



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

**NATIONAL COORDINATING
COMMITTEE ON THERAPEUTIC
GOODS**

**SCHEDULING POLICY
FRAMEWORK
FOR
MEDICINES AND POISONS**

For stakeholder consultation
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INTRODUCTION

This *Scheduling Policy Framework* has been developed by the National Coordinating Committee on Therapeutic Goods (NCCTG), a subcommittee of the Australian Health Ministers' Advisory Council (AHMAC). The NCCTG oversees the development of a national approach to regulatory policy and administrative protocols relating to the availability and accessibility of medicines and poisons in Australia. NCCTG comprises representatives of each Australian State and Territory Government, the Australian Government and the New Zealand Ministry of Health.

The *Scheduling Policy Framework* will replace the Interim Guidelines for the National Drugs and Poisons Schedule Committee (NDPSC) and will be maintained by the NCCTG with input from the Department of Health and Ageing (the Department) and the Expert Advisory Committees on Medicines and Chemicals Scheduling.

This document should be read in conjunction with the Scheduling Standard (*Standard for the Uniform Scheduling of Medicines and Poisons*). Please note that this document may be subject to change following the development of the scheduling legislation.

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CHAPTER 1: THE SCHEDULING PROCESS

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1. INTRODUCTION

The *Scheduling Policy Framework* sets out the national system for applying access restrictions on medicines and other poisons (including agricultural, veterinary, domestic and industrial chemicals) where there is a potential risk to public health and safety. Poisons are scheduled according to the degree of risk and the level of control required over availability to protect consumers. State and territory governments are responsible for imposing legislative controls on the supply of poisons. Generally, these controls flow from the schedule in which the poison has been included.

The new provisions to separate arrangements for the scheduling of medicines and poisons will be set out in the *Therapeutic Goods Act 1989* (the Act) and Therapeutic Goods Regulations 1990 (the Regulations). They will be developed to ensure operational effectiveness in the current regulatory environment while providing for the existing high level of scheduling uniformity across Australian states and territories.

This section sets out the key aspects of the agreed separate models for the scheduling medicines and poisons in Australia. This includes:

- a single point of reference for scheduling policy through the National Coordinating Committee on Therapeutic Goods (NCCTG);
- the Secretary of the Department of Health and Ageing (or delegate) being the decision-maker on the scheduling of medicines and poisons;
- two separate expert scheduling advisory committees (for medicines and poisons) to advise the decision-maker;
- a single Poisons Standard (the *Standard for the Uniform Scheduling of Medicines and Poisons*); and
- a single scheduling secretariat to ensure ongoing consistency and cohesiveness of the process.

2. BACKGROUND

The National Competition Policy *Review of Drugs, Poisons and Controlled Substances Legislation* (the Galbally Review) recommended new separate arrangements for the scheduling of medicines and poisons in Australia (Recommendation 7). This recommendation included replacing the National Drugs and Poisons Schedule Committee with two separate committees which will focus on the scheduling of medicines and poisons respectively. The Council of Australian Governments (COAG) agreed to Recommendation 7 being progressed by the Australian Health Ministers' Conference (AHMC).

Implementation of the revised scheduling arrangements was anticipated to coincide with the commencement of the now suspended joint Australia New Zealand Therapeutic Products Regulatory Scheme.

More recently, COAG in responding to recommendations from the Productivity Commission *Research Report on Chemicals and Plastics*, supported the implementation of reforms proposed under the Galbally Review to separate the medicines and poisons scheduling processes.

3. KEY ASPECTS OF MODEL

Scheduling Policy

The NCCTG has responsibility for overarching policy principles, guidance and protocols on scheduling (including procedural guidelines). The *Scheduling Policy Framework* will allow reviewers (including any expert advisory committees or evaluators / decision-makers) within the Therapeutic Goods Administration (TGA) or the Office of Health Protection (OHP) to judge the best fit for new substances and to facilitate the assessment process of scheduled substances when an application for rescheduling is received or new knowledge or practice emerges.

Decision Maker

The Secretary of the Department (or delegated decision-maker) will make decisions on the scheduling of medicines and poisons. In practice, this means that for medicines, the decision-maker will be an officer of the TGA and for poisons, the other decision-maker will be an officer of the OHP. Further, entries in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) relating to other therapeutic goods for human use, substances that may be administered to humans and substances that may be subject to human abuse will all be administered by the TGA. Entries in the SUSMP relating to agricultural veterinary, domestic and industrial chemicals will be managed by the OHP.

When making a decision in relation to the scheduling of a substance the decision-maker will be required to take into account the relevant matters specified in the Act, the Regulations and subsequently the regulatory principles, processes and guidelines set out in the *Scheduling Policy Framework*. When amending entries within other Parts, Schedules and Appendices of the SUSMP the decision-maker must comply with the *Scheduling Policy Framework*.

Decisions to amend the SUSMP will be legislative in character.

Expert Advisory Committees

A Medicines Scheduling Expert Advisory Committee and Chemicals Scheduling Expert Advisory Committee will be established to provide advice on the scheduling of medicines and poisons to the relevant decision-maker. Recommendations of the Expert Advisory Committees will be published on the TGA Internet site.

The Poisons Standard

The SUSMP will include a record of the decisions of the Department and be maintained by the Scheduling Secretariat. Decisions of the Department (in terms of the entry in the SUSMP) will be a recommendation to the Australian states and territories.

The SUSMP will be considered to be a Legislative Instrument for the purposes of the *Legislative Instruments Act 2003* (LIA). On that basis the authoritative version of the SUSMP will be required under the LIA to be registered and published on the Federal Register of Legislative Instruments (FRLI) in electronic form. It will not be a disallowable instrument to ensure certainty in the continuing application of state and territory laws which refer to the SUSMP.

Implementation

It is envisaged that in all cases Australian states and territories will adopt (by reference) the scheduling recommendations in the SUSMP and give them effect through their relevant drugs and poisons legislation. However, each state and territory reserves the right to implement a different scheduling decision to that included in the SUSMP to take account of local circumstances. As the NCCTG is committed to the principle of national uniformity, any decision to depart from a scheduling entry in the SUSMP will need to be fully justified in an annual report to the NCCTG.

