



INTERIM GUIDELINES

FOR THE

**NATIONAL DRUGS AND POISONS
SCHEDULE COMMITTEE**

CONTENTS

INTRODUCTION	1
Membership	1
CHAPTER 1: GUIDELINES FOR COMMITTEE PROCEDURES	2
CHAPTER 2: GUIDELINES FOR APPLICATION AND INFORMATION REQUIREMENTS	4
APPLICATION AND INFORMATION REQUIREMENTS	5
Scheduling of New Medicines and New Forms of Medicines Registered for Human Therapeutic Use	5
Rescheduling of Medicines	6
Scheduling of Agricultural and Veterinary Chemicals	7
Rescheduling of Agricultural and Veterinary Chemicals	7
Scheduling of Domestic or Other Chemicals	7
Rescheduling of Domestic or Other Chemicals	7
BASIC INFORMATION	7
Language	7
Applicant's Details	7
Sponsor Declaration	8
Purpose of Application	8
Justification for the Proposal	8
FORMAT OF THE APPLICATION	8
Structure	8
Cover/Title Page	9
Table of Contents	9
Summary	9
Body of the Application	10
Additional information	10
PRODUCTION OF THE DOCUMENT	11
Production Details	11
Bibliographic and Reference Material	12
LODGEMENT OF APPLICATIONS TO NDPSC	12
Number of Copies	12
ADDRESS FOR APPLICATIONS	13
New Medicines and New Forms of Medicines Registered for Human Use	13
New Applications or Rescheduling of Agricultural, Veterinary or Other Pesticidal Substances	13
Re-scheduling of Medicines, New and Rescheduling Applications for Domestic or Other Chemicals	13
CONTENT OF APPLICATIONS (data/information requirements)	14
Name of the Chemical/Active Constituent	14
End-use Product details (Agricultural, Veterinary, Domestic Chemicals)	15
Physico-Chemical Properties of the Active Ingredient	15
Pharmacology (if applicable)	15
Toxicology	15
Toxicological database	16
Statistical Analysis	17

Clinical data _____	17
Occupational health and safety (if applicable) _____	17
Regulatory Status _____	17
Monitoring for Public Health Impact _____	18
Education _____	18
CHAPTER 3: GUIDELINES FOR CLASSIFICATION OF MEDICINES AND POISONS	19
THE CLASSIFICATION OF MEDICINES AND POISONS - GENERAL _____	20
SCHEDULE 1 _____	22
SCHEDULE 2 _____	23
Description _____	23
Purpose _____	23
Assessment Factors _____	23
Characteristics of the medicine _____	23
Indications for use _____	24
Public Health _____	24
Marketing experience _____	24
SCHEDULE 3 _____	25
Description _____	25
Purpose _____	25
Assessment Factors _____	25
Characteristics of the Medicine _____	25
Indications for use _____	26
Public Health _____	26
Marketing experience _____	26
Advertising _____	26
SCHEDULE 4 _____	27
Description _____	27
Purpose _____	27
Assessment Factors _____	27
Characteristics of the Medicine _____	27
Indications for Use _____	27
SCHEDULE 5 _____	28
Description _____	28
Purpose _____	28
Assessment Factors _____	28
Toxicity _____	28
Clinical considerations if for therapeutic use _____	29
Public Health _____	30
SCHEDULE 6 _____	31
Description _____	31
Purpose _____	31
Assessment Factors _____	31
Toxicity _____	31
Public Health _____	32

SCHEDULE 7	33
Description	33
Purpose	33
Assessment Factors	33
Toxicity	33
Public Health	34
SCHEDULE 8	35
Description	35
Purpose	35
Assessment Factors	35
CHAPTER 4: GUIDELINES FOR PUBLIC CONSULTATION	36
CHAPTER 5: GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION	38

INTRODUCTION

The National Drugs and Poisons Schedule Committee (NDPSC) is a statutory committee established under the *Therapeutic Goods Act 1989* (as amended) ("the Act") and the *Therapeutic Goods Regulations 1990* (as amended). The Act and regulations are available on-line at <http://www.health.gov.au/tga/docs/html/legis.htm>.

The decisions of NDPSC in relation to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) have no force in Commonwealth law but are recommended for incorporation into State and Territory drugs/poisons legislation.

Membership

A representative of the Commonwealth.

A representative from each of the State and Territory Health Authorities.

A representative of the Therapeutic Goods Administration (TGA).

A representative of the Australian Pesticides and Veterinary Medicines Authority (APVMA).

A representative from Medsafe, the agency of the New Zealand government with responsibility for the regulation of human medicines.

