

# **NATIONAL COORDINATING COMMITTEE ON THERAPEUTIC GOODS**

## **SCHEDULING POLICY FRAMEWORK**

**FOR**

**MEDICINES AND POISONS**

Draft for consultation

May 2007

*This framework implements the scheduling model for medicines, endorsed by the Australian Health Ministers' Conference (AHMC) in April 2006, and the scheduling model for poisons, endorsed by AHMC in November 2006. Key aspects of the model have been highlighted in the framework to assist in its consideration.*

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**CHAPTER 1: GUIDELINES FOR  
CLASSIFICATION OF MEDICINES AND POISONS**

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# THE CLASSIFICATION OF MEDICINES AND POISONS

## INTRODUCTION

This document has been developed by the National Coordinating Committee on Therapeutic Goods (NCCTG). The NCCTG oversees the development of regulatory policy and administrative protocols relating to the availability and accessibility of therapeutic products under the joint regulatory scheme administered by the Australia New Zealand Therapeutic Products Authority (the Authority), including scheduling of substances.

NCCTG comprises representatives of all Australian State and Territory Governments and the New Zealand Ministry of Health.

## GENERAL

*This document should be read in conjunction with the Scheduling Standard.*

*This section highlights the following key aspects of the agreed scheduling model for medicines and poisons:*

- *a single scheduling policy framework to apply to medicines and poisons, as developed by the NCCTG;*
- *splitting of the National Drugs and Poisons Schedule Committee (NDPSC) into two committees: a medicines scheduling committee and a chemicals scheduling committee;*
- *the Medicines Scheduling Committee as an expert advisory committee to advise the Authority with members selected from relevant experts in Australia and New Zealand;*
- *the Chemicals Scheduling Committee as an expert advisory committee to advise the Australian Department of Health and Ageing Agency with members selected from relevant experts in Australia; and*

PLEASE NOTE THAT THIS SECTION MAY BE SUBJECT TO CHANGE FOLLOWING THE DEVELOPMENT OF THE POISONS SCHEDULING LEGISLATION

The scheduling classification sets access controls on medicines and poisons (including agricultural, veterinary, domestic and industrial chemicals) when there is a potential risk to public health and safety. Medicines and poisons are classified according to the degree

of control recommended over their availability to the public in order to protect health and safety.

The Australian and New Zealand Governments have agreed to establish a single model for the scheduling of medicines for human use<sup>1</sup> under the Australia New Zealand Therapeutic Products Authority (the Authority). At the time of publication of this document, Agricultural and Veterinary Chemical Products have a permanent exemption status and Hazardous Substances, Industrial Chemicals and Dangerous Goods (which includes domestic chemicals) have a special exemption status under the trans-Tasman Mutual Recognition arrangements. The Australian Department of Health and Ageing (the Department) will undertake the scheduling of poisons (including agricultural, veterinary and domestic chemicals) on behalf of the Australian Government, while in New Zealand the Environmental Risk Management Authority will continue to regulate poisons on behalf of the New Zealand Government.

A harmonised model for the scheduling classification of medicines has been developed for Australia and New Zealand. The model developed for the scheduling classification of poisons applies only to Australia. However, both scheduling models have been aligned wherever possible.

Under this model two expert advisory scheduling committees will be established, one for medicines [the Medicines Scheduling Committee (MSC)] and the other for poisons, an Australian only function (the Chemicals Scheduling Committee). The MSC is expected to include expertise from both Australia and New Zealand and make recommendations to the Authority on access to medicines for implementation in both countries. Scheduling decisions made by the Authority and the Department will be communicated to stakeholders via an electronic register, the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Scheduling Standard) published on the Authority's website.

In the interests of ensuring ongoing consistency and cohesiveness in the decision-making process between the two committees, the Authority will maintain:

- a single scheduling policy framework;
- a single secretariat to support both scheduling committees; and
- a single Scheduling Standard.

In order to ensure that public health and safety 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 they are contingent, conditional and dependent. 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

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<sup>1</sup> Medicines that contain substances, which are included in the New Zealand Misuse of Drugs Act 1975, are subject to different labelling requirements in Australia and New Zealand. These are typically controlled substances in Schedule 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons*.

the schedules is not significant as scheduling decisions are made on balance of the available evidence.

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

- What is the hazard?
- What is the risk?
- How widespread is the risk?
- In what circumstances will the risk arise?
- Who or what is most at risk?
- Is harm or injury liable to occur?

The Schedules in the Standard 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 Standard. The scope encompassed by the substance may vary according to the interpretation of “substance” in Section 1.02. Note that the effect of the first part of this section, up to, but not including the words “But not including:” is intended to increase the scope of the entry. Conversely, the provisions in the second part following the same words decrease the scope of an entry under the specified conditions or circumstances. Finally, each entry in a Schedule may include conditions that increase or decrease the scope of the entry, or under specific conditions may exempt the substance entirely from the requirements of the Standard.

## **MEDICINES**

The scheduling policy framework as it applies to medicinal substances supports the broader health policy frameworks in Australia and New Zealand 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 process reflects the need for a healthcare professional to be involved in the supply of certain medicinal substances in order to facilitate safe and quality use. The scheduling decision considers a number of factors such as the toxicity of the substance, purpose of use, potential for abuse, safety in use and the need for the substance.

The model for the scheduling of medicinal substances for human use consists principally of four schedules: Schedule 2, Schedule 3, Schedule 4 and Schedule 8, with consistent factors for inclusion in each schedule. The numbering of these schedules signifies

increasingly stricter controls. The model for making scheduling decisions embodies a “cascading principle” in which a substance is first assessed using the factors for Schedule 4. Should sufficient factors pertain, the substance remains in that Schedule unless the additional factors for Schedule 8 are also valid (in which case it would fit in Schedule 8). If the factors for Schedule 4 are not pertinent, the substance is assessed against the Schedule 3 factors and if warranted, subsequently against the Schedule 2 factors.