Costs

The costs associated with scheduling of medicines and poisons will be fully recovered from the relevant industry sectors.

A Cost Recovery Impact Statement (CRIS) is being prepared for the proposed cost recovery arrangements for scheduling. It is expected that the draft CRIS will be released for public comment during the second quarter of 2009.

4. THE SCHEDULING PROCESS

Scheduling

Generally, scheduling of a new substance (ie a substance on which a scheduling decision has not already been made) will take place as part of the evaluation and approval/clearance process for a medicine by the TGA or for a poison by the OHP following referral from the Australian Pesticides and Veterinary Medicines Authority (APVMA) (for agricultural/veterinary chemicals). For industrial/domestic chemicals, scheduling of a new substance will occur when the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) makes a recommendation to the decision-maker for scheduling of an industrial chemical based on the outcome of its risk assessment.

The decision-maker may refer the matter to the Medicines Scheduling Expert Advisory Committee, the Chemicals Scheduling Expert Advisory Committee or any other relevant committee/s for advice. In this case the decision-maker is required to take into account the recommendation of the expert advisory committee(s) before making a decision.

Rescheduling

The decision-maker must refer all rescheduling proposals for medicines and poisons to the Medicines Scheduling Expert Advisory Committee or the Chemicals Scheduling Expert Advisory Committee respectively for advice and must have regard to this advice before making a decision on rescheduling.

Submissions made in the interests of public health and safety

The Department, the Medicines Scheduling Expert Advisory Committee or the Chemicals Scheduling Expert Advisory Committee may consider the scheduling of a substance on their own initiative where it is in the interests of public health and safety.

Public Consultation.

All proposals to be considered by the Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee will be subject to public consultation except where otherwise directed by the decision-maker.

Any public submission received will be published on the website (other than aspects which are commercial-in-confidence).

Public consultation of the scheduling of a new substance under consideration will not routinely occur unless it is in the public interest to do so.

All rescheduling proposals must be considered by either the Medicines Scheduling Expert Advisory Committee or the Chemicals Scheduling Expert Advisory Committee and will be subject to public consultation.

Recommendations of the Expert Advisory Committees will be made public.

Urgent scheduling

Provisions will be made for urgent scheduling where the Department is satisfied that it would be in the interest of public health and safety to urgently schedule/reschedule a substance.

Notification of decisions

As soon as practicable after a decision is made by the decision-maker the Department must publish the decision on the TGA Internet site along with the reasons for the decision. The Department is also required to notify the applicant (and where relevant those persons who made public submissions) that they may seek a reconsideration of the decision.

In cases where a scheduling decision is made with regard to new substances, where the application has not been referred to either the Medicines Scheduling or Chemicals Scheduling Expert Advisory Committee, only the applicant will be advised of the scheduling decision.

Reconsideration of decisions

All scheduling decisions (not being reconsiderations of a decision) can be reconsidered by the Secretary or delegate of the Department (other than the original decision maker) at the request of the applicant. The applicant or any interested party that made a submission during the consultation period will be able to request a reconsideration of a rescheduling decision on the grounds that a relevant matter in the legislation was not taken into account, an irrelevant matter was taken into account, or the NCCTG scheduling policy was incorrectly applied.

In considering an application for reconsideration, the Department may seek advice from the Medicines Scheduling Expert Advisory Committee or the Chemicals Scheduling Expert Advisory Committee.

As scheduling decisions are legislative in character, the merits of the decisions of the decision-maker will only be reviewable under the *Judiciary Act 1903*.

Date of effect of decisions

Before amending the SUSMP the Department will be required to publish a notice advising of the amendment together with the date of effect.

Scheduling decisions on new substances would come into effect at or before the time of registration (where relevant). All other scheduling decisions would come into effect no more than six months after the decision was made unless otherwise specified.

5. SCHEDULING EXPERT ADVISORY COMMITTEES

The Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee will be established under the *Therapeutic Goods Act 1989*. The procedures for the Scheduling Expert Advisory Committees will be set down in the Therapeutic Goods Regulations 1990 or the NCCTG *Scheduling Policy Framework*.

Functions

Each Scheduling Expert Advisory Committee will:

- make recommendations to the Secretary regarding the classification and scheduling of substances including the need to impose additional controls in relation to such substances where requested by the Secretary;
- reconsider scheduling decisions referred by the Secretary;
- provide advice to the Secretary in relation to the broader regulatory policy framework that sets out restrictions on accessibility and availability of substances;
- provide input to the Secretary on the Guidelines including the National Coordinating Committee on Therapeutic Goods *Scheduling Policy Framework*; and
- provide advice and make recommendations to the Secretary in relation to any other matter referred by the Secretary; and
- any other functions prescribed in the Regulations.

Recommendations of the Scheduling Expert Advisory Committees are to be made public. Additionally, the Scheduling Expert Advisory Committees will be able to make submissions to the Department on proposed changes to the SUSMP and have the power to establish sub-committees with the agreement of the Department.

Responsibilities of the Committees

Each Scheduling Expert Advisory Committee will provide advice to the Secretary on the following types of proposals to amend the SUSMP.

Proposal	Advisory Committee
Rescheduling of substance included in a therapeutic good (human medicine)	MSEAC
Rescheduling of agricultural or veterinary chemical	CSEAC
Rescheduling of industrial, domestic or personal use chemical	CSEAC
Scheduling of a new substance (agricultural, veterinary or industrial) that may meet the criteria for inclusion in Schedule 7	CSEAC

Proposal	Advisory Committee
Scheduling of a substance that may meet the criteria for inclusion in Schedule 9	MSEAC
Proposal to amend or include an entry in Appendices A, C, G	Joint meeting
Proposal to amend or include entry in Appendices D, H, K, L, M, N	MSEAC
Proposal to amend or include entry in Appendices E, F, I, J	CSEAC
Proposal to amend or include a provision in Parts 1 to 3 that affects only therapeutic goods.	MSEAC
Proposal to Amend Parts 1 to 3 that affects only agricultural, domestic, industrial or veterinary chemicals	CSEAC
Any other proposal to amend Parts 1 to 3	Joint meeting
Any proposal to amend Appendices A, C, or G that affects both human medicines and other poisons	Joint Meeting
Any proposal to amend this document (the <i>Scheduling Policy Framework</i>)	Joint meeting and NCCTG

Membership

There will be two classes of experts on the Scheduling Expert Advisory Committees. Firstly, ‘nominated’ expert members to reflect the cooperative nature of the scheduling process between the Commonwealth and the states and territories, and to encourage scheduling uniformity across Australia. Secondly, ‘appointed’ expert members would be selected from applications received from a broad range of government bodies (including the APVMA and NICNAS), academic institutions, healthcare, consumer and industry groups, and the public.

