SCHEDULING POLICY FRAMEWORK

FOR

MEDICINES AND POISONS

Draft for consultation
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CHAPTER 1: GUIDELINES FOR CLASSIFICATION OF MEDICINES AND POISONS

THE CLASSIFICATION OF MEDICINES AND POISONS – GENERAL

The scheduling classification sets access levels 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[1] under the Joint Agency. As 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 Joint Agency will therefore continue to provide services in relation to the scheduling of poisons (including agricultural, veterinary and domestic chemicals) on behalf of the Australian Government and 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.

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 the schedules is not significant as decisions are usually made on balance.

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.

MEDICINES

The scheduling policy framework as it applies to medicines 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.

[1] 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 medicines will remain under a special exemption of the TTMRA until long-term arrangements are put in place. These are typically controlled substances in Schedule 8 of the *Standard for the Uniform Scheduling of Medicines and Poisons.*

The scheduling classification process reflects the need for a healthcare professional to be involved in the supply of certain medicines 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 trans-Tasman model for the scheduling of medicines 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 medicine scheduling recommendations or 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 not meet the factors for any schedule, it would generally be expected that the factors for "general sale" would be appropriate.

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

The Joint Agency makes the decisions (as entered into the *Standard for the Uniform Scheduling of Medicines and Poisons*) on the classification of active ingredients and on applications for the rescheduling of medicines, taking into account the recommendation of the Medicines Scheduling Committee and any other relevant expert committee/s.

When considering applications for scheduling of medicines in Australia and New Zealand all relevant information as established under Rule {X} of the Joint Rules is considered, with emphasis given to public health and safety matters.

These 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;
- the extent and duration of market exposure outside Australia and New Zealand; 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 medicines to the Joint Agency must also comply with any joint guidelines issued by the Australian Health Ministers' Advisory Council and the New Zealand Ministry of Health, as notified to the Joint Agency for the purposes of Section X of the Joint Rules.

- **Rescheduling**

The rescheduling process takes into consideration relevant market experience and distribution of use of the medicines in Australia and New Zealand or overseas. While this is assessed on a case by case basis, it is generally expected that an application for rescheduling to a lower schedule or "general sale" would be supported by at least two years of local clinical use or post-marketing experience with the medicine or other suitable evidence such as an appropriate period of distribution and use in comparable markets overseas being a country with a well-developed pharmacovigilance system.

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.

The Medicines Scheduling Committee

The Medicines Scheduling Committee is a statutory committee established under the Therapeutic Products Act and the {name of Joint Rules).

Membership

Membership of the committee consists of between 10 to 16 members with expertise in one or more of the following areas:

- The regulation of medicines scheduling in New Zealand or at State/Territory level in Australia;
- Toxicology;
- Pharmacy practice;
- Medical practice;

- Therapeutic product industry issues;
- Consumer issues;
- Clinical pharmacology.

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

(URL address)

POISONS (Australia only)

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.

Schedule 4 and Schedule 8 may also contain veterinary chemicals which should be available on prescription from a veterinarian.

The model for making poisons scheduling classification recommendations or 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 the factors for "general sale" would be appropriate.

The numerical ranges included in the factors related to toxicity in Schedules 5, 6 and 7 are indications only, which need to be considered in the context of other toxicity data. 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.

The Joint Agency makes the scheduling decision (as entered into *the Standard for the Uniform Scheduling of Medicines and Poisons*) on the classification of poisons and considers applications for the rescheduling of poisons to apply in Australia, taking into consideration the recommendation of the Poisons Scheduling Committee and any other relevant expert committee/s.

When considering applications for scheduling of poisons in Australia only, all relevant information as established under Section [X] of the Australian only Regulations is considered, with emphasis given to public health matters.

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.

Please note that the matter related to the extent and duration of market exposure is not included in the poisons considerations as it relates only to medicines. The overseas regulatory status of a poison will continue to be a consideration.

Any expert advisory committee making a recommendation on the scheduling or re-scheduling of poisons to the Joint Agency must also comply with any guidelines issued by the Australian Health Ministers' Advisory Council as notified to the Joint Agency for the purposes of Section X of the Australian only Regulations.