A representative from the Environmental Risk Management Authority, the agency of the New Zealand government with responsibility for the regulation of agricultural, veterinary and household chemicals.

Experts with expertise in:

toxicology

clinical pharmacology

veterinary medicine/pathology

occupational health

An industry representative.

A consumer representative.

A representative of practising pharmacists.

The current membership of the NDPSC and the Secretariat contact details may be found at the NDPSC website:

<http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc.htm>

CHAPTER 1: GUIDELINES FOR COMMITTEE PROCEDURES

Statutory procedures for the Committee are prescribed in the *Therapeutic Goods Regulations 1990*. These are available on-line at:

<http://www.health.gov.au/tga/docs/html/legis.htm> .

CHAPTER 2: GUIDELINES FOR APPLICATION AND INFORMATION REQUIREMENTS

(Incorporating minor editorial modifications as at March 2003)

APPLICATION AND INFORMATION REQUIREMENTS

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

Medicines (Registered for Human Therapeutic Use)

Agricultural and Veterinary Chemicals

Domestic or other Chemicals

Sponsors of products containing substances which may be poisons, or other interested parties may apply to the National Drugs and Poisons Schedule Committee (NDPSC) for scheduling or rescheduling of a medicine, chemical or class of medicines or chemicals.

NDPSC may also initiate a review of a medicine, chemical or class of medicine or chemicals 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.

Scheduling of New Medicines and New Forms of Medicines Registered for Human Therapeutic Use

New medicinal substances contained in products for which registration is sought are evaluated by the Therapeutic Goods Administration. The outcomes of this process are provided to the National Drugs and Poisons Schedule Committee for the consideration of appropriate scheduling of that medicinal substance.

Scheduling is considered in terms of the classification criteria (contained in the Section entitled "Guidelines for Classification of Medicines and Poisons").

Usually, a new medicinal substance will fulfil the classification criteria of a prescription medicinal substance (e.g. the use of which requires professional medical management or monitoring, or the safety of which requires further evaluation).

If an applicant believes that they can justify an alternative schedule entry for a new medicine, an application should be provided to the NDPSC with suitable evidence (see "Rescheduling of Medicines").

Rescheduling of Medicines

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, NDPSC 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).
- any relevant Australian experience with the medicine including a different route of administration.

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

The reclassification of any scheduled medicine to a schedule of lesser or greater restriction or by removal from the schedules requires the production and consideration of the information detailed under the headings contained under "Content of Applications" of the chapter NDPSC Guidelines for Application and Information Requirements.

If there are relevant data, which have not been evaluated by an Australian regulatory agency, they should be submitted in their original form. If applicants wish, they can provide an evaluation by an independent clinical, pre-clinical or pharmaceutical chemical scientist as appropriate. The format of such a submission should be as outlined in the relevant sections of the Australian Guidelines for the Registration of Medicines Vol 1 as summarised under the headings contained in "Content of Applications" of the chapter NDPSC Guidelines for Application and Information Requirements.

Scheduling of Agricultural and Veterinary Chemicals

Sponsors of new and existing Agricultural and Veterinary Chemicals and new forms of Agricultural and Veterinary Chemicals are not required to make application for scheduling directly to the NDPSC as the National Registration Authority (APVMA) provides information for the purpose of scheduling as part of the registration process.

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 Interim Requirements for the Registration of Agricultural and Veterinary Products by the APVMA (June 1993 or as periodically amended).

Scheduling of Domestic or Other Chemicals

Interested parties or sponsors of products, which may contain poisons, may apply to NDPSC for scheduling. 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.

Rescheduling of Domestic or Other Chemicals

Sponsors of new products and new forms of products, which contain scheduled poisons and which are not required to be evaluated by the TGA or the APVMA, may apply for rescheduling to the NDPSC. 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 NDPSC Guidelines for Application and Information Requirements. The relevant data should be submitted in their original form and applicants may wish to provide an evaluation by an independent toxicologist.

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.

Sponsor Declaration

Applications to NDPSC 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

- Sponsor'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 forwarded to the NDPSC Secretary.

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 Committee recommends the use of a standard framework 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

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 199?

- 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" (Australian Government Publishing Service).

LODGEMENT OF APPLICATIONS TO NDPSC

Number of Copies

Applicants must provide:

- Twenty-five (25) 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 Secretary, if the application is bulky or contains more than one large volume, two (2) copies of the supporting reference material (one for departmental archiving and one for evaluation). Further copies may be required.

The application must be in writing to the Secretary of NDPSC and any facsimile (02 6270-5353) or e-mail (NDPSC@health.gov.au) correspondence must be confirmed by receipt of the original signed document.