Should the medicine or a proposed use for the medicine, not meet the factors for inclusion in any schedule, none of the requirements of the Standard will apply to that medicine or use. This may be recorded as an exemption from the Standard 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 and pack size restrictions. If any of the conditions of an exemption are not met, then the requirements of the Scheduling Standard will still apply.

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

Please note that New Zealand has proposed only to recognise recommendations for scheduling of substances for human therapeutic use included in Schedules 2, 3 and 4 of the Scheduling Standard.

Therapeutic products which include substances included in Schedules 5 or 6 of the Scheduling Standard are exempted from the scope of those entries under Section 1.02 of Part 1 of the Standard.

## **Scheduling**

The Authority will make initial decisions on the scheduling of a new substance (ie a substance on which a scheduling decision has not already been made). This will take place during the evaluation and approval processes that occur prior to a product licence being issued. It will be required to take into account any recommendation or advice of the MSC and any other relevant expert advisory committee/s.

When making a decision in relation to a substance the Authority must take into account the relevant matters specified under Section 10.09 of the Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006 (Administration Rule).

These are –

- (1) (a) the toxicity and safety of the substance;
- (b) the risks and benefits associated with the use of the substance;
- (c) the potential hazards associated with the use of the substance;
- (d) the extent and patterns of use of the substance;

- (e) the dosage and formulation of the substance;
- (f) the need for access to the substance, taking into account its toxicity compared with other substances available for a similar purpose;
- (g) the potential for abuse of the substance;
- (h) the purposes for which the substance is to be used;
- (i) any other matters that the Authority considers necessary to protect public health and safety, including the risks (whether imminent or long-term) of death, illness or injury resulting from its use;

and may take into account the labelling, packaging and presentation of the substance.

- (2) In taking into account the matters mentioned in subsection (1), the Authority must comply with the relevant policy guidelines (if any).
- (3) The Authority must also take into account:
  - (a) any advice or recommendation of the Medicines Scheduling Committee, or another expert advisory committee to which the Authority has referred the proposed scheduling for advice or recommendation of that committee; and
  - (b) any public submissions made in accordance with legislated requirements relating to public consultation on proposed scheduling.

## **Rescheduling**

The Authority will refer all rescheduling proposals to the MSC for advice and must have regard to this advice before making a decision on rescheduling. The rescheduling process takes into consideration relevant market experience and distribution of use of the substance in Australia and New Zealand or overseas. It is generally expected that an application for rescheduling to a lower schedule or for an exemption from the requirements of the Scheduling Standard would be supported by at least two years of local clinical use or post-marketing experience with the 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 and New Zealand; or
- any available information from post-marketing surveillance (spontaneous and any post marketing surveillance studies, local or overseas); or
- any relevant previous Australian or New Zealand consideration of scheduling of the medicinal substance (eg. different route of administration).
- any relevant Australian or New Zealand experience with the medicine including a different route of administration.

## **Notification of decisions**

The Authority as soon as practicable after a scheduling decision is made must publish on its website the decision and the reasons for the decision. It also is required to notify the applicant (and those persons who made public submissions) that they may provide a further submission for reconsideration of the decision.

## **Reconsideration of decisions**

Reconsideration of a scheduling decision can be made on the grounds of a relevant matter which the Authority must take into account when scheduling a substance (section 10.09 of the Administration and Interpretation Rule) or if the NCCTG scheduling policy framework was incorrectly applied.

The submission for reconsideration must be made within 20 working days after the decision is published on the Authority's website. Submissions for reconsideration and the grounds for the reconsideration must be published on the Authority's website. Additionally, the Authority may refer the request for reconsideration to the MSC for advice. The Authority must have regard to advice provided by the MSC, and in reconsidering the scheduling decision either confirm the decision, vary the decision or set aside the decision and make a new decision in place of the decision.

As soon as possible after reconsidering a scheduling decision, the Authority must notify the person who requested the review of the result and reasons and publish them on the Authority's website.

It is expected that the merits of the scheduling decisions of the Authority will be reviewable in Australia and New Zealand on the basis of an error of law by the courts in each country.

## **The Medicines Scheduling Committee**

The Medicines Scheduling Committee is a statutory committee established under the Australia New Zealand Regulatory Scheme (Administration and Interpretation) Rule 2006. The functions and constitution of the Committee are prescribed in the Administration Rule. The prescribed functions include the following:

- give advice and make recommendations to the Authority in relation to the scheduling and rescheduling of medicines in accordance with the legislation;
- maintain the guidance document within the scheduling framework developed by the NCCTG and ensure the consistency and transparency of the guiding framework for making scheduling decisions;
- review scheduling decisions made by the Authority where appropriate and make proposals on these changes to the Authority.

## Membership

The MSC will comprise at least 12 but not more than 16 members. The Authority, New Zealand (as represented by the New Zealand Ministry for Health) and the Australian States/Territories will each be able to nominate one expert member.

The nominated members will be required to be qualified in one of more of the following areas:

- expertise in the regulation of medicines in Australia or New Zealand;
- toxicology;
- currently engaged in pharmacy (as a practicing community pharmacist);
- currently engaged in general medical practice (as a practicing medical practitioner); or
- clinical pharmacology.

The MSC will also include two other members:

- one member with expertise in therapeutic product industry issues; and
- one member with expertise in consumer issues.

In accordance with current practice, it is anticipated that nominations for the above members would be sought from appropriate peak-body organisations or regulatory agencies.

Members of the MSC will be appointed by the Therapeutic Products Ministerial Council with appointment decisions based on recommendations from the Authority. The Chair must be a person nominated to that office by the Authority and will also be appointed by the Ministerial Council.

The current membership of the Medicines Scheduling Committee and the Secretariat contact details may be found at the Authority website:

<URL address will be inserted here>

## **POISONS (Australia only)**

*Please note: the following section may be subject to change following the development of the poisons scheduling legislation.*

Similar to medicines, the scheduling classification process for poisons considers a number of factors such as the toxicity of the substance, purpose of use, potential for abuse, safety in use and the need for the substance.

The Australian model for the scheduling of poisons consists principally of four schedules. Schedule 5, 6, and 7 represent increasingly stricter container and labelling requirements

with special regulatory controls over the availability of the poisons listed in Schedule 7. Schedule 9 contains 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. A number of poisons are included in Appendix C of the Scheduling Standard which lists substances, other than those included in Schedule 9, of such danger to health as to warrant prohibition of sale, supply and use.

Schedule 2, 4 and Schedule 8 may also contain veterinary chemicals which should be available through pharmacies or on prescription from a veterinarian.

The model for making poisons scheduling decisions embodies a “cascading principle” in which a poison is first assessed using the factors for Schedule 7. Should sufficient factors pertain, the poison remains in that Schedule unless the additional factors for Schedule 9 are valid (in which case it would fit in Schedule 9). If the factors for Schedule 7 are not pertinent, the substance is assessed against the Schedule 6 factors and if warranted, subsequently against the Schedule 5 factors. Should the poison not meet the factors for any schedule, it would generally be expected that exemption from scheduling requirements would be appropriate. Chemicals may also be assessed against the factors used for medicines in Schedules 2, 4, and 8 where this is appropriate.

The numerical ranges included in the factors (Refer Chapter 2) related to toxicity in Schedules 5, 6 and 7 are indications only, which need to be considered in the context of the overall toxicological profile. The values are based on the OECD recommended end points for toxicological testing, where available. If the acute toxicity value in another animal species is lower, a tighter restriction may apply.

It is likely that the factors for Schedules 5, 6 and 7 will need to be reviewed should a national decision be made in Australia to adopt the Globally Harmonised System for the Classification and Labelling of Chemicals in the consumer product sector.

## **Scheduling**

The Secretary of the Department makes the scheduling decision on the classification of poisons and considers applications for the rescheduling of poisons to apply in Australia, taking into consideration any recommendation or advice from the Chemicals Scheduling Committee.

When considering applications for scheduling of poisons in Australia only, all relevant criteria as established under Commonwealth poisons legislation must be addressed

These considerations include –

- the toxicity and safety of the substance;
- the risks and benefits associated with the use of the substance;
- the potential hazards associated with the use of the substance;
- the extent and patterns of use of the substance;
- the dosage and formulation of a substance;

- the need for access to a substance taking into account its toxicity and intended use compared with other substances available for a similar purpose;
- the potential for abuse of a substance;
- the purpose for which a substance is to be used; and
- any other matters that are considered necessary to protect public health, including the risks (whether imminent or long term) of death, illness, or injury resulting from its use; and may take into account the labelling, packaging and presentation of the substance.

Any expert advisory committee making a recommendation on the scheduling or re-scheduling of poisons to the Secretary of the Department must also comply with any relevant policy guidelines.

All agricultural and veterinary (agvet) chemical products sold or supplied in Australia must be assessed and registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) as required under the *Agricultural and Veterinary Chemicals Code Act 1994* before they can be supplied, distributed or sold anywhere in Australia. The Department provides toxicological assessment and advice on new agricultural and veterinary chemicals and products as a component of the registration process.

All industrial chemicals are regulated under the Industrial Chemicals (Notification and Assessment) Act 1989.

### **Rescheduling**

The Secretary of the Department makes the scheduling decision on the rescheduling of poisons and must take into account the recommendation or advice from the Chemicals Scheduling Committee.

The schedule in which a poison is placed may depend on the stage of the life cycle of the product. Information about chronic health hazards (particularly in consumer products) may only become available after extensive use by consumers. The exposure assessment and determination of the likelihood of injury will be included in the consideration of rescheduling.

Exposure assessments should be based on data and/or conservative assumptions. Assessment of the risk and the approach to extrapolating animal data to humans should also involve a conservative margin of safety through establishment of uncertainty factors. Human toxicity experience is given precedence over animal data.

### **The Chemicals Scheduling Committee**

The Chemicals Scheduling Committee will be a statutory expert advisory committee established under new Commonwealth poisons legislation and will:

- provide advice to the Secretary on scheduling matters concerning chemicals, including on;

- proposals to change the scheduling classification of a poison;
- proposals to schedule new chemicals; and
- challenges to scheduling decisions.
- advise the Secretary regarding those chemicals that require scheduling or rescheduling;
- maintain the guidance document within the scheduling framework developed by the NCCTG and ensure the consistency and transparency of the guiding framework for making scheduling decisions;
- review scheduling decisions made by the Secretary and where appropriate make proposals on these changes to the Secretary.

## **Membership**

The membership of the Committee consists of between 11 to 16 members and includes;

- One nominated expert member from each State and Territory
- One nominated expert member from the Office of Chemical Safety
- The regulatory agencies NICNAS and APVMA

and OCS nominated members which have professional expertise in one of more of the following areas:

- The regulation of State/Territory scheduling of chemicals for public health purposes;
- Veterinary medicine or veterinary pathology;
- Toxicology;
- Industrial<sup>2</sup> and domestic chemicals;
- Agricultural and veterinary chemicals;
- Clinical aspects of human poisoning;
- Consumer issues;
- Industry issues;
- Occupational health, with expertise preferably also as a medical practitioner.

In addition the Committee will have a permanent observer nominated from the New Zealand Environmental Risk Management Authority.

The current membership of the Chemicals Scheduling Committee and the Secretariat contact details may be found at the Department's website:

<URL address will be inserted here>

## **SCHEDULING MATTERS WHICH MAY IMPACT ACROSS MEDICINES AND POISONS**

### Joint working parties

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<sup>2</sup> 'Industrial chemicals' as defined in the NICNAS legislation.

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

#### Joint meetings

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

Where matters of interest to both the Medicines Scheduling Committee and the Chemicals Scheduling Committee are identified, sufficient time is to be allowed for the Medicines Scheduling Committee and the Chemicals Scheduling Committee to jointly discuss these matters, including any matters relating to scheduling policy.

Recommendations on scheduling policy are to be referred to the National Co-ordinating Committee on Therapeutic Goods as a sub-committee of the Australian Health Ministers' Advisory Council for consideration.

#### **The Scheduling Standard**

The Authority will maintain the Scheduling Standard as a register, by electronic means, and make it available for inspection on the Authority's website. It will include a record of the Authority's scheduling decisions as well as the decisions relating to the scheduling of poisons which will apply in Australia only.

Before amending the Scheduling Standard in relation to medicines, the Authority will be required to publish a notice in the Authority Gazette advising of the amendment together with the date of effect. The electronic Scheduling Standard would be updated as the date of effect falls due.

The Authority will make the medicine scheduling decisions (in terms of the entry in the Scheduling Standard) which will be a scheduling recommendation to New Zealand (as they relate to medicines in Schedules 2, 3 and 4) and to the Australian States and Territories who will give it legal effect.

The Department will make scheduling decisions for poisons (in terms of the entry in the Standard) which will be a scheduling recommendation to the Australian States and Territories.

It is envisaged that in almost all cases Australian jurisdictions and New Zealand will adopt-by-reference the Authority's/Department's scheduling decisions.

**CHAPTER 2: GUIDELINES FOR  
CLASSIFICATION OF MEDICINES AND POISONS  
(SCHEDULING FACTORS)**

Schedule 1 of the Scheduling Standard is currently unused.

## PROPOSED FACTORS FOR PHARMACY MEDICINES AND POISONS (SCHEDULE 2)

1. **The quality use of the medicine or restricted veterinary chemical can be achieved by labelling, packaging, and/or provision of other information; however access to advice from pharmacy or veterinary trained personnel is available at the point of sale to maximise the safe and effective use of the medicine or veterinary chemical.**

The medicine or veterinary chemical 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 or veterinary intervention. However, the availability of a pharmacist or veterinarian at the point of sale supports the consumer in selecting and using the appropriate medicine, where necessary.

2. **The use of the medicine or veterinary chemical 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 or veterinary chemical at established therapeutic dosage levels is unlikely to produce dependency and the medicine is unlikely to be misused, abused or illicitly used.** Medicines or veterinary chemicals, which do not meet this factor, are not suitable to be classified as Schedule 2 Pharmacy Medicines or veterinary chemicals, irrespective of any other applicable factors.

4. **The risk profile of the medicine or veterinary chemical 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 or veterinary professional 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 or veterinary chemical 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 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 MEDICINES and POISONS (SCHEDULE 4)**

- 1. The ailments or symptoms that the medicine is used for require medical, veterinary or dental intervention<sup>2</sup>.**  
Diagnosis, management or monitoring of the medical condition is such that it requires medical, veterinary or dental intervention before the medicine is used.
- 2. The use of the medicine / poison 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 medicine / poison, 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 medicine / poison.**
- 5. The margin of safety between the therapeutic and toxic dose of the medicine / poison is such that it requires medical, veterinary or dental intervention to minimise the risk of using the medicine / poison.**
- 6. The seriousness or severity and frequency of the interactions of the medicine / poison (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 medicine / poison 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.

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<sup>2</sup> For the purposes of this document medical, veterinary or dental intervention is considered to include other authorised prescribers as described in relevant legislation of States and Territories Australia or New Zealand.

**8. The experience of the use of the medicine / poison under normal clinical conditions is limited.**

Unexpected effects of the medicine / poison 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.

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## PROPOSED FACTORS FOR 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<sup>3</sup> (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 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<sup>3</sup> and 3000 mg/m<sup>3</sup> (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 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<sup>3</sup> (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.

AUSTRALIA ONLY

**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

## **PROPOSED FACTORS FOR CONTROLLED MEDICINES AND VETERINARY CHEMICALS (SCHEDULE 8) (AUSTRALIA ONLY)**

- 1. The medicine / veterinary chemical contains a substance 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 medicine / veterinary chemical 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 medicine / veterinary chemical contains a substance that by reason of its novelty or properties could substantially increase the risk of producing dependency, misuse, abuse or illicit use.**

## **PROPOSED FACTORS FOR PROHIBITED SUBSTANCES (SCHEDULE 9) (AUSTRALIA ONLY)**

- 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 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 3: OTHER GUIDELINES RELATING TO THE  
SCHEDULING OF MEDICINES AND POISONS**

## Exemptions for labelling requirements for medicines:

(refer to section 2.03 in the Scheduling Standard)

(1) The following criteria may be used when considering a request for label exemption:

- (a) Whether the lack of availability of the medicine as a consequence of the label bearing the incorrect signal heading, would be likely to have a negative impact on public health;
- (b) Whether the medicine is a Schedule 2 medicine which has been reclassified to Schedule 3, or the vice versa;
- (c) Whether the medicine is a Schedule 4 medicine which has been reclassified to Schedule 3;
- (d) Whether the medicine is subject to a decision taken by the Authority to allow a variation to a Schedule and where the labelling requirements are not yet in effect;
- (e) Whether the medicine is a Schedule 2 medicine which has been reclassified to open sale and incorrectly labelled product should be permitted for open sale or continue to be restricted to pharmacies;
- (f) The likely impact on the distribution chain of incorrect labelling and the steps the applicant proposes to take to minimise that impact; and
- (g) The practicability of re-labelling the medicine to comply with the signal heading requirements.

(2) The labelling exemption from an appropriate authority referred to in subsection (1) must be limited to no more than 12 months from the effective date of the decision for retail supply of the specified medicine.