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 Joint Agency provides toxicological assessment and advice on new agricultural and veterinary (AgVet) 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 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 considerable additional data regarding potential exposures to consumers under normal conditions of use or foreseeable misuse. Where this exposure assessment and determination of the likelihood of injury reveal the potential for harm to occur, as a result of the expected exposures is insignificant, the substances may be rescheduled to a lower schedule.

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 Poisons Scheduling Committee

The Poisons Scheduling Committee is a statutory committee established under the Australian Therapeutic Products Act and the {name of Australian Regs).

Membership

Membership of the Committee consists of between 10 to 16 members with expertise in one of more of the following areas:

- The regulation of State/Territory scheduling of poisons for public health purposes;
- Veterinary medicine or veterinary pathology;
- Toxicology;
- The regulation of industrial[2] and domestic chemicals;
- The regulation of agricultural and veterinary chemicals;
- Clinical aspects of human poisoning;
- Consumer issues;
- Agricultural, veterinary and domestic chemical industry issues;
- Occupational health, with expertise preferably also as a medical practitioner.

The current membership of the Poisons Scheduling Committee and the Secretariat contact details may be found at the Joint Agency website

(URL address)

[2] 'Industrial chemicals' as defined in the NICNAS legislation.

SCHEDULING MATTERS WHICH IMPACT ACROSS MEDICINES AND POISONS

Joint working parties

Where the Joint Agency requires advice on particular scheduling issues which impact across medicines and poisons, the Joint Agency may establish a joint working party consisting of members of the Medicines Scheduling Committee and the Poisons Scheduling Committee and other persons, to inquire into, and report back to the Joint Agency.

Joint meetings

Given the potential overlap of membership and interests, it is expected that the meetings of the Medicines Scheduling Committee and the Poisons Scheduling Committee will be run over consecutive meeting days.

Where matters of interest to both the Medicines Scheduling Committee and the Poisons Scheduling Committee are identified, sufficient time is to be allowed for the Medicines Scheduling Committee and the Poisons 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.

PROPOSED FACTORS FOR MEDICINES GENERALLY CONSIDERED TO NOT REQUIRE SCHEDULING

1. **The quality use of the medicine can be achieved through consumer self diagnosis, treatment and management.**
   The medicine is used to either maintain or enhance health, or for the treatment of minor ailments or symptoms of medical conditions, which are capable of being diagnosed, managed and monitored by the consumer.

2. **The safe use of the medicine is well established.**

3. **The use of the medicine at normal therapeutic dosage levels is rarely known to produce dependency or is unlikely to be misused, abused or illicitly used.**

4. **The risk profile of the medicine is low and well defined. The risks are identifiable by appropriate packaging and labelling and are manageable by consumers through appropriate packaging and labelling and any consumer medicine information provided.**

5. **The use of the medicine at normal therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.**

PROPOSED FACTORS FOR PHARMACY MEDICINES (SCHEDULE 2)

1. **The quality use of the medicine can be achieved by labelling, packaging, and/or consumer medicine information; however access to advice from pharmacy trained personnel is available to maximise the safe use of the medicine.**
   The medicine is for minor ailments or symptoms that can easily be recognised and managed by the consumer without the need for medical intervention. However, the availability of a pharmacist supports the consumer in selecting the appropriate medicine, where necessary.

2. **The use of the medicine is substantially safe and the potential for harm from inappropriate use is low.**

3. **The use of the medicine at normal 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.**
   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 normal 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 but pharmacist intervention is required to ensure the quality use of the medicine.**
   The consumer can identify the ailments or symptoms that the medicine is used for but counselling and verification by a pharmacist is required. Pharmacist-consumer dialogue is necessary to reinforce and/or expand on aspects of the use of the medicine.

2. **The use of the medicine at normal 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 by 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. **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.**
   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 normal 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 VETERINARY CHEMICALS (SCHEDULE 4)

1. **The ailments or symptoms that the medicine 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 medicine is used.