ADDRESS FOR APPLICATIONS

New Medicines and New Forms of Medicines Registered for Human Use

Applications for scheduling for new medicines are not required to be made as scheduling of such products is carried out in conjunction with the medicine registration process with the TGA.. The address for registration applications is set out in the TGA publication, the Australian Guidelines for the Registration of Medicines.

New Applications or Rescheduling of Agricultural, Veterinary or Other Pesticidal Substances

Applications for scheduling for the above categories should be forwarded to the APVMA to the address set out in the APVMA Guidelines.

Re-scheduling of Medicines, New and Rescheduling Applications for Domestic or Other Chemicals

Applications for schedule changes must be submitted in accordance with the Scheduling Guidelines and lodged with the National Drugs and Poisons Schedule Committee at the following address:

Postal

The Secretary,
National Drugs and Poisons Schedule Committee (MDP 88)
PO Box 100
WODEN ACT 2606

Delivery

The Secretary
National Drugs and Poisons Schedule Committee
(Notify: 6270-4352)
Department of Health and Ageing
Therapeutic Goods Administration
Edmund Barton Building
Basement Dispatch Area
Broughton St Ramp
BARTON ACT 2600

Applications to the National Drugs and Poisons Schedule Committee should be accompanied by a covering letter addressed to the Secretary, stating -

- full trade name of the product.
- accepted common name(s) of active constituent(s).
- brief purpose of submission (i.e. what is requested and expected).
- brief summary details of supporting documentation.
- name, position, telephone and fax numbers of contact person.

All subsequent correspondence and documentation relating to the application should be identified with the common name (or proposed common name) of the product, as well as the distinguishing name under consideration, the file number and the name of the contact person.

Companies seeking scheduling should update regularly their advice to the Secretary of the names, positions, telephone and facsimile numbers of the people authorised to undertake scheduling matters on their behalf.

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 NDPSC, APVMA or TGA 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 by NDPSC.

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 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

- Approved indications for medicines
- 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, New Zealand, 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.

CHAPTER 3: GUIDELINES FOR CLASSIFICATION OF MEDICINES AND POISONS

Including modifications made March 2003 to exclude references inconsistent with the
Therapeutic Goods Act 1989 or the *Therapeutic Goods Regulations 1990*

THE CLASSIFICATION OF MEDICINES AND POISONS - GENERAL

To facilitate appropriate and effective scheduling and ensure that public health objectives are met consistently, all scheduling decisions routinely should include consideration of certain essential factors. 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.

The assessment factors listed in this document for each schedule are a guide only and should not be taken as an inflexible standard from which there is no deviation. Their publication endeavours to describe the current approach to scheduling in Australia. The Committee is cognisant of trans-Tasman and international harmonisation issues that may require the timely and regular review of these assessment factors and some existing substances.

When considering applications for scheduling all relevant information as established under Section 52E of the Act is considered, with emphasis given to public health matters.

These considerations include -

- (a) the toxicity and safety of a substance;
- (b) the risks and benefits associated with the use of a substance;
- (c) the potential hazards associated with the use of a substance;
- (d) the extent and patterns of use of a substance;
- (e) the dosage and formulation of a substance;
- (f) the need for access to a substance, taking into account its toxicity compared with other substances available for a similar purpose;
- (g) the potential for abuse of a substance;
- (h) the purposes for which a substance is to be used;
- (i) any other matters that the Committee considers 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 a substance.

The Committee must also comply with any guidelines of the Australian Health Ministers' Advisory Council or the subcommittee of the Council known as the National Co-ordinating Committee on Therapeutic Goods, notified to the Committee for the purposes of Section 52E of the Act.

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, NDPSC 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).
- any relevant Australian experience with the medicine including a different route of administration.

SCHEDULE 1

Not currently in use.

SCHEDULE 2

Description

Schedule 2 poisons are substances or preparations for therapeutic use -

- which are substantially safe in use but where advice or counselling is available if necessary
- for minor ailments or symptoms which -
 - can be easily recognised by the consumer.
 - do not require medical diagnosis or management.

Purpose

To allow effective medicines or preparations, for which pharmacist advice on use may be required by the consumer, to be available to the public, without a prescription, from a pharmacy or where a pharmacy service is not available, from a licensed person.

Assessment Factors

Characteristics of the medicine

The medicine or preparation in normal use should have the following characteristics -

- Suitability for self treatment of a minor ailment or symptom capable of being monitored by the consumer
- Extremely low abuse potential.
- Low potential for harm from inappropriate use.
- Low or well characterised incidence of adverse effects or side-effects, and contra-indications for which advice or counselling is available.
- Only minor or well characterised interactions with commonly used substances or food for which advice or counselling is available.

