domestic or domestic garden purposes.

Supply of liquid preparations containing paraquat

(3) A poison included in Schedule 7 that is a liquid preparation containing paraquat must not be supplied unless it is coloured blue or green and contains sufficient stenching agent to produce an offensive smell.

Supply if authorisation required by appropriate authority

Timeline for implementation

New Poisons Standard structure and format

Nov 2022

Publication of the **Therapeutic Goods (Poisons Standard - February 2023) Instrument 2022** (commencement date: 1 Feb 2023)

Transition period

Opportunity for States and Territories to make changes to their legislation, and all stakeholders to familiarise themselves with the changes

1 Feb 2023

1. Repeal of the **Therapeutic Goods (Poisons Standard - February 2023) Instrument 2022**

2. Publication and commencement of the proposed **Therapeutic Goods (Poisons Standard - February) Instrument 2023** containing:
   - planned (1 Feb) changes to substance entries (I.e. usual update), and
   - new structure and format

For any further questions about these changes or the Poisons Standard in general, you can contact us at:

medicines.scheduling@health.gov.au

Survey - Poll

How did we go?

We'll be back with you in **1 minute.**

1. Please open SLIDO *(located from your APPS icon)*
2. Open the POLL tab
3. Complete short survey
4. We'll then commence Q&A

Anonymous or Open responses welcome

Questions

Dr Adam Cook

Director, Scheduling Section,
Regulatory Engagement Branch

Navreen Kular

Acting Principal Lawyer, Legal Advisings and Legislation, Regulatory Legal Services Branch

Q&A

More information

TGA website	https://www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration