



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

# Scheduling handbook

## Guidance for amending the Poisons Standard

Version 1.1, July 2019

**TGA** Health Safety  
Regulation

**Copyright**

© Commonwealth of Australia 2019

This work is copyright. You may reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given specific written permission from the Commonwealth to do so. Requests and inquiries concerning reproduction and rights are to be sent to the TGA Copyright Officer, Therapeutic Goods Administration, PO Box 100, Woden ACT 2606 or emailed to <[tga.copyright@tga.gov.au](mailto:tga.copyright@tga.gov.au)>.

# Contents

<b>About the scheduling handbook</b>	<b>6</b>
<b>Principles of scheduling</b>	<b>6</b>
<b>The Poisons Standard</b>	<b>6</b>
Parts 1, 2 and 3	7
The schedules	7
Appendices	8
How are the schedules implemented	8
<b>Secretary's delegate and working party</b>	<b>9</b>
Secretary's delegate	9
Proactive identification and review of substances	9
<b>Decisions on scheduling</b>	<b>9</b>
Risk-benefit analysis	9
The scheduling factors	10
Amending Parts 1, 2 or 3 of the Poisons Standard	10
Amending the schedules (Part 4 of the Poisons Standard)	10
The cascading principle	11
Medicines	11
Veterinary chemicals	11
Other chemicals	11
Substances that are both medicines and chemicals	11
Decisions not to schedule	12
Exempted from scheduling	12
With reasonable safety	12
<b>Advisory committees</b>	<b>13</b>
Functions of ACMS and ACCS	13
Subcommittees	13
Advisory committee procedures	13
Publication of recommendations	13
Secretariat	13
Committee membership	14
Nominated members	14
Appointed members	14

Confidentiality and Conflict of Interest .....	14
Costs .....	14
<b>How items are allocated to ACMS and ACCS _____</b>	<b>14</b>
Joint meetings .....	14
Proposals to go to the ACMS .....	15
Proposals to go to ACCS .....	15
Proposals to go to joint meetings.....	15
<b>Amending the Poisons Standard _____</b>	<b>16</b>
<b>The applicant or proposer _____</b>	<b>16</b>
Amendments initiated by the Secretary .....	16
<b>Application or proposal? _____</b>	<b>16</b>
Chemical applications and proposals .....	16
Medicine applications and proposals .....	17
<b>Acceptance of the application _____</b>	<b>17</b>
<b>Decision to refer to ACMS or ACCS _____</b>	<b>17</b>
Changes to Parts 1, 2 or 3 .....	18
New prescription medicine .....	18
New (non-therapeutic) chemical substances .....	20
Rescheduling.....	20
<b>Applications not referred to an advisory committee _____</b>	<b>20</b>
Scheduling decisions not referred to a committee: process diagram .....	21
<b>Process when seeking advice from ACMS or ACCS _____</b>	<b>22</b>
Scheduling decisions referred to an advisory committee: process diagram	22
Consultation phase 1.....	23
Committee advice.....	23
Interim decision.....	23
Consultation phase 2 (where relevant).....	23
Final decision .....	23
<b>Appealing the final decision _____</b>	<b>24</b>
<b>Reconsideration of substances from prescription to OTC classification</b>	<b>24</b>
Parallel Process for pharmacy-only (S 2) and pharmacist-only (S 3) medicine applications and rescheduling: process diagram .....	25
Rescheduling of substances with potential Appendix M criteria .....	26
<b>Appendix M criteria _____</b>	<b>26</b>
<b>Notification of decisions _____</b>	<b>27</b>
<b>Date of coming into effect _____</b>	<b>27</b>

**Adoption and implementation of decisions \_\_\_\_\_ 28**

**Scheduling Working Group \_\_\_\_\_ 28**

## About the scheduling handbook

The handbook provides guidance for stakeholders on how the Poisons Standard is amended and provides details of the processes that underpin the scheduling policy. Read this handbook in conjunction with the *Scheduling policy framework for medicines and chemicals*.

The *Scheduling policy framework* and *Scheduling handbook* support the broader public health policy frameworks in Australia for both the quality use of human medicines and the safe use of chemicals.

The Australian Health Ministers' Advisory Council (AHMAC) has responsibility for the policy principles for scheduling and other poisons regulatory controls, as set out in the *Scheduling policy*.



Scheduling decisions are made under the *Therapeutic Goods Act 1989 (CTH)* and Therapeutic Goods Regulation. The Commonwealth (through the Therapeutic Goods Administration of the Department of Health) also provides and funds the Secretariats for Medicines and Chemicals scheduling. This handbook is to support the activities of the Secretariats, in particular those interacting with the Secretariats such as applicants for the scheduling or re-scheduling of substances.

## Principles of scheduling

The quality use of (human) medicines framework incorporates the selection of appropriate therapeutic management options, appropriate choice of medicines (where a medicine is considered necessary) and safe use. Scheduling classification supports this framework by determining the need for particular health professionals to be involved in the supply of medicinal substances to promote their safe and quality use. Labelling of products using specific phrases, called **signal headings**, emphasises this need for intervention by particular health professionals.

Scheduling also supports safer use of agricultural, veterinary and domestic chemical products through labelling with **specific alert phrases** aligned to the risk associated with the substance, or **signal headings** emphasising the need for intervention by particular professionals, where required. Where necessary the scheduling of certain veterinary medicines reinforces the need for intervention by a veterinary practitioner to promote safe use. The Poisons Standard also establishes the required packaging and necessary label information for the safe use of domestic chemical products.

## The Poisons Standard

The Poisons Standard is considered to be a Legislative Instrument for the purposes of the *Legislation Act 2003(CTH)*. It must be registered and published on the [FRL website](#) in electronic form. In order to ensure certainty in the continuing application of state and territory laws, the Poisons Standard is **not** a disallowable instrument.

Scheduling decisions are legislative in character, so the lawfulness of the Secretary's decision is **not reviewable** under the *Therapeutic Goods Act 1989*, in the Commonwealth Administrative Appeals Tribunal or in the Federal Court.

For general information about the Poisons Standard, see *An introduction to the Poisons Standard*.

## Parts 1, 2 and 3

Part 1 provides definitions and interpretation of terms relevant to the Poisons Standard and the scheduling process.

Parts 2 and 3 provide a description of the nature of controls, including access, labelling, packaging, supply etc., recommended to be implemented by states and territories for scheduled substances.

## The schedules

The schedules are in Part 4 of the Poisons Standard and comprise lists of substances, referred to as entries. These entries are subject to the conditions and requirements for that schedule, which are set out in Parts 2, 3 and 4 of the Poisons Standard. Details of factors for determining the relevant schedule are set out in the *Scheduling policy*.