The membership of the Scheduling Expert Advisory Committees is expected to encompass as far as reasonably practicable the widest possible range of expertise outlined below.

Medicines Scheduling Expert Advisory Committee

The Medicines Scheduling Expert Advisory Committee will comprise at least eleven but not more than fifteen members.

Members must have requisite expertise in one or more of the following areas:

- The regulation of the scheduling of medicines in the Commonwealth, or an Australian State or Territory;
- Toxicology;
- Clinical pharmacology;
- Pharmacy practice;
- Medical practice;
- Consumer health issues relating to therapeutic goods; or
- Industry issues relating to the regulation of therapeutic goods.

Observer status will be granted to New Zealand in the interests of furthering trans-Tasman harmonisation of medicine scheduling. The New Zealand Ministry for Health will be invited to nominate a person with expertise in the regulation of the scheduling of medicines in New Zealand.

Chemicals Scheduling Expert Advisory Committee

The Chemicals Scheduling Expert Advisory Committee will comprise at least eleven but not more than fifteen members.

Expert members must have requisite expertise in one or more of the following areas:

- The regulation of the scheduling of chemicals in the Commonwealth, or an Australian State or Territory;
- Toxicology;
- Clinical aspects of human poisoning;
- Occupational health, with expertise preferably also as a medical practitioner.
- Veterinary medicine or veterinary pathology;
- Management of industrial and domestic chemicals;
- Management of Agricultural and veterinary chemicals;
- Consumer health issues relating to chemicals; or
- Industry issues relating to the regulation of chemicals.

New Zealand will be granted observer status in the interests of furthering closer trans-Tasman ties on the regulation of chemicals. The New Zealand Environmental Risk Management Authority will be invited to nominate a person with expertise in the regulation of chemicals in New Zealand.

Appointment of members

The Commonwealth Minister for Health and Ageing will appoint committee members with appointment decisions based on recommendations from the Department. The appointment is to be in writing. In appointing a committee member, the Minister is entitled to appoint whoever the Minister believes to be appropriately qualified. It is intended that members are appointed on the basis of expertise rather than to represent a particular jurisdiction or interest. Appointment of substitutes will be made at the same time.

A member is to be appointed for a term stated in the member's appointment but must not be longer than three years. Such members can be appointed for a further term of up to three years but may not serve more than three consecutive terms.

All committee members will be required to make an undertaking with regard to confidential information and conflict of interest.

Appointment of Chair

The chair of both the Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee must be a Commonwealth officer nominated by the Department. They will be appointed by the Commonwealth Minister for Health and Ageing in writing. The Chair holds that office for the term stated in the appointment and may be appointed for further terms.

Resignation

A Member may resign by signed notice given to the Commonwealth Minister for Health and Ageing.

The Chair may resign as both Chair and as a committee member by signed notice to the Minister.

Voting

All members of the Scheduling Expert Advisory Committees will have equal voting rights.

A decision (to make a recommendation to the delegate) is made at a Committee meeting by a majority of the votes of the members present and voting. The Chair or presiding member at a Committee meeting has the deliberative vote and in the event of a tied vote has the casting vote. The quorum will be two thirds of the committee members.

Joint meetings

Given the potential overlap of membership and interests, meetings of the Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee may be run over consecutive meeting days.

Where matters of interest to both the Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee are identified, sufficient time is to be allowed for both committees to jointly discuss these matters, including any matters relating to the *Scheduling Policy Framework*.

A recommendation arising from a joint meeting is a recommendation to the Secretary from both advisory committees.

Recommendations on the *Scheduling Policy Framework* are to be referred to the National Coordinating Committee on Therapeutic Goods for consideration.

Joint working parties

Where the decision-maker requires advice on particular scheduling issues which potentially impact across medicines and poisons, the Department may establish a joint working party consisting of members of the Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee and other persons to inquire into, and report back to the Department.

SECRETARIAT

In the interests of ensuring ongoing consistency and cohesiveness in the decision-making process between the Medicines Scheduling and Chemicals Scheduling Expert Advisory Committees, there will be a single secretariat to support both committees located in the TGA.

**CHAPTER 2: GUIDELINES FOR THE DECISION-MAKER
AND THE SCHEDULING COMMITTEES**

GUIDELINES FOR THE DECISION-MAKER

Procedures for the decision-maker will be set out in the *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulations 1990* and this document.

GUIDELINES FOR THE SCHEDULING COMMITTEES

The Medicines Scheduling Expert Advisory Committee and the Chemicals Scheduling Expert Advisory Committee will be committees established under the *Therapeutic Goods Act 1989*. Procedures for both committees will be set down in the *Therapeutic Goods Regulations 1990* and in the *Scheduling Policy Framework*.

GUIDELINES FOR AMENDING INTRODUCTION, PARTS 1-3 AND PART 5 OF THE SCHEDULING STANDARD

GUIDELINES FOR AMENDING PARTS 1-3

Applications to include a new regulatory provision or vary an existing regulatory provision may be made according to legislation. The application may be made in conjunction with or independent of a proposal for a new or existing product made to the TGA or APVMA.

The Secretary of the Department of Health and Ageing (the Secretary) may make a new regulatory provision or vary an existing regulatory provision in Parts 1-3 of the SUSMP following consultation with one or both of the Scheduling Expert Advisory Committees depending on the scope (see below) of the proposed regulatory provision.

In making a decision to amend Parts 1-3 the decision-maker will need to consider:

- the scope of the proposed provision (whether the provision applies to just human medicines, poisons that are not human medicines or all poisons);
- the effect of the proposal on existing entries in the Schedules and Appendices;
- the regulatory need and justification for the change; and
- the potential implications of the change.

