NATIONAL COORDINATING COMMITTEE ON THERAPEUTIC GOODS

SCHEDULING POLICY FRAMEWORK FOR MEDICINES AND CHEMICALS

Effective date 1 July 2010

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PREFACE

This *Scheduling Policy Framework* (SPF) 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 chemicals in Australia. NCCTG comprises representatives of each state and territory Government, the Australian Government and the New Zealand Ministry of Health.

The SPF replaces the Interim Guidelines for the National Drugs and Poisons Schedule Committee and will be maintained by the NCCTG with input from the Department of Health and Ageing and the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS).

This document should be read in conjunction with Part 6-3 of the *Therapeutic Goods Act 1989*, Part 6 Divisions 3A-3D of the Therapeutic Goods Regulations 1990 and the Poisons Standard (*Standard for the Uniform Scheduling of Medicines and Poisons* or SUSMP).

Revision History

This table records the document's history of changes.

Version No	Section No	Date	Brief description
1.0	All	11 August 2009	First version – consultation draft
2.0	Chapters 1-4	December 2009	Post SPF consultation – considered by NCCTG
3.0	All	May 2010	Post consultation on the Regulations – considered by NCCTG
4.0	All	June 2010	Post consideration by NCCTG

ACRONYMS

ACCS	Advisory Committee on Chemicals Scheduling
ACMS	Advisory Committee on Medicines Scheduling
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
APVMA	Australian Pesticides and Veterinary Medicines Authority
COAG	Council of Australian Governments
DoHA	Department of Health and Ageing (the Department)
NCCTG	National Coordinating Committee on Therapeutic Goods
NICNAS	National Industrial Chemicals Notification Assessment Scheme
OHP	Office of Health Protection
OTC	Over the counter
SPF	Scheduling Policy Framework
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration

CHAPTER 1: THE SCHEDULING PROCESS

1. INTRODUCTION

The *Scheduling Policy Framework* (SPF) sets out the national system for applying access restrictions on all poisons: medicines for human therapeutic use, veterinary, agricultural, 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.

Provisions for the scheduling of medicines and chemicals are set out in the Act and the Regulations. They have been developed to ensure operational effectiveness in the current regulatory environment while providing for the existing high level of scheduling uniformity across states and territories.

The key aspects of the agreed model for the scheduling medicines and chemicals in Australia 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 chemicals and other changes to the Poisons Standard;
- two separate Committees: the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) to advise the decision-maker;
- a single Poisons Standard as the Commonwealth legislative instrument; 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, 2001) recommended new separate arrangements for the scheduling of medicines and chemicals in Australia (Recommendation 7). This recommendation included replacing the National Drugs and Poisons Schedule Committee with two separate committees that focus on the scheduling of medicines and chemicals respectively. The Council of Australian Governments (COAG) agreed to Recommendation 7 being progressed by the Australian Health Ministers' Conference (AHMC).

This work was progressed with the intention of implementing the revised scheduling arrangements in the context of the joint Australia New Zealand Therapeutic Products Regulatory Scheme. However due to the postponement of a joint regulatory agency in July 2007, implementation of the revised scheduling arrangements has continued in an Australia-only context.

In October 2008, COAG in responding to recommendations from the Productivity Commission Research Report on *Chemicals and Plastics Regulations* (2008) supported the

implementation of reforms proposed under the Galbally Review to separate the medicines and chemicals scheduling processes and for decisions to be made by the Secretary of the Department.

3. KEY ASPECTS OF THE MODEL

3.1 Scheduling Policy

The NCCTG has responsibility for policy principles, guidance and protocols on scheduling (including procedural guidelines) and other poisons regulatory controls. The SPF will allow for decision-makers, any expert advisory committees, reviewers or evaluators 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.

3.2 Secretary's delegate

The Secretary makes 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 Act, in accordance with the Regulations as well as any guidelines notified by the NCCTG and AHMC including this document.

In practice, persons to whom the Secretary has delegated decision-making responsibility, being persons holding appropriate positions within the relevant areas of the Department (eg within the TGA and the OHP) will make the decisions.

When making a decision in relation to the scheduling of a substance the decision-maker may seek advice from the Committees, and/or any other expert committee, person or entity.

If it is considered for any reason that it is necessary to vary the policy framework, the matter can be referred to the NCCTG.

3.3 Implementation of decisions

The decision made by the Secretary will be incorporated in the Poisons Standard. The Poisons Standard includes a record of scheduling related decisions of the Department and is maintained by the Scheduling Secretariat on behalf of the Secretary of the Department. Decisions to amend the Poisons Standard are recommendations to the states and territories.

States and territories will give effect to these decisions by adoption of the Poisons Standard through their relevant legislation.

4. THE SCHEDULING PROCESS

4.1 Application to amend the Poisons Standard

An application proposing to amend the Poisons Standard may be made to the Secretary of the Department under s.52EAA of the Act.

In order to be accepted, an application must be supported by sufficient information and be in a form approved by the Secretary. The form of the application and the information requirements are set out in Chapter 4 of this document. The form of an application may also include such additional information notified by the NCCTG to the Secretary for this purpose.

The fee to accompany any application to amend the Poisons Standard is set out in a Schedule to the Regulations.

Applications related to agricultural and veterinary chemicals will be referred by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

In certain circumstances the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) will refer an industrial or domestic chemical for scheduling based on the outcome of a risk assessment.

4.2 Decision making process

Under Division 3D of Part 6 of the Regulations the Secretary may refer a scheduling proposal to an expert advisory committee. It is expected that all rescheduling proposals (i.e. where the substance has previously been scheduled) will be referred to the relevant Committee for advice. The referral of new substance applications to a scheduling committee will not occur routinely for new human therapeutic substances evaluated by the TGA. New chemical scheduling proposals to include a new substance in Schedule 7 will be referred to the ACCS given the broad level of interest in such applications. Other new chemical scheduling proposals are also likely to be referred to the ACCS unless the proposal is straight forward and the chemical has been subject to the APVMA registration process.

4.2.1 Applications referred to a Committee

Where the delegate decides to refer an application received under s.52EAA of the Act or a proposed amendment initiated by the Secretary to either or both of the Committees, the delegate is required to follow the process detailed in subdivision 3D.2 of Part 6 of the Regulations.

1st Phase of Consultation

The delegate must publish a notice setting out the matter to be considered by the Committee(s) along with a call for public submissions in the manner detailed in reg 42ZCZK. Full details of public notifications are contained in Chapter 5.

The submissions received must be considered along with the proposal by the Committee which will then provide advice to the delegate. Upon considering the advice of the Committee (and/or any other committee or person as required under section 52E of the Act) the delegate will make an interim decision on the proposed amendment.

Where no submissions are received in the initial phase of consultation there is no interim decision. The delegate makes a final decision having regard for the advice of the committees as required by reg 42ZCZO and taking into account all the matters referred to in section 52E of the Act.

2nd Phase of Consultation (where relevant)

The Secretary must publish the interim decision in keeping with the requirements of reg 42ZCZP, which includes a call for further submissions from those who made a submission in the 1st phase and from the applicant. Full details of public notifications are contained in Chapter 5.

After considering any submissions received in the 2nd phase of consultation as required by reg 42ZCZQ, the delegate must make a final decision as provided in reg 42ZCZR taking into account all of the matters referred to in section 52E of the Act. This process is referred to as a reconsideration of the interim decision in the Regulations.

Any public submissions must be relevant to the proposed amendment or interim decision (whichever is relevant) and must address the matters set out in section 52E of the Act (see Chapters 2 and 3 of this document).

4.2.2 Applications not referred to a Committee

Where an application to amend the Poisons Standard is received under section 52EAA and the delegate chooses not to refer the proposed amendment to a Committee the delegate must follow the process detailed in Subdivision 3D.3 of Part 6 of the Regulations.

Consistent with reg 42ZCZU, where the decision is to amend the Poisons Standard in the manner set out in the application, the delegate can make a final decision without making an interim decision taking into account of the matters referred to in section 52E of the Act.