Reference to a substance in a schedule or an appendix of the Poisons Standard:

- Ü includes those descriptions covered in subsection 1(2)(a) to (g) in Part 1 of the Poisons Standard
- Ù does not include those descriptions covered in subsection 1(2)(h) to (k) in Part 1 of the Poisons Standard

The schedules reflect the level of risk mitigation to be applied to reduce the assessed risk to public health to an acceptable level for each substance.

Substances are classified into schedules as follows:

- Schedule 1 is currently not in use.
- Schedules 2, 3, 4, and 8 include medicinal substances intended for human therapeutic use and have increasingly restrictive regulatory controls on their availability in the order stated. Schedules 4 and 8 also include veterinary medicines.
- Schedules 5, 6 and 7 include poisons (including veterinary chemicals), with increasing regulatory controls on their availability. Veterinary medicines available without prescription are generally included in Schedules 5 and 6. Controls over poisons in Schedules 5 and 6 are through packaging and labelling.
- Schedule 9 includes substances that have a high propensity for dependency and abuse. These substances should be available only for prescribed purposes such as analysis, and medical or scientific research, including clinical trials, conducted with the approval of Commonwealth and/or State/Territory health authorities. Otherwise, the possession, use, sale or supply of substances in Schedule 9 is generally prohibited.
- Schedule 10 includes poisons, other than those that cause dependence, of such danger to health as to warrant prohibition of sale, supply and use.

The numbering of Schedules 2, 3, 4, and 8 signifies an increasing level of professional healthcare intervention combined with increasingly stricter restrictions on availability. For Schedules 5, 6 and 7 the numbering signifies increasingly stricter container and labelling requirements. Unscheduled substances can also be made available on general sale.

## Appendices

The appendices of the Poisons Standard support the schedules by detailing substances that do not require scheduling, require additional labelling or access, or other information that isn't captured in the schedules.

The appendices are:

- Appendix A – General exemptions
- Appendix B – Substances considered not to require control by scheduling
- Appendix C – Superseded by Schedule 10
- Appendix D – Additional controls on possession or supply of poisons included in Schedules 4 or 8
- Appendix E – First aid instructions for poisons
- Appendix F – Warning statements and general safety directions for poisons
- Appendix G – Dilute preparations
- Appendix H – Schedule 3 medicines permitted to be advertised
- Appendix I – Superseded by Part 2 Section 7
- Appendix J – Schedule 7 poisons requiring additional controls on availability and use
- Appendix K – Medicines required to be labelled with a sedation warning
- Appendix L – Requirements for dispensing labels for human and veterinary medicines
- Appendix M – Additional requirements for Schedule 3 medicines

Details of factors to be considered for the appendices are set out in the *Scheduling Policy Framework*.

## How are the schedules implemented

Controls on substances through scheduling are given legal effect through relevant State and Territory legislation. Hence, implementation of these controls may differ depending on the State/Territory.

Specific jurisdictions may also impose additional restrictions on access to a substance and/or labelling and packaging.

Licences and applications for access to scheduled substances are administered through the jurisdictions and other regulatory agencies (i.e. the TGA or the APVMA).

More information on State and Territory implementation (including contact details) is available at: [State/Territory scheduling information](#).

# Secretary's delegate and working party

## Secretary's delegate

The Secretary of the Department of Health may make decisions on the scheduling of medicines or chemicals, as well as changes to other parts and appendices of the Poisons Standard, by exercising powers under Sections 52D, 52E and 52EAA of the *Therapeutic Goods Act 1989 (CTH)*, in accordance with the *Therapeutic Goods Regulations 1990* as well as any additional guidelines, including this document.

In practice, decisions are usually made by 'the Delegate', a person to whom the Secretary has delegated decision-making responsibility, being a person holding an appropriate position within a relevant area of the Department of Health, or other Government agency.

## Proactive identification and review of substances

The Secretary may establish a working party drawn from relevant state and territory departments and other stakeholders to consider substances or groups of substances for potential rescheduling on the basis there might be a public health benefit if they were down-scheduled or up-scheduled.

## Decisions on scheduling

Scheduling decisions involve a risk-benefit consideration in the context of protecting public health. This risk-benefit consideration takes into account factors such as those set out in section 52E of the *Therapeutic Goods Act 1989 (CTH)*, including:

- the toxicity of the substance
- the purpose of use (including the diagnostic decision)
- potential for abuse and misuse
- safety in use, including the need for specialist training or personal protective equipment
- the benefits/needs of access to the substance

## Risk-benefit analysis

Scheduling is a regulatory intervention to reduce public health risk to an acceptable level. Therefore, the majority of the matters detailed in section 52E(1) of the *Therapeutic Goods Act 1989 (CTH)*, as well as the assessment factors for each schedule, relate to risk rather than benefit. However, section 52E(1)(a) requires both risk and benefit from the use of a substance to be considered.

Consideration of the scheduling factors along with any other matters required by Section 52E(1) permits the objective assessment of the risk-benefit balance for the consumer at different levels of access and therefore optimal public availability.

Where a substance is proposed to be down-scheduled, performing a risk-benefit analysis using a value-tree framework tool may help determine whether the substance is a suitable candidate for

supply at a particular scheduling level. The [tool developed by Brass and others](#)<sup>1</sup> may help identify potential risks to a down-scheduling proposal and provide an opportunity for applicants to include information to mitigate these risks.

Relevant benefits for a substance proposed to be down-scheduled are only in relation to public health outcomes.

## The scheduling factors

All scheduling decisions include consideration of a standard set of factors, to ensure that public health objectives are consistently met and the application of public health risk considerations is consistent within each Schedule. The factors for each schedule are set out in the *Scheduling Policy Framework* and relate back to the matters required to be taken into account by section 52E(1) of the *Therapeutic Goods Act 1989 (CTH)*.

A process using factors for each schedule allows a degree of judgement by reviewers to find the best fit for a substance in the classification system. The order in which the scheduling factors are listed is not significant, because scheduling decisions are made on balance of available evidence. This is the same for the scheduling of medicines and chemicals.

Factors are considered to be more appropriate than criteria as assessment tools, because:

- each factor may exhibit a high degree of variability (rather than simply the presence or absence of the factor) and it is this variability that may influence the final classification
- there is interaction between the various factors, such that a particular grouping of factors may suggest one classification, whereas taken individually they may not
- in general, the factors are to be considered as a whole in determining the public health risk for the proposal. However, failing to meet one factor may preclude inclusion of the substance in that schedule. This reflects the final assessment of relative public health risk against the classification spectrum.

Other matters may also be taken into account when making a scheduling decision.