GUIDELINES FOR APPENDICES

General Principles

Applicants should note that entries in certain Appendices in Part 5 can only be made in the context of an application to the TGA or APVMA in relation to a proposed or existing product. This would potentially include entries in Appendices A, B, C, G and H for therapeutic goods and Appendices A, B, C, G and J for agricultural and veterinary chemicals.

In addition, changes to certain Appendices in Part 5, in particular Appendices A, B and C can only be considered in the context of an application for rescheduling. For Appendix A, the committee may consider the exemption of a class of products, where the case for rescheduling representative members of the class has shown that they consistently do not

meet the criteria for inclusion in any of the Schedules. In the case of Appendix B, an application can only be made for scheduling of a new substance or rescheduling of an existing poison that, on consideration, does not meet the criteria for inclusion in any of the Schedules where the committee may consider the public benefit of adding an entry to the Appendix, recording the grounds for the exemption. Applicant should note that an application for exemption from the schedules as such cannot be made. A change to an existing entry in Appendix C should be addressed as an application for rescheduling. An application for scheduling of a new substance may be considered for inclusion in Appendix C where the criteria set out below are met.

Where the Appendix may have direct implications for the labelling, storage or supply of a product, an application to vary the specific entry must be made either through the relevant product registration authority (TGA/APVMA) or as set out in legislation. This will include Appendices C, D, G, H, K, L, M and N for therapeutic goods and C, F, E, G, I, J, and M for all other poisons.

Proposed Principles:

Appendix A – General Exemptions

Appendix A provides general exemptions from the provisions in the SUSMP for classes of products where the physical nature of the class, or the use of the class of product, or other legislative controls applicable to the class of product, mitigate to an acceptable level, the public health risk of any included poisons.

An entry to Appendix A may be made by the Secretary where classification of indicative members of the product class has shown they do not meet any of the criteria for inclusion in the Schedules. In addition argument should be provided that:

- demonstrates the likely consistency of the proposed class with respect to the scheduling classification; and
- argues the regulatory need for a class exemption; and
- establishes the benefits of providing a class exemption.

Both Scheduling Expert Advisory Committees would be consulted on a new or amended entry to Appendix A.

Appendix B – Substances Considered Not to Require Control by Scheduling

An entry into Appendix B may be made by the Secretary following consideration of an application for scheduling of a new substance or rescheduling of an existing poison and where the application does not meet any of the criteria for inclusion in Schedule. There is NO application as such to be included in Appendix B and no explicit criteria for inclusion in the Appendix.

The Secretary may make an entry in Appendix B for a new substance and will consult with the appropriate Scheduling Expert Advisory Committee for a rescheduling application.

Appendix C – Substances, Other than Those Included in Schedule 9, of Such Danger to Health As to Warrant Prohibition of Sale Supply and Use

Inclusion of a substance in Appendix C will usually arise either through a member of either of the Scheduling Expert Advisory Committees or at the request of the TGA or OHP. Otherwise, consideration of an entry in Appendix C may occur in relation to an application for scheduling of a new substance or rescheduling of an existing entry in the Schedules.

Unless clearly restricted to either human use or just other poisons excluding human use, then a joint meeting of both Scheduling Expert Advisory Committees will need to be consulted.

An entry in Appendix C may be considered where:

- a public health risk has been identified that requires management;
- the public health risk does not include potential for abuse or other factors which would warrant inclusion in Schedule 9;
- the risk outweighs the benefit to the extent that no other Schedule could provide appropriate access to any proposed or known products;
- possession or supply of the poison is considered to constitute a potential public health hazard, but where the additional criminal sanctions associated with Schedule 9 are considered unnecessary.

Appendix D - Additional Controls on Possession or Supply of Poisons Included in Schedules 4 or 8

An entry in Appendix D may be considered for any human medicine where the assessment of the proposal identifies:

- a specific health risk that may be mitigated by restricting availability through specialist medical practitioners; or
- significant potential for illicit diversion and/or abuse which does not warrant inclusion in Schedule 8 but warrants control of possession; or
- a specific high potential for abuse, particular international restrictions on availability or other matters of national public health policy which when weighed against the need for access to the substance, warrants in addition to inclusion of the substance in Schedule 8, further restrictions on access such as authorisation by the Secretary of the Commonwealth Department of Health and Ageing; and

taking into account the implications for professional practice by the medical profession and regulatory control by the states and territories.

An entry in Appendix D would be made following consultation with the MSEAC

Appendix E – First Aid Instructions for Poisons

Appendix F – Warning Statements and General Safety Directions Handbook

First aid and safety directions for human medicines are assessed as a component of the registration requirements and are included in the TGA publication *Required Advisory Statements for Medicines Labels*. The same directions for agricultural and veterinary chemicals are included in the Department of Health and Ageing publication *First Aid Instructions and Safety Directions Handbook*.

Appendices E and F include first aid and safety directions required to be included on the label to promote safe use of domestic chemical products. The directions supplement the directions for use of the product by identifying specific hazards of the product, appropriate first aid measures following misadventure involving the product, specific precautions to be taken with and any personal protective equipment to be worn during use of the product.

Entries are based on the assessment of the scheduling proposal.

The Secretary may make an entry in these Appendices as part of the scheduling decision for a new substance. An entry or amended entry may also be made in these appendices following a rescheduling application and consultation with the CSEAC. New or amended entries in these appendices may also be made following a separate application in relation to these Appendices and consultation with CSEAC.

Appendix G – Dilute Preparations

An entry in Appendix G exempts the substance from **all** requirements of the SUSMP when used at a concentration at or below that specified in the Appendix. In addition an entry in this Appendix generally places use of the substance at or below this concentration, beyond all state and territory poisons regulations and related regulatory provisions. Many of the principles for this Appendix may be seen for Appendices B and A.

The Secretary may make an entry in the Appendix;

- following consultation with one or both committees, depending on the scope of the entry; and
- where the assessment of the cut-off does not meet the criteria for inclusion in any Schedule; and
- where the assessment of the undiluted substance does not meet the criteria for inclusion in Schedule 7, 8 or 9 or Appendix C; and
- there are no other public health concerns in relation to the proposed entry.