However where the decision is not to amend the Poisons Standard in the manner set out in the application, the delegate must make an interim decision as required by reg 42ZCZV. The delegate must provide the applicant with the reasons for the interim decision and provide an opportunity to make a written submission.

After considering any such submission from the applicant the delegate must make a final decision as provided in reg 42ZCZW, taking into account all of the matters referred to in section 52E of the Act.

4.2.3 Submissions in response to notice of a proposal

Consistent with subdivision 3D.2 of Part 6 of the Regulations all submissions made in response to a notice inviting public submissions and setting out the details of a proposed amendments must be received within the period specified in the notice (which must be at least 20 business days after the publication of the notice).

4.2.4 Submissions after an interim decision

Consistent with subdivision 3D.2 of Part 6 of the Regulations all submissions made in response to an interim decision must be received within 10 business days of notification after publication of the notice [on the TGA internet site] or where the proposed amendment has not been referred to a Committee, within the period specified in the notice (which must be at least 10 business days after the date of the notice).

4.2.5 Interim and final decisions - process for delegates

The delegate must take into account the following when making a final decision after an interim decision:

(i) the original application;
(ii) submissions received in any consultation phase, either from the applicant or the public;
(iii) any advice or recommendation of the advisory committees.

The delegate may in making the final decision:

(i) confirm the interim decision;

(ii) vary the interim decision; or
(iii) set the interim decision aside and make a new decision.

4.3 Notification of decisions

As soon as practicable after making a final decision under regs 42ZCZO, 42ZCZR, 42ZCZU or 42ZCZW the delegate must:

(i) publish the final decision and the reasons for the decision, along with the proposed date of effect on the TGA internet site; and
(ii) amend the Poisons Standard where required, in accordance with the procedures required to amend a legislative instrument.

Each Committee will be notified of scheduling decisions made by the delegate at its next meeting.

Decisions to amend the Poisons Standard come into effect at or before the time of registration (where relevant). All such decisions would come into effect no more than six months after the decision was made unless otherwise specified.

4.4 The Poisons Standard

The Poisons Standard is considered to be a Legislative Instrument for the purposes of the *Legislative Instruments Act 2003* (LIA). It must be registered and published on FRLI 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.

As scheduling decisions are legislative in character, the lawfulness of the delegate's decision is not reviewable under the Act, in the AAT or in the Federal Court.

4.5 Amendments to the Poisons Standard initiated by the Secretary

Under section 52D(3) of the Act the Secretary has power to amend the Poisons Standard on her own initiative. In the Secretary's opinion, there may be a need to initiate a scheduling review on the basis of information that becomes available. This information may be provided to the Secretary by a member of an advisory committee or the Department. When the Secretary decides to amend the Poisons Standard on her own initiative this is a final decision. The Poisons Standard is 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 a Committee for consideration and public consultation.

4.6 Adoption and implementation of decisions

It is envisaged that in all cases 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.

As the NCCTG is committed to the principle of national uniformity, any decision to depart from a scheduling entry in the SUSMP must be fully justified in an annual report to the

NCCTG. A consolidated report of these variances will be published annually by the NCCTG.

5. THE COMMITTEES

The Committees, the Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling, are established under sections 52B and 52C of the Act. The membership and procedures for the expert advisory committees are set out in the Regulations and this document.

5.1 Functions

Each 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; and
- any other functions prescribed by the Regulations.

Recommendations of the expert advisory committees are available on the TGA website.

5.2 Responsibilities of the Committees

As provided for by Subdivision 3D.2 of Part 6 of the Regulations the Secretary's delegate may refer an application or proposal to amend the Poisons Standard to either or both of the Committee(s). They will provide advice to the Secretary on the following types of proposals to amend the Poisons Standard.