- A wide Therapeutic Index.
- Low risk of masking a serious disease.
- Low risk of compromising medical management of a disease.

Indications for use

The ailment or symptom(s) to be treated should -

- not require ongoing or close medical diagnosis or management.
- be easily recognised by the consumer.
- be amenable to short term treatment; or
- be capable of being monitored and self managed by the consumer, with advice and counselling if necessary.

Public Health

For details of these assessment factors see page 20.

Marketing experience

Experience with the distribution and use of the medicine or preparation in Australia or overseas may also be taken into account.

SCHEDULE 3

Description

Schedule 3 poisons are substances and preparations for therapeutic use -

- which are substantially safe in use but require professional advice or counselling by a pharmacist.
- the use of which requires pharmacist advice, management or monitoring.
- which are for ailments or symptoms which -
 - can be identified by the consumer and verified by a pharmacist.
 - do not require medical diagnosis or only require initial medical diagnosis, and do not require close medical management.

Purpose

To allow effective medicines or preparations that require professional advice on use to be made available to the public from a pharmacist without a prescription.

Assessment Factors

Characteristics of the Medicine

The medicine or preparation, in normal use, should have the following characteristics:

- Low abuse potential.
- Low potential for harm from inappropriate use.
- Low incidence of severe adverse effects or side effects which are likely to require medical intervention.
- Only interactions with commonly used medicines or food, which can be managed by a pharmacist.

- Medium to wide Therapeutic Index.
- The risk of masking a serious disease or compromising medical management of a disease can be managed by a pharmacist.
- Only contra-indications that can be dealt with by a pharmacist.
- Safety in use with counselling by a pharmacist.

Indications for use

The ailment or symptom(s) to be treated should:

- not require close medical management or direct supervision by a doctor.
- be easily recognised with assistance from a pharmacist.
- be amenable to short term treatment or capable of being monitored by the consumer with assistance from a pharmacist.

Public Health

For details of these assessment factors see page 20.

Marketing experience

Experience with the distribution and use of the medicine or preparation in Australia or overseas may also be taken into account.

Advertising

Applications for re-scheduling to Schedule 3 are normally considered in conjunction with an application for inclusion in Appendix H - Schedule 3 Poisons Permitted to be Advertised.

Guidelines for the assessment of applications for inclusion in Appendix H are available on-line at:

<http://www.health.gov.au/tga/docs/html/ndpsc/ndpsc3a.htm>

SCHEDULE 4

Description

Schedule 4 poisons are substances and preparations for therapeutic use -

- the use of which requires professional medical, veterinary or dental management or monitoring.
- which are for ailments or symptoms that require professional medical, veterinary or dental diagnosis or management.
- the safety or efficacy of which may require further evaluation.
- which are new therapeutic substances.

Purpose

To make available medicines or preparations the use, supply and prescribing of which should be by registered medical, veterinary or dental practitioners and supply of which by a pharmacist should be on prescription.

Assessment Factors

Characteristics of the Medicine

A medicine or preparation may be classified as a Schedule 4 poison if:

- it has low to moderate abuse potential.
- its use may produce serious side-effects.
- it has a narrow Therapeutic Index.
- its use requires professional medical, veterinary or dental management or monitoring.
- its activity, safety, efficacy or side-effects requires further evaluation.

Indications for Use

- the ailment or symptom(s) it is used for requires professional medical, veterinary or dental diagnosis, management or monitoring.

SCHEDULE 5

Description

Schedule 5 poisons are substances and preparations which-

- have low toxicity or a low concentration.
- have a low to moderate hazard.
- are capable of causing only minor adverse effects to human beings in normal use.
- require caution in handling, storage or use.

Purpose

To allow poisons and preparations of low hazard to be freely available but to further reduce any potential harm through -

- Appropriate packaging.
- Simple label warning(s).
- Safety directions.
- Child-resistant packaging, where appropriate.

Assessment Factors

Toxicity

The numerical ranges given below for acute toxic effects 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 substantially lower, a tighter restriction may be applied.

Human toxicity experience is given precedence over animal data.

- Acute oral toxicity (rat) between 2000 mg/kg and 5000 mg/kg.

- Acute dermal toxicity more than 2000 mg/kg.
- Acute inhalation toxicity (rat) more than 3000 mg/m³ (4 hours).
- Dermal irritation is slight to moderate.
- Eye irritation is slight to moderate.
- Skin sensitisation is slight or nil.
- There is no other significant toxicity.
- Substances should present a low hazard from repeated use and should be unlikely to produce irreversible toxicity.