Appendix H – Schedule 3 Medicines Permitted to be Advertised

Use of Appendix H is being phased out and replaced by legislation under the *Therapeutic Goods Act 1989*. Application to allow or vary the advertising of a Schedule 3 human medicine is to be made to the TGA. The decision will be made by the Secretary taking into account the NCCTG *Guidelines for brand advertising of substances included in Schedule 3 of the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP) (November 2000)*.

Appendix I – Uniform Paint Standard

Application for a new or varied entry to the Appendix (the Paint Standard) must be made according to the legislation. The Secretary will make a decision following consultation with the CSEAC. An application for a new or amended entry to the paint standard will have to provide extensive information on the toxicity and use of any substance, the safety of and public health implications of any proposal.

Appendix J – Conditions for Availability and Use of Schedule 7 Poisons

A new or amended entry to Appendix J will only be considered in the context of a new substance meeting the criteria for Schedule 7 or a rescheduling application for an existing entry in Schedule 7. The Secretary may make a new entry or vary an existing entry following consultation with the CSEAC and will consider the need for any additional state and territory controls over access, training or possession of the substance to ensure its safe use.

Appendix K – Medicines Required to be Labelled with a Sedation Warning

An application to vary an entry in the Appendix can be made according to the legislation. The Secretary may also make a new entry or vary an existing entry following consultation with the MEAC and consideration of an application for a new or existing human medicine

In making the decision the Secretary will consider:

- the potential for sedation in humans exhibited by a medicine in normal use;
- animal or human data demonstrating any impairment of reflexes; and
- the need to warn users of any potential danger of the medication when the user is in control of machinery or an automobile.

Appendix L – Schedule 2 Poisons that Cannot be Sold by Licensed Poisons Sellers

An entry in this Appendix, to prohibit sale of a medicine in Schedule 2 by a registered poisons seller, may be considered following an application by a member of the Scheduling Expert Advisory Committees, the Secretary or a member of the public. In addition an application to vary an existing entry in the Appendix may be made according to legislation. The Secretary may make a new entry or vary an existing entry in the Appendix following consultation with MSEAC. The criteria for excluding a poison from being sold by a licensed poisons seller are still under development but may include potential for diversion, abuse or risk of misuse.

Appendix M – Requirements for Dispensing Labels for Human and Veterinary Medicines

The Secretary may make a new entry or vary an existing entry following consultation with MSEAC for dispensing of human medicines, CSEAC for dispensing of veterinary medicines or both if relevant. An amendment to the Appendix may be considered following a proposal for a new or existing medicine where there are new or varied professional practice requirements for the labelling of the dispensed medicine.

Appendix N – Schedule 3 Medicines Subject to Mandatory Recording Requirements

The Secretary may make a new entry or vary an existing entry in the Appendix following consultation with MSEAC. Criteria for requiring the recording of sale or supply of an S3 medicine are still under development but may include the potential for diversion to illicit use or potential for resale for misuse.

**CHAPTER 3: THE CLASSIFICATION OF MEDICINES AND
POISONS**

DRAFT

CLASSIFICATION OF MEDICINES AND POISONS - GENERAL

In order to ensure that public health objectives are consistently met, all scheduling decisions should include consideration of a standardised set of “factors”. Factors rather than criteria are considered to be more appropriate assessment tools, as:

- 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 in turn may influence the final classification;
- there is interaction between the various factors such that a particular grouping of factors may suggest one classification where taken individually they may not; and
- the factors must be considered as a whole in determining the public health risk for the proposal, not applying any particular order of consideration or weight to any one factor. This reflects the final assessment for each scheduling proposal, of relative public health risk against the classification spectrum.

A process using factors allows a degree of judgement by reviewers to find the best fit for a substance in the classification system, taking into account that the factors for each schedule must be read as a “whole” and are not intended to be considered in isolation. The order in which the factors are included in the schedules is not significant either as scheduling decisions are made on balance of the available evidence. In this respect, there is no inherent or substantive difference between the scheduling of medicines and poisons.

Consideration of these factors permits the objective assessment of the risk/benefit balance for the consumer at different levels of access and therefore optimal public availability. In considering the risk it is necessary to define the hazards and then determine what action is necessary in terms of the amount of regulatory intervention required to reduce the public health risk to an acceptable level. The following questions should be answered to ensure that the risk is understood as completely as possible:

- What is the hazard?
- How widespread is the hazard?
- In what circumstances will the hazard arise?
- What is the likelihood of the hazard occurring?
- Who or what is at risk?
- What are the consequences of the hazard in terms of severity (morbidity and mortality) and duration?

The Schedules in the SUSMP comprise lists of substances (entries) all of which are subject to the conditions and requirements for that Schedule, set out in Parts 2, 3 and 4 of the SUSMP. The Schedules are compilations of varying levels of risk treatments available to reduce the assessed public health risk to an acceptable level. What the substance refers to in the schedule entry will vary according to the interpretation of “substance” in Part 1 subsection 1(2) of the SUSMP.

PRINCIPLES OF SCHEDULING

The *Scheduling Policy Framework* supports the broader public health policy frameworks in Australia both for the quality use of medicines and safe use of chemicals.

For the quality use of medicines, which incorporates the judicious selection of management options, appropriate choice of medicines (where a medicine is considered necessary) and safe and effective use; the scheduling classification reinforces the need for particular healthcare professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use. Labelling with specific phrases (signal heading) also emphasises this need for intervention by particular health professionals. The scheduling decision considers a number of factors such as the toxicity of the substance, diagnosis and the purpose of use, potential for abuse, safety in use and the need for the substance.

The *Scheduling Policy Framework* also supports safer use of agricultural, veterinary and domestic chemical products through labelling with specific “alert” phrases keyed to the major threat level or phrases emphasising the need for intervention by particular professionals (where warranted) (signal headings). Where necessary the scheduling of veterinary chemicals reinforces the need for intervention by veterinary professionals to promote safe and effective use. The scheduling decision considers a number of factors including the toxicity of the substance, purpose of use, potential for abuse, safety in use, the need for specialist training or personal protective equipment for safe or effective use and the need for access to the substance. The SUSMP also establishes the required packaging and all necessary label information for the safe and effective use of domestic chemical products.