## **CHAPTER 4: GUIDELINES FOR PUBLIC CONSULTATION**

*This section will need to be reviewed when the poisons scheduling legislation has been finalised.*

## GUIDELINES FOR PUBLIC CONSULTATION

*This section outlines the public consultation process of the agreed scheduling model for medicines and poisons:*

- *single round of stakeholder consultation with all information released publicly as the basis for consultation (other than information considered to be commercial-in-confidence); and*
- *applicant / stakeholder able to request reconsideration of scheduling and rescheduling decisions on specified grounds, respectively.*

### 1. Medicines

All medicine scheduling proposals to be considered by the Medicines Scheduling Committee will be subject to public consultation. The public consultation provisions for the Medicines Scheduling Committee are set out in the draft Australia New Zealand Regulatory Scheme (Administration and Interpretation) Rule 2006.

#### New Substances

Public consultation of the scheduling of a new substance being considered for a product licence will not routinely occur. The Authority 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 Medicines Scheduling Committee.

The Authority 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 Authority will refer all rescheduling proposals to the Medicines Scheduling Committee for consideration and these proposals will be subject to public consultation. The Authority must publish in the Authority Gazette, before a meeting of the Medicines Scheduling Committee at which the proposed scheduling is to be considered, a notice as outlined in Section 10.11 of the Administration Rule, inviting public submissions. The notice will detail each of the scheduling proposals (other than commercial-in-confidence information) and invite public submissions. (*Refer Chapter 4 for further information.*)

The Authority must consider all public submissions, received by the closing date, addressing a matter in Section 10.09 of the Administration and Interpretation Rule, The Authority must also publish on its website all public submissions received in (other than aspects which are commercial-in-confidence).

The Authority will refer these submissions to the Medicines Scheduling Committee for review and advice. The Authority or a member of the Medicines Scheduling Committee may also prepare a rescheduling proposal for the consideration of the committee.

### **Urgent scheduling**

The Administration Rule includes provisions for urgent scheduling where the Authority is satisfied that it would be in the interest of public health and safety to urgently schedule/reschedule a substance. Under these circumstances, the Authority may make a scheduling decision without public consultation. The Authority must, however, reconsider the scheduling decision as soon as practicable after making the decision and invite public submissions.

## **2. Poisons**

PLEASE NOTE THAT THESE MATTERS MAY BE SUBJECT TO CHANGE FOLLOWING THE DEVELOPMENT OF THE CHEMICALS SCHEDULING LEGISLATION
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### **Scheduling and rescheduling**

The Department must publish details of the poison to be considered for scheduling or rescheduling, and invite public submissions to be made by a date mentioned in the notice. The closing date must be at least 4 weeks after publication of the notice.

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

The Department will refer the evaluation of the application and details of relevant submissions to the Chemicals Scheduling Committee for review and advice. The Department or a member of the Chemicals Scheduling Committee may also prepare a proposal for the consideration of the committee.

## **3. Commercial-in-confidence information – medicines/substances and poisons**

The following information is considered to be commercial-in-confidence and will 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.

*(Refer Chapter 5 – Guidelines for use of commercial-in-confidence information)*

DRAFT

**CHAPTER 5:**  
**GUIDELINES FOR USE OF**  
**COMMERCIAL-IN-CONFIDENCE INFORMATION**

*The release of information as part of the proposed consultation arrangements for scheduling was reviewed following the stakeholder consultation in October 2006 on the scheduling-related provisions of the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006.*

*Arrangements for use of commercial-in-confidence material for poisons are to be developed in conjunction with the new poisons scheduling legislation but would be cognisant of existing provisions in relevant Commonwealth chemicals legislation.*

## **Guidelines for use of commercial-in-confidence information**

### General

Certain information submitted directly to the Authority, Commonwealth Department of Health and Ageing, NICNAS or the APVMA for the purposes of scheduling or rescheduling is recognised as commercial-in-confidence. This information includes sales data, product formulation details, manufacturing method, sponsor name and product name.

Applicants should clearly identify any other information considered confidential in their submissions, which they would not like divulged through the public consultation process and provide a justification for the claim of confidentiality. Any further claims for confidentiality should be based on the relevant freedom of information legislation or proprietary rights restricting disclosure. Information that is already in the public domain will not be considered confidential.

Applicants for product licensing, assessment or registration should recognise that scheduling is an integral part of these processes and that information provided for licensing, assessment or registration may also be considered for the purposes of scheduling or rescheduling.

Commercial-in-confidence information disclosed to the relevant regulatory authority may be used only for regulatory purposes connected with the role of the Authority, including scheduling of products and substances.

### Medicines

The ANZTPA legislation specifies the circumstances in which information may be released outside of the Authority and to whom. (Refer Section 10.03 of the Administration and Interpretation Rule and Section 241 of the Australian Therapeutic Products Bill 2007).

Under the Code of Conduct which applies to officers of the Authority, an employee must not disclose information which was received in confidence by the Authority. Breaches of the Code of Conduct are grounds for disciplinary action, including termination of employment.

All members of expert committees to the Authority will be required to sign confidentiality agreements regarding the release of information which is provided to them in exercising their expert advisory roles. A breach of this agreement is an offence under Section 70 of the Australian Crimes Act 1914.

## Principles in the Handling of Commercial-in-Confidence Information

As part of the decision making process, the Authority undertakes a process of consultation with interested parties and the community. In this process:

1. Commercial-in-confidence information is disclosed to the officers of the Authority who have a responsibility for the substance or product. This information may also be disclosed to members of the Medicines Scheduling Committee and the Scheduling Secretariat and other expert committees advising the Authority.
2. Members of the Medicines Scheduling Committee or other expert committees advising the Authority are not free to use commercial-in-confidence or confidential information for purposes other than licensing, registration, assessment or scheduling and related matters.
3. Explicit permission should be obtained from the suppliers of commercial-in-confidence information if the information is to be used for any purposes other than scheduling and related matters, other than where provided for in the therapeutic product legislation.
4. If an evaluation, report or decision document includes commercial-in-confidence information, the confidential parts will not be made publicly available.

The Authority has developed consistent protocols for the receipt and management of information relevant to scheduling, including effective and secure storage of documents or information that is commercially sensitive. This includes but is not limited to information concerning manufacturing processes, sales data, intellectual property, personal information and other commercial-in-confidence information.