Proposal	Committee
Rescheduling of substance included in a therapeutic good (human medicine)	ACMS
Rescheduling of agricultural or veterinary chemical	ACCS
Rescheduling of industrial, domestic or personal use chemical	ACCS
Scheduling of a new substance (agricultural, veterinary or industrial) that may meet the criteria for inclusion in Schedule 7	ACCS
Scheduling of a substance that may meet the criteria for inclusion in Schedule 9	ACMS
Proposal to amend or include an entry in Appendices A, C or G for: 1. human therapeutic use, or 2. some other use excluding human therapeutic use, or 3. where both of these situations apply.	 ACMS ACCS Joint meeting
Proposal to amend or include entry in Appendices D, H, K, & L	ACMS

Proposal	Committee
Proposal to amend or include entry in Appendices E, F ,I , J	ACCS
Proposal to amend or include a provision in Parts 1 to 3 that affects only therapeutic goods.	ACMS
Proposal to amend or include a provision in Parts 1 to 3 that affects only agricultural, domestic, industrial or veterinary chemicals	ACCS
Any other proposal to amend Parts 1 to 3	Joint meeting

Recommendations on proposals to amend the SPF are to be referred to the NCCTG for consideration. Minor editorial changes to the SPF can be undertaken by the Secretariat without referral to the NCCTG.

5.3 Membership

The committees are staffed in accordance with Subdivisions 3A.2 and 3B.2 of Part 6 of the Regulations,

There are two kinds of members on the expert advisory committees:

5.3.1. Nominated members

To reflect the cooperative nature of the scheduling process and to encourage scheduling uniformity across Australia, the Commonwealth and each state and territory may nominate a member for each Committee. These nominations must be made in writing to the Commonwealth Minister for Health and Ageing for the term nominated by the jurisdiction. Temporary nominees, to attend in the primary member's absence, can be nominated at the same time.

5.3.2 Appointed members

Appointed members are 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 Minister appoints in writing whoever the Minister believes to be appropriately qualified, upon recommendations from the Department. Members are appointed on the basis of expertise rather than to represent a particular jurisdiction or interest group. Acting members can be appointed at the same time.

A member is 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.

5.3.3 Confidentiality and Conflict of Interest

All members are required to make an undertaking in relation to confidential information and conflicts of interest.

5.3.4 Expertise

The membership of each Committee is expected to encompass as far as reasonably practicable the widest possible range of expertise outlined below.

Advisory Committee on Medicines Scheduling
The Advisory Committee on Medicines Scheduling will comprise up to15 expert members with expertise in one or more of the following areas:

- the regulation of scheduled medicines in Australia;
- toxicology or pharmacology;
- clinical pharmacology;
- pharmacy practice;
- medical practice;
- consumer health issues relating to the regulation of therapeutic goods; and
- industry issues relating to the regulation of therapeutic goods.

Advisory Committee on Chemicals Scheduling
The Advisory Committee on Chemicals Scheduling will comprise up to 15 expert members with requisite expertise in one or more of the following areas:

- the regulation of scheduled chemicals in Australia;
- toxicology;
- clinical aspects of human poisoning;
- occupational health, with expertise preferably also as a medical practitioner.
- veterinary medicine or veterinary pathology;
- industrial or domestic chemicals;
- agricultural or veterinary chemicals;
- consumer health issues relating to the regulation of chemicals; and
- industry issues relating to the regulation of chemicals.

5.4 Committee procedures

The Committees are required to conduct and hold meetings in accordance with subdivision 3A.3 and 3B.3 of Part 6 of the Regulations.

5.4.1 Subcommittees

The Committees may, with the agreement of the Secretary of the Department of Health and Ageing, form subcommittees to undertake discrete bodies of work as provided for in Divisions 3A and 3B of Part 6 of the Regulations.

5.4.2 Appointment of Chair

The chair of each Committee is appointed by the Minister from within the existing Committee membership. The Chair holds that office for the term stated in the appointment and may be appointed for further terms. The Regulations also provide for an acting Chair to be appointed by the Minister, to assume the role and responsibilities of the Chair when he or she is unable to perform his or her duties.

5.4.3 Resignation

Both appointed and nominated members may resign by signed notice to the Minister. The states and territories may nominate a replacement member at the same time.