Substances can be classified into schedules as follows:

- Schedules 5, 6, 2, 3, 4, and 8 include medicinal substances intended for human therapeutic use and have consistent, increasingly restrictive factors for inclusion in each schedule.
- Schedules 4, 5, 6, 7 and 8 all include poisons, with increasingly strict special regulatory controls on the availability of the poisons listed in Schedules 4, 7 and 8. A limited number of veterinary medicines are currently included in Schedule 2. However, consideration will need to be given to whether inclusion of veterinary medicines in this schedule should be phased out. Veterinary medicines are not included in Schedule 3.
- Schedule 9 includes substances that should be available only for 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 in general, prohibited.
- A number of poisons are included in Appendix C of the SUSMP which also lists substances, other than those included in Schedule 9, which are of such danger to health as to warrant prohibition of sale, supply and use.

The numbering of the schedules 2, 3, 4, and 8 signifies increasingly stricter professional intervention combined with increasingly stricter restrictions on availability. For the schedules 5, 6 and 7 the numbering signifies increasingly stricter container and labelling requirements. Appendix J may also include additional special controls on availability, use of specialist equipment and training of users.

The model for making scheduling decisions embodies a “cascading principle”.

For **medicines**, a substance is first assessed using the factors for Schedule 8. If the factors for Schedule 8 are not pertinent, the substance is assessed against the Schedule 4 factors and if not applicable, against the Schedule 3 factors, and if not applicable, against the Schedule 2 factors. Finally the medicine may be assessed against the factors for Schedules 6 and 5 if relevant.

For **poisons**, a substance is first assessed using the factors for Schedule 9, however the highly restricted criteria for this schedule mean that very few substances are likely to be considered for, or included in this schedule. If the factors for Schedule 9 are not pertinent, the substance is assessed against the Schedule 7 factors, and if warranted, subsequently against the Schedule 6 or Schedule 5 factors.

For veterinary chemicals, assessment against the factors for Schedules 8, 4, 3 and 2 may be followed by Schedules 7, 6 and 5 as relevant.

Notwithstanding the above, the cascading principle also applies to substances that are both medicines and poisons. In this case, consideration is given to the therapeutic and non-therapeutic use of the substance and its toxicity. Assessment would be made against the factors for Schedule 7 and the factors for Schedule 8, and where these are not relevant, “cascading” to Schedules 6 and 4 respectively and so on through Schedules 5, 3, and 2.

Exemption from scheduling requirements would be appropriate, where the substance does not meet the factors for ANY schedule. That is the decision can only be made by exclusion, there are no factors as such for exemption from the Schedules. This may be recorded as a general exemption where warranted, for a class of products in Appendix A (see below), a specific exemption from the SUSMP for the substance in Appendix B or as an exemption from an entry in a Schedule. An exemption may be subject to conditions including but not limited to, the maximum concentration, use, labelling, packaging and pack size restrictions.

This model allows the best fit to be found using a systematic approach and also facilitates the reclassification process for substances when new knowledge or practice emerges that materially alters the public health risk or when an application for rescheduling is received.

CHAPTER 4: THE SCHEDULING FACTORS

(Schedule 1 of the SUSMP is currently unused.)

PROPOSED FACTORS FOR PHARMACY MEDICINES (SCHEDULE 2)

- 1. The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist is available to maximise the safe and effective use of the medicine.**
The medicine is for minor ailments or symptoms that can easily be recognised and are unlikely to be confused by the consumer with other more serious diseases or conditions. Treatment can be managed by the consumer without the need for medical intervention. However, the availability of a pharmacist at the point of sale supports the consumer in selecting and using the appropriate medicine.
- 2. The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.**
Suitable for diagnosis and treatment by the consumer in the management of minor ailments.
- 3. The use of the medicine at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.** Medicines which do not meet this factor, are not suitable to be classified as Schedule 2 Pharmacy Medicines, irrespective of any other applicable factors.
- 4. The risk profile of the medicine is well defined and the risk factors can be identified and managed by a consumer through appropriate packaging and labelling and consultation with a medical if required.**
There is a low and well-characterised incidence of adverse effects; interactions with commonly used substances or food and contra-indications.
- 5. The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.**
Appropriate labelling and packaging can manage any risks.

PROPOSED FACTORS FOR PHARMACIST ONLY MEDICINES (SCHEDULE 3)

- 1. The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.**

The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use. Pharmacist-consumer dialogue is necessary to reinforce and/or expand on aspects of the safe and effective use of the medicine.

- 2. The use of the medicine at established therapeutic dosages is not expected to produce dependency. Where there is a risk of misuse, abuse or illicit use identified, the risk can be minimised through monitoring by a pharmacist.**

- 3. The risk profile of the medicine is well defined and the risk factors for adverse effects and interactions are known, identifiable and manageable by a pharmacist.**

- 4. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or a pharmacist.**

The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

- 5. The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.**

Pharmacist-consumer dialogue is required to detect the risk of masking a serious disease or compromising medical management of a disease, and to deal with it appropriately.

PROPOSED FACTORS FOR PRESCRIPTION ONLY MEDICINES AND PRESCRIPTION ANIMAL REMEDY (SCHEDULE 4)

- 1. The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention².**
Diagnosis, management or monitoring of the medical condition is such that it requires medical, veterinary or dental intervention before the substance is used.
- 2. The use of the substance requires adjunctive therapy or evaluation.**
Adjunctive therapy could include other medicines, non-pharmacological measures, or specialised medicine delivery devices. Evaluation could include laboratory tests or additional clinical assessments.
- 3. The use of the substance at established therapeutic dosage levels, may produce dependency but has a moderate propensity for misuse, abuse or illicit use.**
Control of access and duration of therapy by a medical, veterinary or dental practitioner is required.
- 4. The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance.**
- 5. The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical, veterinary or dental intervention to minimise the risk of using the substance.**
- 6. The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner.**
- 7. The use of the substance has contributed to, or is likely to contribute to, communal harm.**
For example the development of resistant strains of microorganisms. Appropriate use, and/or the decision to continue treatment, requires evaluation by a medical, veterinary or dental practitioner.
- 8. The experience of the use of the substance under normal clinical conditions is limited.**
Unexpected effects of the substance may only become evident after widespread use by a medical, veterinary or dental practitioner. Close monitoring of the patient is required by a medical, veterinary or dental practitioner to monitor for unanticipated effects.