*(Refer Chapter 4 - Guidelines for Public Consultation)*

**CHAPTER 6:  
GUIDELINES FOR  
APPLICATION AND INFORMATION REQUIREMENTS**

*Medicines and Poisons Scheduling Guidelines*

*This section requires further refinement in order to be consistent with ANZTPA and Departmental requirements as they evolve.*

## **APPLICATION AND INFORMATION REQUIREMENTS**

The application guidelines describe general information required for scheduling / rescheduling of –

- Medicines (ie for therapeutic use in humans);
- Agricultural and Veterinary Chemicals; and
- Domestic or other Chemicals.

Sponsors of products or other interested parties may apply to the relevant regulatory authority<sup>3</sup> for scheduling or rescheduling of a medicine, poison or class of medicines or poisons, in keeping with the processes of that authority or directly to the Department for domestic chemicals.

The relevant regulatory authority, or an expert committee advising that authority (including the Medicines Scheduling Committee and the Chemicals Scheduling Committee), may also initiate a review of a medicine, poison or class of medicine or poison for re-scheduling purposes, particularly if public health concerns arise, and request a sponsor to provide particular information.

As the application and information guidelines are intended to be comprehensive some requirements may not be relevant to all applications. This document serves as a guideline for submission of applications for scheduling or rescheduling, in the absence of any other specific guidelines issued by a relevant regulatory authority. Further information on requirements can be obtained from the relevant regulatory authority when submitting applications for scheduling of a new substance.

### **Scheduling of a new active substance for therapeutic use in a Class 2 medicine**

New medicinal substances contained in products for which licensing is sought are evaluated by the Authority. This process includes the consideration of appropriate scheduling of that medicinal substance. This scenario occurs most commonly for new prescription medicines. However, it may on occasion apply to OTC or complementary medicines. Schedule 3 of the Australian and New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006 sets out which regulatory stream will evaluate the application. The scheduling aspects of the application are required to comply with any relevant guidelines issued by that regulatory stream.

In making a recommendation on whether or not a product licence should be granted for the product which contains the new medicinal substance, the expert committee advising the relevant regulatory stream may also make a recommendation on whether the substance should be included in a schedule to the Scheduling Standard and if so, which schedule is the most appropriate.

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<sup>3</sup> The Authority for medicines for human use, the Australian Pesticides and Veterinary Medicines Authority for agricultural and veterinary chemicals.

## **Scheduling of a new active substance for therapeutic use in a Class 1 medicine**

This scenario will apply most commonly to substances intended for use as active ingredients in Class 1 medicines (e.g. new herbs or new sunscreens agents). Substances that are scheduled cannot be used as ingredients in Class 1 medicines.

A 'New substance application form' should be submitted to the relevant non-prescription medicines regulatory area (OTC or Complementary Medicines).

If the sponsor wishes the substance to be included in the list of permitted ingredients that can be used in Class 1 medicines, the submission should include the relevant information and data specified in regulatory guidelines for OTC or complementary medicines. If the Authority determines that the substance does not meet criteria for inclusion in the permitted ingredients list, the scheduling of the substance is to be referred to the Medicines Scheduling Committee for advice.

If the sponsor wishes the substance to be included in Schedule 3 (pharmacist only) or Schedule 2 (pharmacy), the submission should include the relevant information and data specified in regulatory guidelines for OTC or complementary medicines together with information and data to establish that the substance meets the relevant factors for the proposed schedule.

## **Rescheduling of medicines**

The most common scenario will be an application for 'down-scheduling' of an existing product from prescription medicine to a non-prescription classification or from one non-prescription classification to a less restrictive one.

The sponsor should submit an application to the Authority. The rescheduling application is based on this Guideline and includes information and data that the substance meets the scheduling factors for the proposed classification. The relevant regulatory area of the Authority will evaluate the application (the OTC medicines regulator where the proposal is for Schedule 2 or Schedule 3, the prescription medicines regulator for Schedule 4 or Schedule 8 and the complementary medicines regulator for products classified by the Medicines Rule as complementary medicines).

The Medicines Scheduling Committee will make a recommendation on the rescheduling application to the Authority based on the evaluation report and any stakeholder submissions received as part of the consultation process.

In relation to the reclassification of a medicinal substance from prescription only (Schedule 4) status to a lower non-prescription classification (Schedule 3, Schedule 2) or exempt from scheduling, the Authority normally requires at least two years of local clinical use or local post-marketing experience with the medicinal substance before considering a proposal.

Applications made before the expiry of this timeframe will be considered when suitable evidence is provided. This could include:

- evidence from comparable overseas countries where the medicinal substance is available in non-prescription products (such as Canada, Sweden, Netherlands, New Zealand, United States, United Kingdom and Europe generally); or
- relevant public “exposure” information in comparable countries with a greater population base than Australia (such as in previous paragraph); 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); or
- any relevant Australian experience with the medicine including a different route of administration.

If the rescheduling submission contains new indications which require Authority approval, applications for both the rescheduling of medicines and the new indications can be sent simultaneously.

**The following regulatory areas are responsible for providing evaluations on rescheduling applications for medicines to the Medicines Scheduling Committee**

Change in scheduling	Evaluation area of Authority
Schedule 4 to Schedules 3, 2 or open selling	OTC Medicines Regulator or Complementary Medicines Regulator in consultation with Prescription Medicines Regulator
Open selling, Schedules 2 or 3 to Schedule 4	As appropriate
Schedule 3 to Schedule 2 Schedule 2 to open selling Open selling to Schedule 2 or 3 Schedule 2 to Schedule 3	OTC Medicines Regulator or Complementary Medicines Regulator

## **Scheduling of Agricultural and Veterinary Chemicals**

Applicants of new and existing Agricultural and Veterinary Chemicals and new forms of Agricultural and Veterinary Chemicals are required to make application for scheduling directly to the Australian Pesticides and Veterinary Medicines Authority (APVMA). The APVMA provides information to the Department for the purpose of scheduling veterinary and agricultural chemicals as part of the health risk assessment process for registration of new agricultural and veterinary chemicals.