## Amending Parts 1, 2 or 3 of the Poisons Standard

In making a decision to amend the introduction or Parts 1, 2 or 3 the Secretary considers:

- the scope of the proposed provision (e.g. whether the provision applies to poisons that are not human medicines, or to all poisons)
- the effect of the proposal on existing entries for poisons in the schedules and appendices
- the regulatory need and justification for the change
- the potential implications of the change for jurisdictions (e.g. compliance activities)

## Amending the schedules (Part 4 of the Poisons Standard)

When considering a new substance application (i.e. a substance for which a scheduling decision has not already been made), the Secretary will consider whether to include the new substance in the schedules of the Poisons Standard based on the Scheduling factors set out in the Scheduling Policy.

---

<sup>1</sup> Brass EP, Lofstedt R, Renn O. Improving the decision-making process for non-prescription drugs: a framework for benefit-risk assessment. *Clin Pharmacol Ther* 2011; 90(6):791-803.

If the substance is to be included in any Schedule, the Secretary will decide:

- the name or description of the substance to be used
- the scope of the entry and the schedule(s) in which the substance is to be included
- which other parts of the Poisons Standard may also apply to the substance

Rescheduling applications are only made in relation to substances that have an existing (individual substance or class) entry or entries in the Poisons Standard.

When considering a rescheduling application the Secretary will decide:

- the scope of the entry and the schedule(s) in which the substance is to be included
- which other parts of the Poisons Standard may also apply to the substance

## **The cascading principle**

The model for making scheduling decisions embodies a 'cascading principle'. This model exemplifies the precautionary principle for public health and allows the best fit to be found using a systematic approach. This approach also facilitates the reclassification process when new knowledge or practices emerge that materially alters the public health risk, or when an application for rescheduling is received.

### **Medicines**

For medicines, a substance is first assessed against the factors for Schedule 10, 9 and 8. If those factors are not applicable, the substance is assessed against the Schedule 4 factors and if not applicable, against the Schedule 3 factors. If the Schedule 3 factors are not applicable, then it is assessed against the Schedule 2 factors.

### **Veterinary chemicals**

Veterinary chemicals are assessed against the factors for Schedules 8 and 4 may be followed by assessment against Schedules 7, 6 and 5, as applicable. Veterinary chemicals will not be assessed against the criteria for Schedules 3 or 2.

### **Other chemicals**

Other chemicals are first assessed using the factors for Schedules 10 and 9. However the highly restricted criteria for Schedule 9, relating to the propensity for dependence and abuse, means that very few substances are likely to be considered for, or included in, this schedule. If the factors for Schedules 10 or 9 are not applicable, the substance is assessed against the Schedule 7 factors, and if not applicable, against the Schedule 6 and then the Schedule 5 factors.

### **Substances that are both medicines and chemicals**

The cascading principle also applies to substances that are both medicines and chemicals. A substance classified into Schedule 4 when used therapeutically, may appear in Schedules 5 and/or 6 and/or 7 when intended for non-therapeutic use, or for use in the treatment of animals.

## Decisions not to schedule

Where a substance does not meet the factors for **any** schedule, it should, in the interests of transparency and consistency, be listed in Appendix B. Listing in Appendix B means a decision has been made to not schedule the substance. However, inclusion of a substance in Appendix B should **not** be used to infer that the substance is generally recognised as safe; in this context it has been found to not require scheduling on the balance of risk and benefit.

## Exempted from scheduling

The term 'exempted from scheduling' is applicable where other forms of the same substance are listed in the schedule(s). This may include preparations of higher strength, of different pack size, for other indications or uses, in a different formulation or for use by different patient groups.

There are a number of mechanisms by which a substance, which appears in one or more schedules, is exempted from scheduling under certain defined circumstances. These mechanisms are:

- A general exemption for substances in Schedules 1 to 6, at a concentration not exceeding 10 mg/kg
- an exemption for a class of products through Appendix A
- an exemption for a substance specific to the reason for its entry in Appendix B
- an exemption for dilute preparations through Appendix G
- an exemption for impurities in a pesticide at a concentration at or below the maximum content for that substance specified for that pesticide in the *Standards for Active Constituents* as published by the APVMA
- a conditional exemption from within a Schedule

An exemption may be subject to conditions including, but not limited to, the maximum concentration, use, strength, dose, labelling, packaging and pack size restrictions.

In accordance with the cascading principle, exemption of a particular medicinal preparation to allow supply from general sales outlets (such as supermarkets) means that it does not meet the factors for Schedules 2, 3, 4 or 8. Medicinal preparations exempted from scheduling must be determined to be able to be supplied, with reasonable safety, without any access to health professional advice.

## With reasonable safety

The term 'with reasonable safety' means:

- the consumer is able to identify and self-manage the condition for which the medicine is intended without health professional input
- the risk of the consumer confusing their condition with more serious diseases or conditions is very small
- the risks to health from the medicine are small and can be managed with packaging and labelling. Risks to be assessed include, but are not limited to, risks from adverse reactions, drug/food interactions and contraindications
- the risk of inappropriate use and misuse is negligible
- there is little need to take any special precautions in handling
- there is net public health benefit from wider availability for the consumer

## Advisory committees

The Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) are established under sections 52B and 52C of the *Therapeutic Goods Act 1989 (CTH)*, respectively. The membership, functions and procedures for the expert advisory committees are set out in the *Therapeutic Goods Regulations 1990* and this handbook [section 52E(2), *Therapeutic Goods Act 1989 (CTH)*].

### Functions of ACMS and ACCS

Each advisory committee will:

- make recommendations to the Secretary regarding the classification and scheduling of substances
- make recommendations to the Secretary in relation to other changes to the current Poisons Standard
- reconsider a recommendation at the request of the Secretary
- provide advice to the Secretary in relation to restrictions (including restrictions as to accessibility and availability) to be imposed in respect of particular substances
- provide advice to the Secretary in relation to any other matter referred by the Secretary
- perform any other functions prescribed by the *Therapeutic Goods Regulations 1990*

### Subcommittees

The advisory committees may, with the agreement of the Secretary of the Department of Health, form subcommittees to undertake discrete bodies of work as provided for in Divisions 3A.3 and 3B.3 of Part 6 of the *Therapeutic Goods Regulations 1990*.

### Advisory committee procedures

The advisory committees are required to conduct and hold meetings in accordance with subdivision 3A.3 and 3B.3 of Part 6 of the *Therapeutic Goods Regulations 1990*.

If an evaluation of a proposal has been undertaken or commissioned by the TGA, the evaluator may be invited to attend, and participate, in the meeting.

### Publication of recommendations

Recommendations of the expert advisory committees and a summary of reasons for the recommendations are published on the TGA website in the context of the scheduling delegate's interim decision.

### Secretariat

The [Scheduling Secretariat](#) is located within the Department of Health.

---

## Committee membership

The scheduling advisory committees are filled in accordance with subdivisions 3A.2 and 3B.3 of Part 6 of the *Therapeutic Goods Regulations 1990*.

There are two kinds of members on the expert advisory committees, nominated and appointed members.