2. **The use of the medicine / veterinary chemical 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 / veterinary chemical, at normal therapeutic dosage levels, may produce dependency but has a low 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 / veterinary chemical.**

5. **The margin of safety between the therapeutic and toxic dose of the medicine / veterinary chemical is such that it requires medical, veterinary or dental intervention to minimise the risk of using the medicine / veterinary chemical.**

6. **The seriousness or severity and frequency of the interactions of the medicine / veterinary chemical (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 / veterinary chemical 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 medicine / veterinary chemical under normal clinical conditions is limited.**
   Unexpected effects of the medicine / veterinary chemical may only become evident after widespread use by a medical, veterinary or dental practitioner. Close monitoring

[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 States and Territories Australia or New Zealand.

of the patient is required by a medical, veterinary or dental practitioner to monitor for unanticipated effects.

PROPOSED FACTORS FOR CONTROLLED MEDICINES AND VETERINARY CHEMICALS (SCHEDULE 8)

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 normal 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)

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 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.**

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 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 (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/handler from the known danger(s) of the substance if it is inhaled, taken internally or if penetrates the skin. Potential harm is reduced through labelling which informs the consumer/handler 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^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 low 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^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 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.

CHAPTER 2: GUIDELINES FOR PUBLIC CONSULTATION

GUIDELINES FOR PUBLIC CONSULTATION

1. Medicines

New applications received

Before making a decision on the scheduling of a new medicine the Managing Director must consider whether, having regard to the nature of the medicine and its use, it would be in the public interest to consult on the proposed scheduling (eg a substance whose purpose of use is as an abortifacient would be considered to meet this criteria). If the Managing Director is satisfied that it would be in the public interest, the Managing Director must publish details of the medicine to be considered for scheduling (other than those aspects which are commercial-in-confidence), and invite public submissions to be made by a date mentioned in 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 Managing Director must make publicly available all submissions received (other than aspects which are commercial-in-confidence).

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

Rescheduling

The Managing Director must publish details of the medicine to be considered for rescheduling (other than those aspects which are commercial-in-confidence), 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 Managing Director must make publicly available all submissions received (other than aspects which are commercial-in-confidence).

The evaluation of the application and details of relevant submissions are to be referred to the Medicines Scheduling Committee for review and advice. The Managing Director or a member of the Medicines Scheduling Committee may also prepare a submission for the consideration of the committee.

2. Poisons

New applications received and rescheduling

The Managing Director 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 Managing Director must make publicly available all submissions received (other than aspects which are commercial-in-confidence).

The Managing Director will refer the evaluation of the application and details of relevant submissions to the Poisons Scheduling Committee for review and advice. The Managing Director or a member of the Poisons Scheduling Committee may also prepare a submission for the consideration of the committee.

3. Commercial-in-confidence information – medicines and poisons

The following information is accepted as being commercial-in-confidence and will not be publicly disclosed:

- sales data;
- product formulation details;
- manufacturing processes.

If an applicant is 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 would need to be justified with reference to intellectual property rights and freedom of information legislation.

CHAPTER 3: GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION

GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION*

Certain information submitted directly to the Joint Agency or through the APVMA for the purposes of scheduling or rescheduling is recognised as confidential. This information includes sales data, details of manufacturing processes and formulation details. This information must be clearly marked as confidential in the submission to the relevant regulatory authority. Applicants should clearly identify any other confidential information in their submissions or specific sections and provide a justification for any further claim of confidentiality. Any further claims for confidentiality should be based on relevant freedom of information legislation or intellectual property rights. Information that is already in the public domain will not be considered confidential.

Applicants for 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.

Confidential information disclosed to the Joint Agency may be used only for specified purposes, including scheduling of products and substances. The therapeutic products legislation specifies the circumstances in which information may be released outside of the Joint Agency and to whom. *(note: it is expected that the provisions of Sec 25A and Sec 61 of TG Act will continue to apply*). Under the Code of Conduct which applies to officers of the Joint Agency, an employee must not disclose information which was received in confidence by the Joint Agency. Breaches of the Code of Conduct are grounds for disciplinary action, including termination of employment.