² For the purposes of this document medical, veterinary or dental intervention is considered to include other authorised prescribers as described in relevant legislation of Australian States and Territories.

PROPOSED FACTORS FOR LABEL USE OF “WARNING” (SCHEDULE 5)

1. The substance is non-corrosive and has a low toxicity-

Acute oral toxicity (rat) is between 2000 mg/kg – 5000 mg/kg. Acute dermal LD50 is more than 2000 mg/kg. Acute inhalation LC50 (rat) is more than 3000 mg/m³ (4 hours).

Dermal irritation is slight to moderate. Eye irritation is slight to moderate. Immediate, prolonged or repeated contact with the skin or mucous membranes may cause slight to moderate inflammation. Skin sensitisation is slight or nil.

2. The substance has a low health hazard.

The substance presents a low hazard from repeated use and is unlikely to produce irreversible toxicity. There is no other significant toxicity (eg respiratory sensitisation, mutagenicity, carcinogenicity, reproductive toxicity etc).

3. The substance is capable of causing only minor adverse effects to humans in normal use.

Specialised equipment should not be necessary for safe use.

4. The likelihood of injury in handling, storage and use can be mitigated through appropriate packaging and simple label warnings.

Adequate packaging and labelling protects the consumer from the known danger(s) of the substance if it is inhaled, taken internally or if it penetrates the skin. Potential harm is reduced through labelling which informs the consumer about the safety measures to apply during handling and use (including safety directions) and child resistant packaging (where appropriate).

5. The substance has a low potential for causing harm.

Potential harm is reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

PROPOSED FACTORS FOR LABEL USE OF “POISON” (SCHEDULE 6)

- 1. The substance has a moderate to high toxicity, which may cause death or severe injury (including destruction of living tissue) if inhaled, taken internally, or in contact with skin or eyes.**

Acute oral LD50 (rat) is between 50 mg/kg – 2000 mg/kg. Acute dermal toxicity is between 200 mg/kg and 2000 mg/kg. Acute inhalation LC50 (rat) is between 500 mg/m³ and 3000 mg/m³ (4 hours).

Dermal irritation is severe. Eye irritation is severe. Skin sensitisation is moderate to severe.

- 2. The substance has a moderate health hazard.**

The substance presents a moderate hazard from repeated use and moderate risk of producing irreversible toxicity.

- 3. Reasonably foreseeable harm to users can be reduced through strong label warnings, extensive safety directions and child-resistant packaging (where appropriate).**

Adequate packaging and labelling protects the consumer from the known danger(s) of the substance. Potential harm is reduced through labelling which informs the consumer about the safety measures to apply during handling and use (including safety directions) and child resistant packaging.

- 4. The substance has a moderate potential for causing harm.**

Potential harm is reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

PROPOSED FACTORS FOR DANGEROUS POISONS (SCHEDULE 7)

1. The substance has a high to extremely high toxicity.

Acute oral LD50 (rat) is 50 mg/kg or less. Acute dermal LD50 is 200 mg/kg or less. Acute inhalation LC50 (rat) is 500 mg/m³ (4 hours) or less. Dermal irritation is corrosive. Eye irritation is corrosive.

2. The substance has a high health hazard.

The substance presents a severe hazard from repeated and unprotected use or a significant risk of producing irreversible toxicity, which may involve serious, acute or chronic health risks or even death if it is inhaled, taken internally or penetrates the skin.

3. The dangers of handling the poison are such that special precautions are required in its manufacture, handling or use.

The dangers associated with handling the substance are too hazardous for domestic use or use by untrained persons and warrant restrictions on its availability, possession or use.

4. The substance has a high potential for causing harm at low exposure.

The substance should be available only to specialised or authorised users who have the skills necessary to handle them safely. Restrictions on their availability, possession, storage or use may apply.

For Schedules 5, 6 and 7 the following definitions apply:

Eye irritation

Slight	no corneal opacity
Moderate	corneal opacity, reversible 7 days
Severe	corneal opacity not reversible 7 days
Corrosive	irreversible tissue damage in the eye following application of a test substance to the anterior of the eye

Skin irritation

Slight	slight irritation at 72 hours
Moderate	moderate irritation at 72 hours
Severe	severe irritation at 72 hours
Corrosive	irreversible tissue damage in the skin following application of a test substance

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PROPOSED FACTORS FOR CONTROLLED DRUGS (SCHEDULE 8)

- 1. The substance is included in Schedule I or II of the *United Nations Single Convention on Narcotic Drugs 1961* or in Schedule II or III of the *United Nations Convention on Psychotropic Substances 1971*.**
- 2. The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.**
- 3. The substance has an established therapeutic value but by reason of its novelty or properties carries a substantially increased risk of producing dependency, misuse, abuse or illicit use.**

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PROPOSED FACTORS FOR PROHIBITED SUBSTANCES (SCHEDULE 9)

- 1. The substance is included in either Schedule IV to the *United Nations Single Convention on Narcotic Drugs, 1961* or in Schedule I to the *United Nations Convention on Psychotropic Substances 1971*.**
- 2. The substance has either no currently established therapeutic value, or taking into consideration the danger to the health of individuals and of the community (both immediate and imminent) associated with the use of the substance as compared to the therapeutic advantages of the substance, the benefits are substantially outweighed by the risks.**
Dangers are such to warrant limiting use to strictly controlled medical and scientific research.
- 3. The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use.**
A high level of control is required through prohibition of use, possession, administration, prescription, sale or distribution to prevent abuse, misuse or diversion into illicit activities.

**CHAPTER 5: GUIDELINES FOR APPLICATION AND
INFORMATION REQUIREMENTS**

DRAFT

SCHEDULING AND RESCHEDULING

Application and information requirements for scheduling of new substances and rescheduling of existing substances are to be included in those already in place for the evaluation of the relevant medicine or poison, where a regulatory framework exists.