### Nominated members

To reflect the cooperative nature of the scheduling process and to encourage scheduling uniformity across Australia, the Australian Government and each state and territory may nominate a member for each advisory committee (ACMS and ACCS). These members are nominated on the basis of their knowledge and experience in regulation of scheduled medicines and poisons and **not as a representative** of a government. Nominated members independently assess the merit of a proposal based on their expertise and consideration of the submissions about the proposal.

### Appointed members

Appointed members are selected from employees of a broad range of government agencies, academic institutions, healthcare, consumer and industry groups, and the general public.

The Minister appoints in writing whomever the Minister believes to be appropriately qualified, upon recommendations from the Department. Members and acting members are appointed on the **basis of expertise** rather than to represent a particular jurisdiction or interest group.

### Confidentiality and Conflict of Interest

All members are required to make an undertaking in relation to [confidential information and conflicts of interest](#).

### Costs

Participation at advisory committee meetings by members employed by the Commonwealth or states and territories, as well as implementation of recommendations decisions, will be borne by the respective government employers.

Appointed members who are not government appointees and are permitted by their employer to be remunerated, are remunerated in accordance with the principles and rates set by the Remuneration Tribunal.

## How items are allocated to ACMS and ACCS

The Secretary may refer an application or proposal to amend the Poisons Standard to either or both of the advisory committee(s), as provided for by Subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990*. The tables below summarise the types of proposals for which each committee will provide advice.

### Joint meetings

Given the potential overlap of membership and interests, meetings of the ACMS and the ACCS may be run consecutively.

Where matters of interest to both advisory committees are identified, sufficient time is to be allowed for both advisory committees to discuss these matters jointly, including any matters

relating to the *Scheduling handbook*. Details outlining the procedures for joint meetings are in Division 3C of Part 6 of the *Therapeutic Goods Regulations 1990*.

A recommendation arising from a joint meeting is a recommendation to the Secretary from each advisory committee.

## Proposals to go to the ACMS

Proposals to go to ACMS:

- Proposal to amend a substance in Parts 1 to 3 that affects only therapeutic goods
- Rescheduling of substance included in a therapeutic good (human medicine)
- Proposal to amend or include an entry in appendices A, G or Schedule 10 for human therapeutic use
- Proposal to amend or include entry in:
  - Appendix D for human therapeutic use
  - Appendices H, K, L or M
  - Appendices E, F or J for human therapeutic use
- Scheduling of a substance that may meet the criteria for inclusion in Schedule 9

## Proposals to go to ACCS

Proposals to go to ACCS:

- Proposal to amend a substance in Parts 1 to 3 that affects only agricultural, domestic, industrial or veterinary chemicals
- Rescheduling of industrial, domestic or personal use chemical
- Rescheduling of agricultural chemical, pesticide or veterinary medicine
- Proposal to amend or include an entry in:
  - Appendices A, G or Schedule 10 for some other use excluding human therapeutic use
  - Appendix D for some other use excluding human therapeutic use
  - Appendices E, F, J for some other use excluding human therapeutic use
- Scheduling of a new substance (agricultural, veterinary or industrial) that may meet the criteria for inclusion in Schedule 7

## Proposals to go to joint meetings

Where any of the proposals above relate to substances that may have a human therapeutic use (including as an excipient) as well as a non-human therapeutic use, the proposal may be referred to a joint meeting to the ACMS and ACCS.

Any proposal to amend a substance in Parts 1 to 3 that is not listed above may also be referred to a joint meeting.

# Amending the Poisons Standard

There are a number of different pathways to produce a decision by the Secretary to amend the Poisons Standard.

An application to amend the Poisons Standard may be made to the Secretary under section 52EAA of the *Therapeutic Goods Act 1989*.

## The applicant or proposer

Applications to amend the schedules and appendices may be made by:

- individuals
- stakeholder organisations
- government bodies

Proposals to change the regulatory provisions in Parts 1 – 3 (either new or amended) may originate from the:

- jurisdictions
- Secretary
- relevant regulator

## Amendments initiated by the Secretary

Under section 52D(3) of the *Therapeutic Goods Act 1989* the Secretary has power to amend the Poisons Standard on their own initiative. A decision to exercise this power would be made on the basis of information that, in the Secretary's opinion, supports an amendment to the Poisons Standard.

This includes, but is not limited to, an emergency scheduling decision needed to address an emerging public health issue (e.g. availability of a new psychoactive substance) or inclusion of a substance in Appendix K (i.e. sedation warning required). This information may be provided to the Secretary by a member of an advisory committee, the Department, or by AHMAC.

When the Secretary decides to amend the Poisons Standard on his or her own initiative, this is a final decision. The Poisons Standard is then amended in accordance with the procedures required to amend a legislative instrument.

However, the Secretary may decide to commence a new process by referring this amendment to an advisory committee for consideration and public consultation. In this case, no application for scheduling is required.

## Application or proposal?

In some cases, a scheduling proposal will be made by the regulator as part of the registration process.

## Chemical applications and proposals

Applications relating to agricultural and veterinary chemicals will, generally, be referred by the APVMA as part of their evaluation and product registration process. Alternatively, applicants may apply directly through the [Chemicals Scheduling Secretariat](#).

In certain circumstances, an industrial or domestic chemical may be referred for scheduling based on the outcome of a risk assessment undertaken by the Department of Health.

## Medicine applications and proposals

For new prescription medicines that are new chemical or biological entities, the registration applicant does not need to apply for scheduling: the regulator will make a scheduling proposal as part of the registration process.

For all other applications related to medicines, applicants apply directly through the [Scheduling Secretariat](#).

## Acceptance of the application

The Secretary will only accept your application if:

- it is in a [form approved by the Secretary](#)
- it is supported by sufficient information

The form includes details of information requirements, and applicants are advised to refer to details in the *Scheduling policy* and this handbook when preparing their application.

The scheduling factors to be addressed by applicants and considered by the Secretary, are part of the *Scheduling policy*.

The applicant is also required to submit a summary for publication outlining the nature of the scheduling proposal, including the name of the substance, the proposed schedule, and a brief description addressing the relevant scheduling factors. Failure to do this may result in the entire scheduling application (less commercially sensitive information) being published in the [call for submissions](#).



When considering proposals to amend the Poisons Standard, the Secretary and advisory committees are to take into account the principles in the Scheduling Policy Framework and processes in this handbook.

## Decision to refer to ACMS or ACCS

The Secretariat will receive and manage applications in accordance with the information below. However, the final decision regarding referral to advisory committees and finalisation of decisions is made by the Secretary.

To identify the likely scheduling path, please refer to the appropriate decision tree:

- Decision tree for the medicine scheduling process
- Decision tree for the chemical scheduling process

These decision trees are intended to illustrate the potential process for the medicines and chemicals and assist stakeholders in managing their applications.