## **Rescheduling of Agricultural and Veterinary Chemicals**

The reclassification of agricultural and veterinary chemicals to a schedule of lesser or greater restriction or by removal from the schedules requires the production and consideration of the information as detailed in the Agricultural and Veterinary Chemical Guidelines published by the APVMA. The Chemicals Scheduling Committee will make a recommendation on the rescheduling application to the Department based on the assessment of the submitted information provided by the Department and any stakeholder submissions received as part of the consultation process.

## **Scheduling and rescheduling of Domestic or Other Chemicals**

Interested parties or sponsors of products, which may contain domestic or other chemicals, may apply to the Department for scheduling or rescheduling. Applications may be referred to NICNAS by the Department as required. 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. The format for these applications should include the relevant information from "Content of Applications".

Sponsors of products which contain scheduled poisons not requiring an application to the APVMA, may apply for rescheduling to the Department. Other parties with an interest in an existing entry in the schedules may also apply for rescheduling to the Department. The reclassification of such poisons to another schedule or by removal from the schedules requires the production and consideration of the information as detailed under the headings contained in "Content of Applications" of the chapter Guidelines for Application and Information Requirements. Also the relevant data should be submitted in their original form and if applicants wish, they may provide an evaluation by an independent toxicologist.

The Chemicals Scheduling Committee will make a recommendation on the scheduling or rescheduling application to the Department based on the evaluation report and any stakeholder submissions received as part of the consultation process.

# BASIC INFORMATION REQUIRED FOR APPLICATIONS FOR SCHEDULING OF MEDICINES AND POISONS

## **Language**

The content of an application should be clearly expressed in English. Where foreign language reference material is included a certified English translation must be provided if it is to be considered.

## **Applicant's Details**

There must be sufficient information to identify the applicant, including –

- The name and address of the applicant.
- The name and position of a contact person.
- The telephone and facsimile numbers.

**If the application is from overseas, the details of the Australian representative should also be provided.**

## **Applicant Declaration**

Applications for a scheduling decision must contain a sponsor declaration certifying that to the best of the applicant's knowledge all information relevant to the application has been submitted and is true and accurate.

## **Purpose of Application**

The application must contain a clear statement of –

- The purpose of the application to the Committee.
- Any proposed change(s) to the Standard and the reason(s) for the change(s).

## **Justification for the Proposal**

The applicant should provide appropriate data and information in the body of the application, summarised, cross referenced and organised to demonstrate that the substance will be safe for the public when supplied and used in the manner proposed.

## FORMAT OF THE APPLICATION

### **Electronic Applications (strongly encouraged)**

**Medicines: available from the Authority website:** <URL address will be inserted here>

**Domestic chemicals:** <URL address will be inserted here>

*Should a non-electronic application be submitted, the document will need to comply with the format requirements outlined below.*

### **Structure**

Using a common format should ensure that applications are complete and more readily assessable.

The structure of the application should be as follows -

- Cover/title page
- Table of contents
- Applicant's Declaration
- Summary
- Body of Application
- Bibliography
- Copies of papers referenced
- Appendices if required

### **Cover/Title Page**

The cover / title page should indicate -

- The subject of the application.
- The name and address of the organisation making the application.
- The date on which the application was submitted.

### **Table of Contents**

The table of contents should tabulate and correlate the titles of each section and major sub-sections of the application with their appropriate page numbers.

### **Summary**

The summary should contain a concise, clear statement of -

- The purpose of the application.
- The major points in the argument, including -
- The proposals arising from such argument.
- An overall summary of the toxicology, clinical data, postmarketing studies and epidemiology of the compound.

Normally, this summary will not extend beyond a few pages.

Tables are favoured as a means of condensing information. Studies reported in the summary should be cross-referenced to the reports in the main submission.

### **Body of the Application**

The body of the application should communicate the aims and justification of the proposal in a concise, clear and logical manner. Whilst the format of each application may vary, the use of a standard framework is recommended, consisting of -

- The purpose of the application
- A general background (including the current scheduling status)
- Introduction of data upon which the application is based including:
  - Technical information
  - The proposals
  - The discussion
  - Proposed indications for use
  - Any product/consumer information

Every submission should also include a full bibliography of all studies provided. As the presentation of the product may have important safety implications an application should indicate –

- The proposed form, strength and amount in a pack.
- The type of packaging to be used (e.g. individual or strip packaging or closure type).
- Any proposed warnings to be included on the label or package insert.
- Any other consumer information to be supplied in the package.

### **Additional information**

The applicant should give details of applications made to other agencies, the results of these applications, where available, and whether any of the data included has been rejected by an overseas regulatory body. If a submission does include data rejected by an overseas regulatory body, an explanation should be provided.

## **CONTENT OF APPLICATIONS (data/information requirements)**

***Note: As the application and information guidelines are intended to be comprehensive some requirements may not be relevant to all applications.***

*Data previously submitted to the Authority/Department or its predecessors, the committee formerly known as the NDPSC, or the APVMA should not be resubmitted unless requested.*

*The documentation should be complete and well organised. It should be presented in sufficient detail to allow independent scientific assessment.*

*Individual animal data may be required at times because summaries and reprints of published material may not contain adequate detail. Individual animal data should not be submitted unless requested.*

### **Name of the Chemical/Active Constituent**

Identified by -

- Its approved name determined as described in Part 1 of the SUSMP.
- Its chemical name in accordance with the rules of the International Union of Pure and Applied Chemistry.
- All proprietary, non-proprietary or other names and any code numbers by which the medicine or poison is known including the CAS Registry number.

### **End-use Product details (Agricultural, Veterinary, Domestic Chemicals)**

Identified by -

- Distinguishing trade name
- Formulation type
- Active constituents and concentration
- Formulation composition
- Basic physical and chemical properties

### **Physico-Chemical Properties of the Active Ingredient**

The chemical nature of the medicine or chemical including -

- The structural formula or such information as may be available concerning the structure of the medicine or chemical.
- All relevant chemical and physical properties.