SCHEDULING AND RESCHEDULING HUMAN MEDICINES

For a human medicine, it is generally expected that an application for rescheduling to a lower schedule or for an exemption from the requirements of the SUSMP would be supported by at least two years of local clinical use or post-marketing experience with the human medicine. Other suitable evidence such as an appropriate period of distribution and use in comparable markets overseas (this being a country with a well-developed pharmacovigilance system) will be considered in lieu of local post-market experience. This requirement will be assessed on a case-by-case basis.

Suitable evidence includes:

- evidence from comparable overseas countries (such as Canada, Sweden, Netherlands, United States, United Kingdom and Europe generally); or
- relevant public “exposure” information in comparable countries with a greater population base than Australia; or
- any available information from post-marketing surveillance (spontaneous and any post marketing surveillance studies, local or overseas); or
- any relevant previous Australian consideration of scheduling of the medicinal substance (eg. different route of administration).
- any relevant Australian experience with the medicine including a different route of administration.

The rescheduling process takes into consideration relevant market experience and distribution of use of the substance in Australia or overseas.

For further information on application requirements for human medicines refer to:

Type of Human Medicine	TGA Guideline
Prescription Medicines	<i>Australian Regulatory Guidelines for Prescription Medicines</i>
Over the Counter (OTC) Medicines	<i>Australian Regulatory Guidelines for OTC Medicines</i>
Complementary Medicines	<i>Australian Regulatory Guidelines for Complementary Medicines</i>

SCHEDULING AGRICULTURAL AND VETERINARY CHEMICALS

Applications for the scheduling of new agricultural and veterinary chemicals are made directly to the APVMA as part of an application for registration of a new agricultural or veterinary product. The scheduling aspect of the application is referred to the Department by the APVMA as part of the health risk assessment process for registration.

Application and information requirements for scheduling new agricultural and veterinary chemicals are prescribed in the *Guidelines for Registering Agricultural and Veterinary Chemicals* published by the APVMA. The guidelines are available on-line at: <insert url>

RESCHEDULING AGRICULTURAL AND VETERINARY CHEMICALS

Applications for rescheduling an existing agricultural and veterinary chemical can be made directly to the APVMA (and referred to the Department). The Chemicals Scheduling Expert Advisory Committee will make a recommendation to the Department on the rescheduling application based on the assessment of the submitted information provided and any stakeholder submissions received as part of the consultation process.

Application and information requirements for rescheduling existing agricultural and veterinary chemicals are contained in the *Guidelines for Registering Agricultural and Veterinary Chemicals* published by the APVMA. The guidelines are available on-line at: <insert url>

SCHEDULING AND RESCHEDULING OF DOMESTIC AND OTHER CHEMICALS

Applications for scheduling and rescheduling domestic and other chemicals are made directly to the Department. A request for advice regarding scheduling of a domestic or an industrial chemical with domestic use may also be made by NICNAS as a result of the assessment process for these substances. Applications may also be referred to NICNAS for technical advice by the Department as required. The format for NICNAS applications is contained in the <insert Publication name>. This is available on-line at: <insert url>

<NOTE: Application guidelines and information requirements for domestic and other chemicals will be refined from the existing requirements in the Interim Guidelines for the NDPSC. >

CHAPTER 6: GUIDELINES FOR PUBLIC CONSULTATION

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GUIDELINES FOR PUBLIC CONSULTATION - GENERAL

All matters to be considered by the scheduling expert advisory committees will be subject to public consultation except where otherwise directed by the delegate.

The Department must publish on the TGA Internet site details of the matter to be considered or the substance to be considered for scheduling where referred to an expert advisory committee, or rescheduling, and invite public submissions to be made by a date mentioned in the notice. The closing date must be at least four weeks after publication of the notice. The meeting date must be at least two weeks after the closing date.

Provided that a submission is directly relevant to the matter for consideration and is submitted before the required date it must be considered by the committee. The Department must make publicly available all submissions received (other than aspects which are commercial-in-confidence).

New Substances

Public consultation of the scheduling of a new substance under consideration will not routinely occur. The Department may consider it would be in the public interest to do so, having regard to the nature of the substance concerned and its use. In these circumstances the scheduling proposal would be referred to the relevant scheduling committee.

The Department will take into account the following when deciding to consult with the public on the scheduling of the new substance:

- the nature of the substance and its use; and
- whether it would be in the public interest to consult.

Rescheduling

The Department must refer all rescheduling proposals to the Medicines Scheduling Expert Advisory Committee or Chemicals Scheduling Expert Advisory Committee for consideration and these proposals will be subject to public consultation. The Department must publish on the TGA Internet site before a meeting of the relevant scheduling committee at which the proposed scheduling is to be considered, a notice inviting public submissions. The notice will detail each of the scheduling proposals (other than commercial-in-confidence information) and invite public submissions. (*Refer Chapter 7 for further information.*)

The Department must consider all public submissions, received by the closing date, addressing a matter in, [insert legislative reference]. The Department must also publish on the TGA Internet site all public submissions received (other than aspects which are commercial-in-confidence).

Urgent scheduling

Provisions will be made for urgent scheduling where the Department is satisfied that it would be in the interest of public health and safety to urgently schedule/reschedule a substance. Under these circumstances, the Department may make a scheduling decision without public consultation or consideration by an expert advisory committee.

**CHAPTER 7: GUIDELINES FOR USE OF CONFIDENTIAL
INFORMATION**

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GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION - GENERAL

Certain information submitted to the Department, APVMA or NICNAS for the purposes of scheduling or rescheduling of a substance is recognised as commercial-in-confidence. Currently, the following information is considered to be commercial-in-confidence for scheduling purposes and it is proposed that such information not be publicly disclosed:

- sales data;
- product formulation details;
- manufacturing method;
- sponsor name; and
- product name.

Should an applicant be of the view that any other information contained in the application which is relevant to scheduling should also be considered to be commercial-in-confidence, this position will need to be justified with reference to intellectual property rights and freedom of information legislation.

These guidelines may be revised in light of the Government's initiatives to increase openness and transparency and the availability of information for consumers.