## Changes to Parts 1, 2 or 3

Changes to Parts 1, 2 or 3 will be undertaken in consultation with the states and territories. The Secretary may also wish to consult with the advisory committees.

The Secretary will refer an application to amend an existing substance in the introduction or Parts 1, 2 or 3 of the Poisons Standard, to the relevant advisory committee for advice.

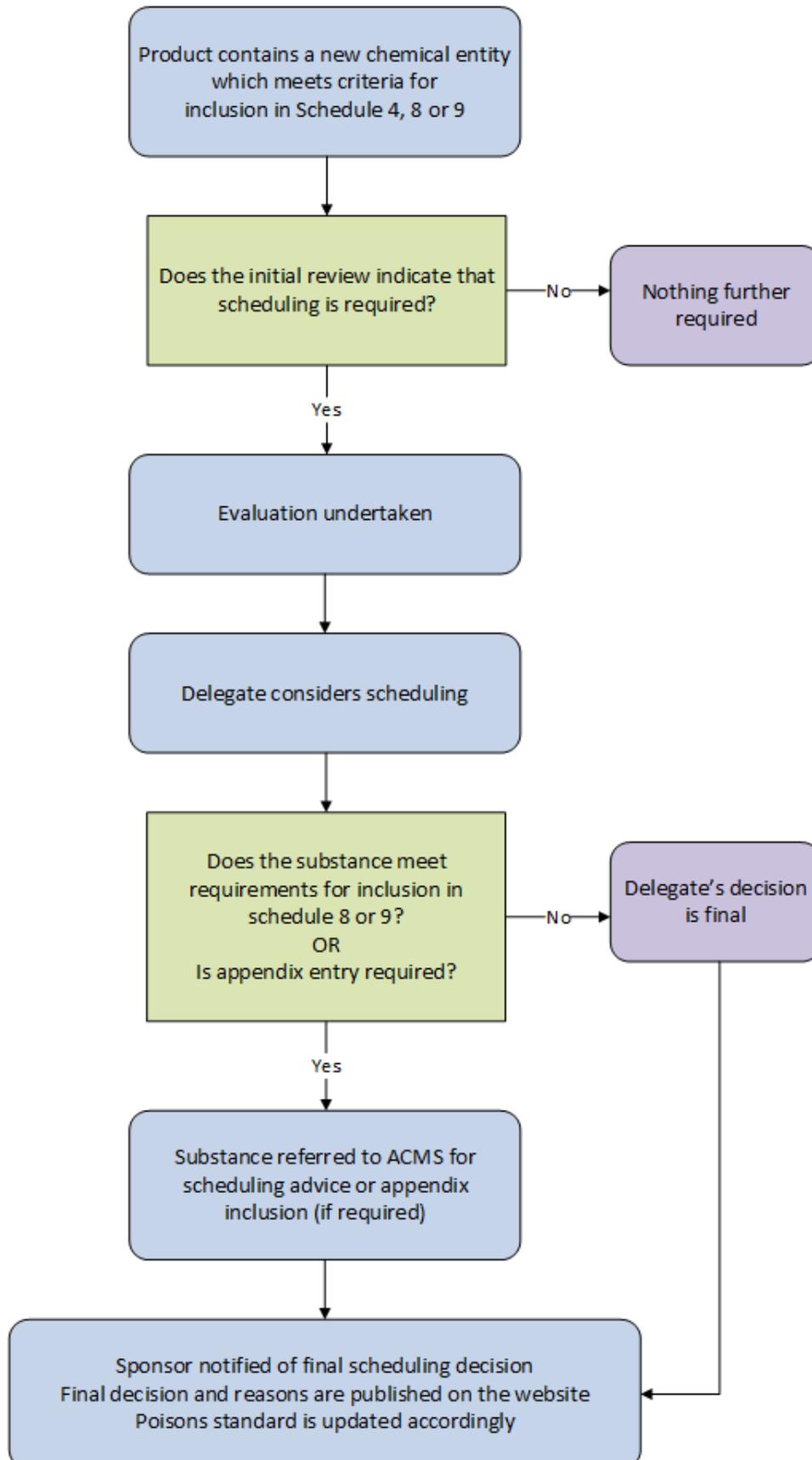
Referral of amendments to Parts 1, 2 or 3 of the Poisons Standard will be referred to AHMAC at the Secretary's discretion.

Minor administrative amendments to the introduction or Parts 1, 2 or 3 may be made by the Secretary without referral to AHMAC or an advisory committee.

## New prescription medicine

Substances evaluated by the TGA as part of the registration process for a new chemical or biological entity (Schedule 4) will not routinely be referred to a scheduling advisory committee.

If a new prescription medicine application results in a proposal for an appendix entry, or inclusion in **Schedule 8**, the TGA will refer this to ACMS for advice due to the significant implications for State and Territory regulation, monitoring and compliance activity.

**New therapeutic chemical or biological entity: scheduling process diagram**

## New (non-therapeutic) chemical substances

New chemical scheduling proposals to include a new substance in **Schedule 7** will be referred to the ACCS, given the compliance activities associated with in such applications.

Other new chemical scheduling proposals may be referred to the ACCS unless:

- the proposal is straight forward and the chemical has been subject to the APVMA registration process
- the proposal relates to a chemical with similar toxicological and use profiles to a chemical that is already scheduled and the safety and use profiles do not differ significantly from the already scheduled substance

## Rescheduling

**Rescheduling** proposals (i.e. where the substance has previously been scheduled) are to be referred to the relevant scheduling advisory committee for advice. An exception to this may be appropriate if:

- the application relates to reclassification of a second (or subsequent) substance in a class where the safety and use profiles do not differ significantly from a substance of that class that has already completed a rescheduling process from, and to, the same schedules
- the proposal relates only to a new or amended entry in Appendix K of the Poisons Standard