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

5.4.4 Voting

All members of the Committees will have equal voting rights. A recommendation arising from the reference of an application by a delegate to the Committee 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.

5.5 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 Committees 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*. Details outlining the procedures for joint meetings are included in Division 3C of Part 6 of the Regulations.

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

6. ADMINISTRATION

6.1 Secretariat

In the interests of ensuring ongoing consistency and cohesiveness in the decision-making process, a single secretariat located in the DoHA supports both Committees.

6.2 Costs

Consultation has been undertaken on a Cost Recovery Impact Statement (CRIS). The Commonwealth Government is currently examining cost recovery arrangements in light of submissions received. Participation at committee meetings by members employed by states and territories, as well as implementation of recommendations, will be borne by the respective jurisdictions.

CHAPTER 2: GUIDELINES FOR AMENDING THE POISONS STANDARD

The principles and factors in these guidelines should be taken into account by the decision-maker and Committees when considering proposals to amend the Poisons Standard.

GUIDELINES FOR AMENDING PARTS 1-3

Should the delegate wish to make a new regulatory provision or vary an existing regulatory provision in Parts 1-3 of the SUSMP, consultation with one or both of the committees, depending on the scope (see below) of the proposed regulatory provision, must first take place.

In making a decision to amend Parts 1-3 the decision-maker needs 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 for poisons in the Schedules and Appendices;
- the regulatory need and justification for the change, and
- the potential implications of the change for jurisdictions.

GUIDELINES FOR AMENDING THE SCHEDULES – PART 4

When considering a new substance application (i.e. a substance for which a scheduling decision has not already been made), the delegate will consider whether to include the new substance in the Poisons Standard based on the Scheduling factors set out in Chapter 3. If the substance is to be included in any Schedule, the delegate must determine:

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

Rescheduling applications may only be made in relation to substances that have an existing entry or entries in the Poisons Standard.

When considering a re-scheduling application the delegate must determine:

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

Detailed guidance for Committees and delegates in relation proposals to amend Part 4 of the Poisons Standard are included in Chapter 3.

GUIDELINES FOR AMENDING THE APPENDICES – PART 5

For products covered by the two Commonwealth product registration schemes, entries in certain Appendices in Part 5 can only be made. This potentially includes entries in Appendices A, B, C, G, H and K for therapeutic goods and Appendices A, B, C, G and J for agricultural and veterinary chemicals.

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 scheduling or rescheduling of an existing poison.

For amendments to Appendices A, C and G, where a proposal is clearly and exclusively related to:

i. human therapeutic use then the ACMS must be consulted; or
ii. some other use excluding human therapeutic use, then the ACCS must be consulted; or
iii. where neither of these situations applies, then a joint meeting must be consulted prior to any decision.

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 this document. This includes Appendices C, D, G, H, K and L for therapeutic goods and C, F, E, G, I, J, and L for all other poisons.

Appendix A – General exemptions

Appendix A provides general exemptions from the controls set out in the Poisons Standard for classes of products where the physical nature of the products, or their use, or other legislative controls applicable to the class of product, mitigate to an acceptable level, the public health risk of any substances in that class.

Inclusion of an entry in Appendix A may be made by the delegate, where classification of representative members from a product or substance class have consistently demonstrated that they do not meet any of the criteria for inclusion in the Schedules. When considering an entry in Appendix A the delegate must consider whether making or amending an entry will:

- be generally consistent with the safety profile of members of the proposed class;
- address a regulatory need for a class exemption; and
- provide a public benefit through the class exemption.

Appendix B – Substances considered not to require control by scheduling

Appendix B is a positive list of substances that have been considered to be exempt from scheduling requirements on the basis of information available at the time. No direct application can be made for inclusion of a substance in Appendix B and there are no explicit criteria for inclusion in the Appendix.

An entry in Appendix B may be made by the delegate following consideration of the application for scheduling if the substance does not meet the factors for inclusion in the Schedules of the Poisons Standard. In this instance the delegate may decide that there is a public benefit gained by adding an entry to Appendix B to record the outcome.