All members of expert committees to the Joint Agency are 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.

Principles in the Handling of Confidential Information

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

1. confidential information is disclosed to the officers of the Joint Agency who have a responsibility for the substance or product. This information may also be disclosed to members of the Medicines Scheduling Committee, Poisons Scheduling Committee and the Scheduling Secretariat and other expert committees advising the Joint Agency.
2. Members of the Scheduling Committees or other expert committees advising the Joint Agency are not free to use confidential information for purposes other than licensing, registration, assessment or scheduling and related matters.
3. Explicit permission should be obtained from the suppliers of confidential 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 confidential information, the confidential parts will not be made publicly available.

The Joint Agency 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.

* - information which is defined as being confidential information is included in Chapter 3: Guidelines for Public consultation.

CHAPTER 4:
GUIDELINES FOR APPLICATION AND INFORMATION REQUIREMENTS

Medicines and Poisons Scheduling Guidelines

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[3] for scheduling or rescheduling of a medicine, poison or class of medicines or poisons, in keeping with the processes of that agency.

The relevant regulatory authority, or an expert committee advising that authority (including the Medicines Scheduling Committee and the Poisons Scheduling Committee), may also initiate a review of a medicine, chemical 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 should 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 II medicine

New medicinal substances contained in products for which licensing is sought are evaluated by the {name of Joint Agency}. 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. The therapeutic products legislation 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 SUSMP and if so, which schedule is the most appropriate.

[3] The Trans Tasman Joint Agency for medicines for human use, the Australian Pesticides and Veterinary Medicines Authority for veterinary chemicals, and agricultural chemicals, NICNAS for domestic and other chemicals.

Scheduling of a new active substance for therapeutic use in a Class I 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 sunscreening 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 ingredients that can be used in Class I medicines, the submission should include the relevant information and data specified in regulatory guidelines for OTC or complementary medicines as well as information and data to establish that the substance meets the factors for 'medicines generally considered not to require scheduling'[3]. If the Agency determines that the substance does not meet the factors for open sale, 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 Joint Agency. 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 Joint Agency 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 and the complementary medicines regulator for products defined in Joint Agency legislation as complementary medicines).

The Medicines Scheduling Committee will make a recommendation on the rescheduling application to the Agency 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 {Joint Agency} 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 {Joint Agency} 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 Joint Agency
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 Joint Agency 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 Poisons Scheduling Committee will make a recommendation on the rescheduling application to the Agency based on the evaluation report provided by the Office of Chemical Safety 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 NICNAS for scheduling. An application for a scheduling decision for a domestic or other chemical 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". The relevant data should be submitted in their original form and if applicants wish, they may provide an evaluation by an independent toxicologist.

Sponsors of products which contain scheduled poisons and which are not required to be evaluated by the {Joint Agency} or the APVMA, or other interested parties may apply for rescheduling to NICNAS. The reclassification of such poisons to a schedule of lesser or greater restriction 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.

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

(note – the remainder of this section could be deleted if each agency develops `its own application form)

BASIC INFORMATION

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.

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 including any proposed change the applicant is seeking.
- The reason for any scheduling or schedule change that is proposed.

Justification for the Proposal

The applicant should provide appropriate data and information to demonstrate that the substance will be safe for the public when supplied and used in the manner proposed.

FORMAT OF THE APPLICATION

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.

PRODUCTION OF THE DOCUMENT

Unless specified elsewhere in the Joint Agency or APVMA guidelines, the guidelines set out below for production of the document should be followed.

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" (6th edn, John Wiley & Sons Australia, Ld).

LODGEMENT OF APPLICATIONS

Number of Copies

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

- Eighteen 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

The address for applications is contained in the relevant Joint Agency 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 NICNAS.

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 {Joint Agency} 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.

CONTENT OF APPLICATIONS (data/information requirements)

Name of the Chemical/Active Constituent

Identified by -

- Its approved name determined as described in Part 1 of the SUSDP.
- 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.