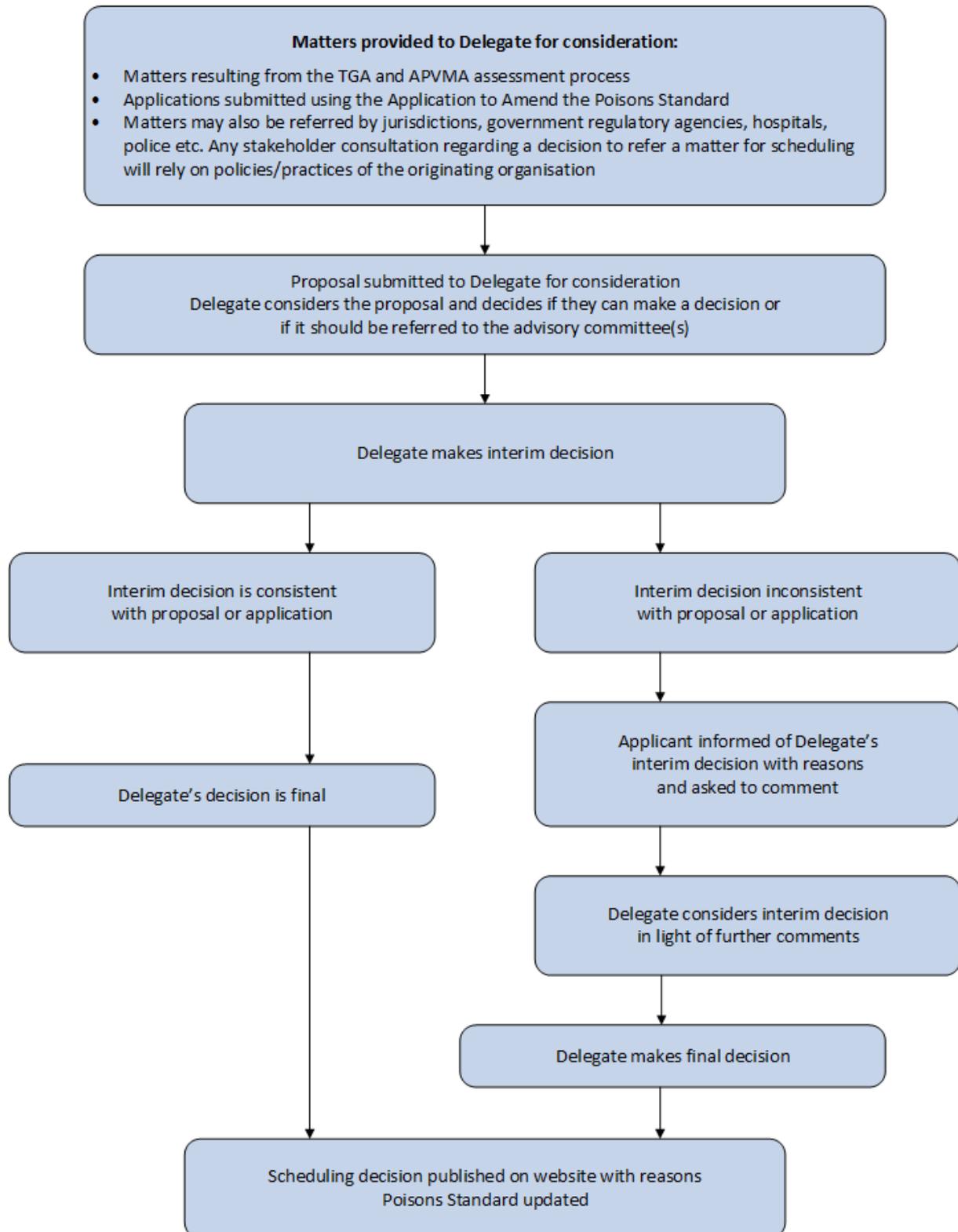
## Applications not referred to an advisory committee

When the Secretary chooses not to refer the proposed amendment to an advisory committee, the Secretary must follow the process detailed in Subdivision 3D.3 of Part 6 of the *Therapeutic Goods Regulations 1990*.

Where the decision is:

- Ü to amend the Poisons Standard in the manner set out in the application, the Secretary may make a final decision **without** making an interim decision, taking into account the scheduling factors in section 52E of the *Therapeutic Goods Act 1989*
- Ū not to amend the Poisons Standard in the manner set out in the application, the Secretary must make an interim decision. The Secretary **must provide the applicant** with the reasons for the interim decision and provide an opportunity to make a written submission in response. After considering any such submission from the applicant, the Secretary must make a final decision, taking into account the scheduling factors in section 52E of the *Therapeutic Goods Act 1989*

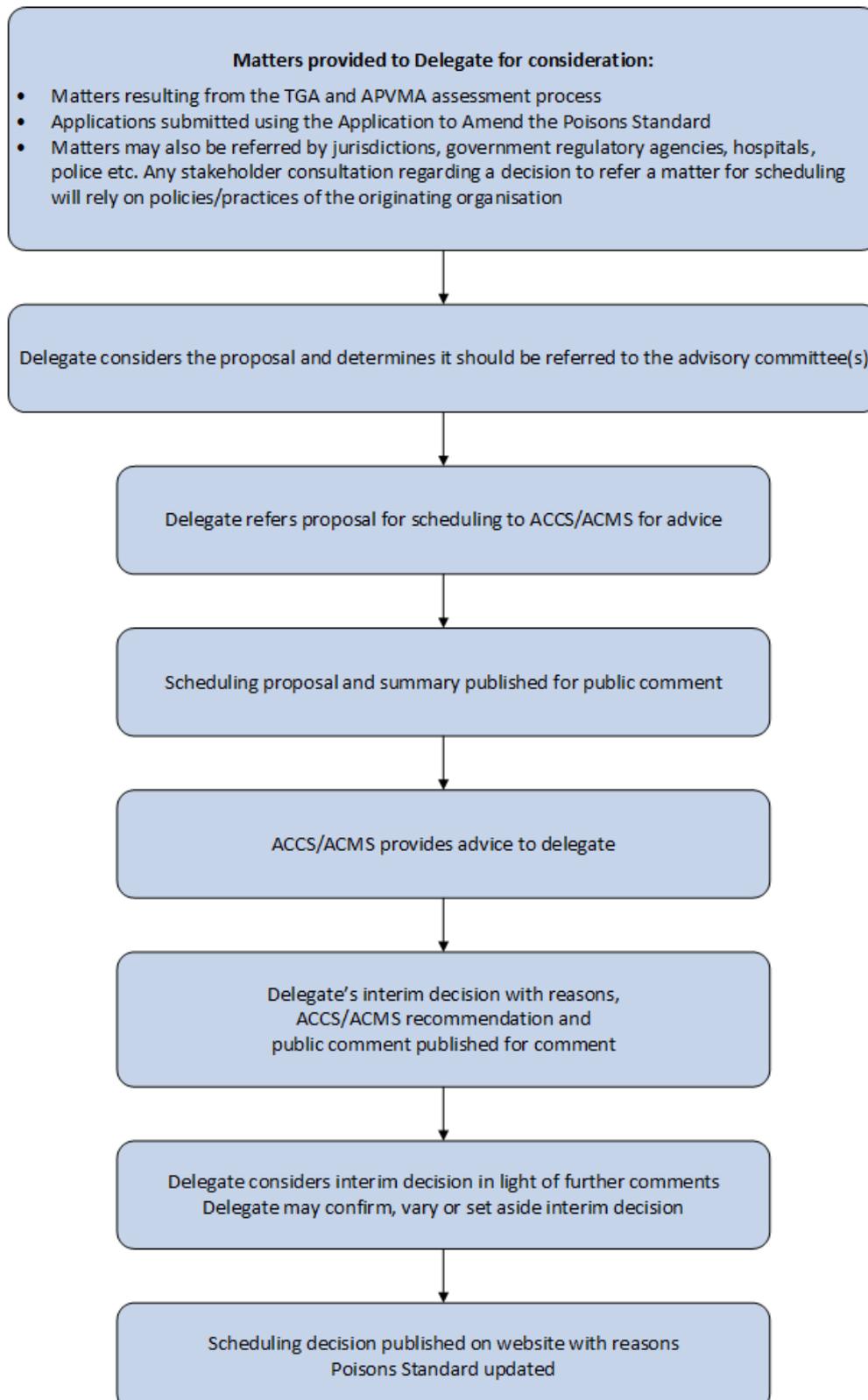
## Scheduling decisions not referred to a committee: process diagram



## Process when seeking advice from ACMS or ACCS

Where an application is referred to ACCS and/or ACMS, the Secretary is required to follow the process set out in subdivision 3D.2 of Part 6 of the *Therapeutic Goods Regulations 1990*.