The delegate may make an entry in Appendix B for a new substance and should consult with the appropriate 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 usually arises either through a member of either of the Committees or at the request of the TGA or OHP.

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, diversion into illicit products or other factors which would warrant inclusion in Schedule 9;
- the risk outweighs the benefit to the extent that no Schedule would provide appropriate public access to any proposed or known products;
- sale, 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;
- a cut-off from the Appendix may be established by the delegate where the substance no longer meets the factors for inclusion in this Appendix or in any other Schedule in the Poisons Standard.

Appendix D – Additional controls on possession or supply of poisons included in Schedules 4 or 8

Inclusion of a substance in Appendix D may be considered by the delegate 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 particular control of possession; or
- a specific high potential for abuse, particular international treaty restrictions on availability or other matters of national public health policy which when weighed against the need for access 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 Department of Health and Ageing or some other appropriate authority;

taking into account the implications for professional practice by affected healthcare practitioners and regulatory control by the states and territories.

Inclusion of a substance in Appendix D should be made following consultation with the ACMS.

Appendix E – First aid instructions for poisons

Appendix F – Warning statements and general safety directions for poisons

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.* Accordingly these two Appendices do not apply to therapeutic goods or agricultural and veterinary chemical products.

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

Entries are based on the assessment of the scheduling proposal and taking into account current best-practice in occupational and emergency medicine.

The delegate 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 ACCS. New or amended entries in these appendices may also be made following a specific application in relation to these Appendices, after consultation with ACCS.

Appendix G – Dilute preparations

An entry in Appendix G exempts the substance from **all** requirements of the Poisons Standard when included in a product at a concentration at or below that specified in the Appendix. 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 substance at the proposed maximum concentration does not meet the criteria for inclusion in any Schedule of the Poisons Standard; and
- where the assessment of the undiluted substance does not meet the factors for inclusion in Schedule 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

The decision-maker should make their determination after taking into account matters set out in 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).* (Note: A review of advertising arrangements for therapeutic goods is under consideration. Until this review has been finalised, Appendix H will be retained in the Poisons Standard.)

Appendix I – Uniform paint standard

The delegate will make a decision following consultation with the ACCS. A new or amended entry to the paint standard will be made following consideration of extensive information on the toxicity and use of the substance in paints, and the safety of and public health implications of the 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 delegate may make a new entry or vary an existing entry following consultation with the ACCS 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

The delegate can make a new entry or vary an existing entry following consultation with ACMS. In making a decision to vary an entry or make a new entry in Appendix K the delegate must consider:

- the potential for sedation in humans exhibited by a medicine in normal use;
- animal or human data demonstrating any impairment of critical motor reflexes and cognitive skills applicable to driving or the operation of machinery;
- the need to warn users of any potential danger of the medication when the user is in control of machinery or an automobile; and
- regulatory implications for the states and territories.

Appendix L – Requirements for dispensing labels for human and veterinary medicines

The delegate can make a new entry or vary an existing entry following consultation with ACMS for dispensing of human medicines, ACCS for dispensing of veterinary medicines or both if relevant. An amendment to Appendix L may be considered following a proposal for a new or existing medicine where:

- specific labelling needs to be applied for safe use of a medicine when dispensed;
- professional practice standards require specific labelling of the medicine when dispensed.

CHAPTER 3: CLASSIFICATION OF MEDICINES AND CHEMICALS INTO THE SCHEDULES

1. PRINCIPLES OF SCHEDULING

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

For the quality use of human medicines, which incorporates the selection of appropriate therapeutic management options, appropriate choice of medicines (where a medicine is considered necessary) and safe use; the scheduling classification underpins 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) emphasises this need for intervention by particular health professionals. The scheduling decision involves consideration of 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 access to the substance.

The SPF 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 certain veterinary chemicals reinforces the need for intervention by veterinary practitioner to promote safe use. The scheduling decision involves consideration of 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 use of domestic chemical products.