### **Pharmacology (if applicable)**

Any known information relating to -

- The structural and pharmacological relationship to other medicines or chemicals.
- The pharmacodynamic and pharmacokinetic profile.
- Interactions, incompatibilities, side effects or adverse reactions.

Any recognised standard such as a pharmacopoeia monograph.

### **Toxicology**

Refer to classification guidelines as an indication of the data package, which is necessary for assigning to a specific schedule.

Submissions should be in accordance with the information provided in the Guidelines and include -

- Brief summary of the known toxicology of the medicine, chemical or product.
- Brief summary of the known metabolism of the medicine, chemical or product.
- Summary of previous submissions if applicable.
- Relevant details of any published and unpublished toxicological investigations of the chemical or product.

### **Toxicological database**

Specific toxicological end points which may be relevant to the application.

If the data submitted are less than outlined below then the sponsor must justify why certain data are omitted. For example, the data may not be available or may have previously been submitted to an Australian regulatory authority, or may not relate to the use pattern. No report which could influence the assessment of the safety of the substance should be omitted.

- Toxicokinetics
- Acute studies
  - Lethality or lowest toxic dose
  - Skin and eye irritancy
  - Skin sensitisation
  - Corrosivity
- Repeat dose studies
  - Short-term
  - Sub-chronic
  - Chronic
- Reproductive studies
  - Teratogenicity
  - Fertility
  - Peri/postnatal
- Carcinogenicity
- Genotoxicity
- Other
  - Mechanistic

- Specific organ toxicity
- Immunotoxicity
- Neurotoxicity
- Toxicity of metabolite and impurities
- Human toxicological data
- Toxicity of mixtures
- In-vitro studies

### **Statistical Analysis**

Appropriate statistical analyses for data relevant to the submission and, where the statistical analyses are complex, interpretive summaries of their validity or significance.

### **Clinical data**

Overseas as well as Australian and New Zealand information should be provided, including –

- Postmarketing reports
- Adverse drug reaction reports
- Additional clinical reports
- Epidemiology studies
- Poisoning reports

### **Occupational health and safety (if applicable)**

Brief summary of occupational health and safety aspects.

### **Regulatory Status**

#### ***Australia / New Zealand***

- Approved indications for medicines

#### ***Australia***

- Approved uses for agricultural or veterinary chemicals

#### ***Overseas***

- Detailed information relating to the classification or regulation of availability of the medicine, chemical or product in significant overseas countries (e.g. Canada, Sweden, Netherlands, United Kingdom, United States of America) including a description of the overseas classification.

## **Monitoring for Public Health Impact**

If evaluation of the public health impact arising from the scheduling change of the medicine, chemical or product is proposed then details should be provided.

## **Education**

If any program for education of distributors, professionals and users or consumers is proposed then details should be provided.

## **PRODUCTION OF THE DOCUMENT**

### **Production Details**

When preparing the application –

- Use a clean legible type face with a line spacing of 1.5x.
- Use standard A4 pages, except where the use of such a format could significantly detract from clarity of communication (eg graphs, charts, etc.).
- Have a minimum margin width of 25 mm to avoid obscuring copy after binding. (In this respect, particular care should be taken with the reverse sides).
- Type, print or copy on both sides of the page to minimise paper volume.
- Number each page at the top or bottom centre of the page.
- Identify headings and sub-headings using capitals and bold type.
- Number the paragraphs.
- Arrange the sections in the order specified above with the sections from "Summary" to "Appendix" separated by coloured interleaves, but not board.
- Insert a header or footer on each page, below the page number, for easy identification of dislodged pages, stating -
  - The name of the substance.
  - The organisation making the application.
    - The date of lodgement of the application. e.g.
    - Name of the Substance
    - Smith & Co, November 200?
- Bind the application so that the pages do not become detached with normal use but open out to enable easy reading; (e.g. spiral binding).
- Reference material must contain -
  - The submission text reference on the top right hand corner of the first page of each reference.
  - Marked sections where a specific part of an article, report, or study is the focus of discussion.

### **Bibliographic and Reference Material**

The applicant should use either the Harvard or Vancouver system of referencing as outlined in the "Style Manual for Authors, Editors and Printers" (6<sup>th</sup> edn, John Wiley & Sons Australia, Ltd).

## LODGEMENT OF APPLICATIONS

### **Electronic applications (strongly encouraged)**

**Medicines:** <URL address will be inserted here>

**Domestic chemicals:** <URL address will be inserted here>

**No hard copies are required to accompany applications lodged electronically. However, should a non-electronic application be submitted, the applicant will need to comply with the following guidelines for lodgement of applications.**

### **Number of Copies**

Unless specified elsewhere in relevant guidelines issued by the APVMA, applicants for scheduling or rescheduling of poisons must provide:

- Twenty copies of the application, the summary or overview including abstracts of reference materials and full bibliography or reference lists for distribution to committee members.
- Subject to negotiation with the Scheduling Secretary, if the application is bulky or contains more than one large volume, two (2) copies of the supporting reference material (one for Agency archiving and one for evaluation). Further copies may be required.

## ADDRESS FOR APPLICATIONS

### **Medicines – scheduling and rescheduling**

#### **Electronic applications (strongly encouraged)**

**Medicines:** <URL address will be inserted here>

**Domestic chemicals:** <URL address will be inserted here>

The address for applications is also contained in the relevant Authority application forms.

### **Agricultural and Veterinary Chemicals – scheduling and rescheduling.**

Applications for scheduling for ag/vet chemicals should be forwarded to the APVMA to the address set out in the APVMA Guidelines.

### **Domestic or Other Chemicals – scheduling and rescheduling**

Applications for schedule changes must be submitted in accordance with the Scheduling Guidelines and lodged with the Department.

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