### Scheduling decisions referred to an advisory committee: process diagram



## Consultation phase 1

The Secretary must [publish a notice](#) on the TGA website outlining the proposed amendments to the Poisons Standard to be considered by the advisory committee(s) along with an invitation for public submissions. The summary provided by the applicant will also be published.

The consultation period will be open for at least 4 weeks.

- The Secretary may proactively seek advice from relevant bodies such as specialist medical colleges, health practitioner associations or professional and industry associations.
- The Secretary will make sponsors and other organisations that might be significantly affected by a scheduling proposal aware that a notice inviting public submissions has been published.

## Committee advice

The relevant scheduling advisory committee(s) will consider the proposal together with the submissions received from the consultation, and will then provide advice or a recommendation to the Secretary.

## Interim decision

An interim decision is not required if no public submissions are received in consultation phase 1 [Regulation 42ZCZO(1)].

If an interim decision is required, the Secretary must [publish the interim decision](#) and the reasons for the decision and include a call for further submissions in relation to the interim decision.

This publication will include the recommendations to the Secretary from the advisory committee and the reasons for the recommendations.

## Consultation phase 2 (where relevant)

Following publication of an interim decision, there is a further consultation period of up to 4 weeks.

## Final decision

The Secretary will take into account the following when making a final decision after an interim decision:

- the original application
- any risk-benefit assessment undertaken by the applicant if the proposal relates to downscheduling of a medicine
- relevant submissions received in any consultation phase, either from the applicant or the public (Regulation 42ZCZQ)
- any advice or recommendation of the advisory committees
- any guidelines of the Australian Health Ministers' Advisory Council

The Secretary may in making the final decision:

- confirm the interim decision
- vary the interim decision
- set the interim decision aside and make a new decision

## Appealing the final decision

Scheduling decisions under subsection 52D(2) are legislative in character as they determine the future lawfulness of conduct as provided for under the Act and the Regulations, such as in relation to advertising, as well as State and Territory legislation. Changes to the Poisons Standard alter the content of the law, and have the indirect effect of imposing or varying obligations or rights. The Federal Court in *Roche Products v National Drugs and Poisons Scheduling Committee* [2007] FCA 1352 held that a decision by the NDPSC to amend the Poisons Standard was legislative in nature and the Court gave several reasons to support that decision which remain applicable.

As scheduling decisions are legislative in character, they cannot be the subject of an appeal under the *Administrative Decisions (Judicial Review) Act 1977* in the Federal Court.

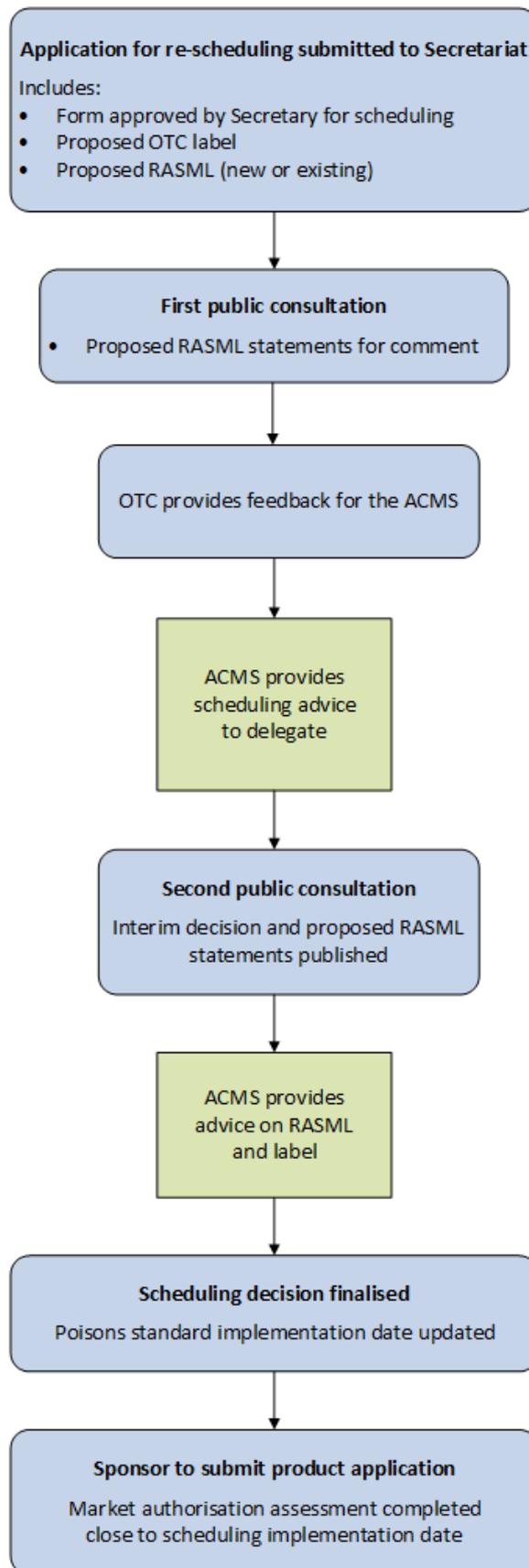
Scheduling decisions under subsection 52D(2) are not “initial decisions” which are open for reconsideration under section 60 of the Act, Therefore they are not reviewable by the AAT.

## Reconsideration of substances from prescription to OTC classification

The following process has been developed to streamline and encourage the rescheduling of substances from Schedule 4 (Prescription Only) to Schedule 3/2 (Pharmacist/Pharmacy Only). The process is described below, and illustrated in the following flowchart.