1.1 The Schedules

Substances can be 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, 5, 6, 7 and 8 include poisons, with increasingly strict special regulatory controls on the availability of the poisons listed in Schedules 4, 7 and 8. Veterinary medicines are not included in Schedule 3. A limited number of veterinary medicines are included in Schedule 2. However, these entries are being phased out.

. 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 which lists substances, other than those included in Schedule 9, 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. Appendix J may also include additional special controls on availability, use of specialist equipment and training of users.

1.2 The cascading principle

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 applicable, 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.

Other substances are 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 applicable, the substance is assessed against the Schedule 7 factors, and if not applicable, against the Schedule 6 and then the Schedule 5 factors.

For veterinary chemicals, assessment 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.

The cascading principle also applies to substances that are both medicines and chemicals. Consideration is given to the therapeutic and non-therapeutic use of the substance and its toxicity. Assessment is 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 (where relevant).

Exemption from scheduling requirements (Appendix B) is appropriate where the substance does not meet the factors for ANY schedule. The decision can only be made by exclusion; that is, there are no factors as such for exemption from the Schedules. An exemption may be recorded as:

- a general exemption where warranted;
- an exemption for a class of products in Appendix A (see above);
- a specific exemption from the SUSMP for the substance in Appendix B; or
- 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 exemplifies the cautionary principle for public health, 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.

2. THE SCHEDULING FACTORS

In order to ensure that public health objectives are consistently met, all scheduling decisions 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 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 are not significant 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 chemicals.

2.1 Risk/benefit analysis

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 which are 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 subsection 1(2) in Part 1 of the SUSMP.

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 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 practitioner 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.

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 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.

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 intervention[2].**
   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. 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.

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/m^3 (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 (e.g. 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.

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/m^3 and 3000 mg/m^3 (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.

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/m^3 (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 the substance 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 surface 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

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.**

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 4: GUIDELINES FOR APPLICATIONS AND INFORMATION REQUIREMENTS

1. 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.

2. 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 (e.g. 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	*Australian Regulatory Guidelines for Prescription Medicines* http://www.tga.gov.au/industry/pm-argpm.htm
Over the Counter (OTC) Medicines	*Australian Regulatory Guidelines for OTC Medicines* http://www.tga.gov.au/industry/otc-argom.htm
Complementary Medicines	*Australian Regulatory Guidelines for Complementary Medicines* http://www.tga.gov.au/industry/cm-argcm.htm

3. 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 *Manual of Requirements and Guidelines* published by the APVMA. The guidelines are available on-line <http://www.apvma.gov.au/morag_ag/index.php>.

4. 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 ACMS will make a recommendation to the decision-maker 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 *Manual of Requirements and Guidelines.*

5. SCHEDULING AND RESCHEDULING 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 available on-line <http://www.nicnas.gov.au/Forms.asp>.

NOTE: Application guidelines and information requirements for domestic and other chemicals are set out in the electronic application template available at the Scheduling committees website.

CHAPTER 5: GUIDELINES FOR PUBLIC CONSULTATION

GUIDELINES FOR PUBLIC CONSULTATION - GENERAL

Public notifications of decisions and consultations related to scheduling matters are to be published on the TGA internet site.

In accordance with Subdivisions 3D.1 and 3D.2 of Part 6 of the Regulations the delegate must publish the following information:

- notification of matters to be considered by Committees and a call for public submissions;
- the submissions received in response to that notification;
- recommendations from the Committees;
- interim decisions of the decision-maker, along with reasons for the decision and a call for further submissions or requests for reconsideration of the interim decision;
- final decisions along with the reasons and proposed date of effect for that decision;

other than that information which is accepted as being commercial-in-confidence or is covered under relevant privacy provisions (refer to Chapter 6).

Where matters are not referred to a Committee the delegate must publish the final decision, along with the reasons for the decision and the date of effect. Committees will be notified at the next meeting of decisions made by delegates.

CHAPTER 6: GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION

GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION - GENERAL

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 any applicant be of the view that any information contained in their scheduling application should 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.

The publication of such information will be made in accord with current guidelines on confidentiality and privacy including any de-identification if required.

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