1. Applications for re-scheduling are submitted to the Secretariat
  - These applications include the form approved by the Secretary, the proposed Over-the-Counter label, and proposed Required Advisory Statements for Medicine Labels (RASML) (new or existing statements).
2. As an application for rescheduling, it is expected that the proposal will be referred to the ACMS for advice. The public notice for first public consultation will include the proposed RASML statements.
  - The TGA will provide feedback on the RASML statements and the label to be included in the agenda papers for consideration by ACMS.
3. ACMS provides scheduling advice to the delegate, including advice on RASML and the proposed label. The advice may also include recommendations for Appendix M specifications.
4. Second public consultation - interim decision and proposed RASML statements.
5. Scheduling decision is finalised and the Poisons Standard is updated with the relevant implementation date.
6. Once the scheduling decision is finalised, the sponsor responsible for the scheduling application can submit an application to the OTC section of the TGA.
7. The market authorisation assessment for the sponsor responsible for the scheduling application will be completed as close as possible to the scheduling implementation date.

## Parallel Process for pharmacy-only (S 2) and pharmacist-only (S 3) medicine applications and rescheduling: process diagram



## Rescheduling of substances with potential Appendix M criteria

Applications to reschedule S4 substances to S3 with Appendix M criteria should generally follow the same procedure as for other substances. Early engagement with the [Scheduling Secretariat](#) is encouraged, noting that the Secretariat cannot anticipate the final decision of the Secretary. Only some applications to reschedule S4 substances to S3 will require Appendix M criteria.

There are seven Appendix M controls that may or may not be applied to S3 substances when considering rescheduling to S3 (see below). These controls are not prescriptive and some or all may be applied on a case by case basis, depending on the specific risks presented by the substance. These controls would be captured in a professional practice standard relating to the substance, with the Appendix M entry specifying that the substance must be supplied in accordance with that practice standard. Specific conditions applied would also be articulated in the final scheduling decision.

It is expected that applicants seeking to reschedule S4 substances to S3 with Appendix M conditions will conduct preliminary discussions with the pharmacy profession, to gauge interest in the supply of these goods over the counter. These discussions should include consideration of Appendix M conditions that may need to apply, and collaboration on the development of training or materials in support of those conditions. This would also require engagement to develop an appropriate professional practice standard that would encompass those conditions.

## Appendix M criteria

One or several criteria may apply to a specific product and would be assessed by the Secretary.

### 1. Specific pharmacist training on the provision of the medicine

A training package would be developed for the goods in question, covering the nature and use of the medicine, conditions being treated and alternative treatments where relevant, risk factors and guidance on when to refer for medical assessment. The training package would also provide guidance on the use of any supporting materials.

Applicants are advised to work with an appropriate pharmacy body to develop a suitable training package and related support materials, for submission as part of their application to reschedule a substance to S3 with Appendix M conditions. Ideally, this would be done in tandem with the development of professional practice standards addressing expected Appendix M conditions. Accreditation of training through existing pharmacy profession pathways is desirable.

### 2. Suitability of the individual patient for supply of the medicine must be assessed by the pharmacist

This condition provides the ability to require the use of clinical decision-making aids by pharmacists, such as questionnaires, checklists or guidelines, in determining the appropriateness of supply of the product as an S3, Appendix M good. This condition also provides the ability to specify, for example, that face to face interviews should be conducted and if appropriately private interview spaces are available and how frequently, whether internet or phone sales are not permitted, or that specific assessments, reasonably available in a pharmacy setting (e.g. blood pressure checks), must be conducted, where such conditions are considered appropriate for the substance in question.

### 3. Specific advice (patient education) is required on supply of the medicine

This criterion covers information that may be considered essential to provide to patients, either verbally or in writing, at the time of supply. This could include information about side effects, drug interactions, health conditions that are contraindicated with the use of the

substance, and education as to why supply might be restricted, the condition being treated and when to seek advice from a medical professional.

4. Limitations on duration/quantity and/or frequency of supply

This criterion provides the ability to further refine the patient population and intended use of the substance, but specifying maximum durations of supply is beyond the existing capacity to specify indication, strength and quantity in the Poisons Standard. Any such restrictions would be tailored to the substance in question and incorporated into professional practice standards.

5. Need for formal diagnosis or periodic review of the condition by a medical practitioner

This criterion would apply to substances where initiation of the medicine and/or changes to dosing or product should be best made after a diagnosis by a medical practitioner.

Pharmacist supply is appropriate if the condition being treated can be stable for extended periods of time and ongoing supply of the medicine, once treatment has been established, does not require frequent monitoring by a medical practitioner.

6. Record keeping and information sharing

Record keeping may apply to any substances for which Appendix M criteria were considered appropriate. In some cases, a record of supply of the goods by pharmacists (for example, through inclusion in dispensing software), would be considered a sufficient measure for record keeping purposes. The need for information sharing about the supply of a substance with other health practitioners (subject to patient consent) would be determined on a case by case basis, but could be achieved through use of My Health records.

7. Additional criteria may be imposed

This criterion provides the flexibility for the Secretary to impose additional conditions on a substance to be rescheduled, if the need for a condition is identified that is not captured by the preceding criteria.

## Notification of decisions

After making a final decision the Secretary must (Regulation 42ZCZX):

- [publish the final decision](#) and the reasons for the decision, along with the proposed date of effect on the TGA website
- amend the Poisons Standard where required, in accordance with the procedures required to amend a legislative instrument

The Secretary will do this as soon as practicable.

Each advisory committee will be notified of scheduling decisions made by the Secretary at its next meeting.

## Date of coming into effect

Decisions to amend the Poisons Standard for new substances come into effect at the time the next Poisons Standard is published, unless stated otherwise.

Decisions for rescheduled medicine substances will generally come into effect no more than six months after the decision was made unless the Secretary is satisfied there is legitimate reason to delay the date of effect.

For rescheduled chemical substances, the decision will come into effect twelve months after the decision was made, unless the Secretary is satisfied there is legitimate reason to alter the date of effect.

## Adoption and implementation of decisions

It is envisaged that the states and territories will adopt (by reference) the scheduling recommendations in the Poisons Standard and give effect to them through their relevant drugs and poisons legislation. However, each jurisdiction reserves the right to implement a different scheduling decision to that included in the Poisons Standard to accommodate local circumstances.

A [consolidated report of these variances](#) is published on the TGA website.

## Scheduling Working Group

Following the 2017 review of the Scheduling Policy Framework, an *ad hoc* working group will be formed to review the scheduling processes and, if required, provide advice on policy matters to AHMAC.

## Version history

<b>Version</b>	<b>Description of change</b>	<b>Author</b>	<b>Effective date</b>
V1.0	Original publication	Regulatory Engagement and Planning Branch	18 January 2018
V1.1	Inclusion of Appendix M guidance	Transparency, Reforms and Evaluation Support Section	30 July 2019

## **Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia  
Email: [info@tga.gov.au](mailto:info@tga.gov.au) Phone: 1800 020 653 Fax: 02 6203 1605  
<https://www.tga.gov.au>

D17-730568