Note:

The eye irritation terms "slight", "moderate", and "severe" have the following meanings -

Severe irritation - Corneal opacity, not reversible 7 days.

Moderate irritation - Corneal opacity, reversible 7 days.

Slight irritation - No corneal opacity.

The skin irritation terms "slight", "moderate", and "severe" have the following meanings -

Severe irritation - Severe irritation at 72 hours.

Moderate irritation - Moderate irritation at 72 hours.

Slight irritation - Slight irritation at 72 hours.

Clinical considerations if for therapeutic use

The condition to be treated must -

- be easily recognised.
- not require professional diagnosis and management.

In use the product must -

- be easy to administer.
- be safe for the person administering it.

- not require specialised equipment.

Public Health

For details of these assessment factors see page 20.

SCHEDULE 6

Description

Schedule 6 poisons are substances and preparations:

- with moderate to high toxicity.
- which may cause death or severe injury if ingested, inhaled or in contact with the skin or eyes.

Purpose

To allow poisons and preparations to be freely available for agricultural, commercial, domestic, horticultural and industrial purposes with minimum restrictions but reduce potential harm through distinctive packaging with:

- strong label warnings.
- more extensive safety directions than for a Schedule 5 poison.
- child-resistant packaging, where appropriate.

Assessment Factors

Toxicity

The numerical ranges given below for acute toxic effects 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 substantially lower, a tighter restriction may be applied.

Human toxicity experience is given precedence over animal data.

- Acute oral toxicity (rat) between 50 mg/kg and 2000 mg/kg.
- Acute dermal toxicity between 200 mg/kg and 2000 mg/kg.
- Acute inhalation (rat) between 500 mg/kg and 3000 mg/ m³ (4 hours).
- Dermal irritation is severe to corrosive.

- Eye irritation is severe to corrosive.
- Dermal sensitization is moderate to severe.
- Any other acute effects are nil to moderate.
- Moderate hazard from repeated use and low risk of producing irreversible toxicity.

Note:

The eye irritation terms "moderate" and "severe" have the following meanings:

Severe irritation - Corneal opacity, not reversible 7 days.

Moderate irritation - Corneal opacity, reversible 7 days.

The skin irritation terms "moderate" and "severe" have the following meanings:

Severe irritation - Severe irritation at 72 hours.

Moderate irritation - Moderate irritation at 72 hours.

Public Health

For details of these assessment factors see page 20.

SCHEDULE 7

Description

Schedule 7 poisons are substances and preparations -

- with high to extremely high toxicity.
- which can cause death or severe injury at low exposures.
- which require special precautions in their manufacture, handling or use.
- which may require special regulations restricting their availability, possession or use.
- which are too hazardous for domestic use or use by untrained persons.

Purpose

To allow dangerous poisons which should have a restricted availability to the general public to be available to specialised or authorised users who have the skills necessary to handle them safely.

Assessment Factors

Toxicity

The numerical ranges given below for acute toxic effects 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 substantially lower, a tighter restriction may be applied.

Human toxicity experience is given precedence over animal data.

- Acute oral toxicity (rat) is 50 mg/kg or less.
- Acute dermal toxicity is 200 mg/kg or less.
- Acute inhalation toxicity (rat) is 500 mg/m³

(4 hour) or less.

- Dermal irritation is corrosive.
- Eye irritation is corrosive.
- Severe hazard from repeated use, or significant risk of producing irreversible toxicity.

Note:

The eye irritation term “corrosive” has the following meaning:

Irreversible tissue damage in the eye following application of a test substance to the anterior surface of the eye.

The skin irritation term “corrosive” has the following meaning:

Irreversible tissue damage in the skin following application of a test substance.

Public Health

For details of these assessment factors see page 20.

SCHEDULE 8

Description

Schedule 8 poisons are substances and preparations for therapeutic use (i.e. medicines):

- which are dependence producing.
- which are likely to be abused or misused.

Purpose

To allow potent medicines to be available for medicinal use with restrictions on manufacturing, trade, distribution, possession and use to prevent abuse, addiction and dependence.

Assessment Factors

A substance or preparation will be classified as a Schedule 8 poison if it:

- is included in Schedule I or II of the WHO Single Convention on Narcotic Medicines.
- is included in Schedule II or III of the WHO Convention on Psychotropic Substances.
- is likely to present a substantial risk of abuse, dependence or misuse for illegal purposes.

CHAPTER 4: GUIDELINES FOR PUBLIC CONSULTATION

Public consultation procedures for the Committee are prescribed in the *Therapeutic Goods Regulations 1990*. These are available on-line at:
<http://www.health.gov.au/tga/docs/html/legis.htm> .

CHAPTER 5: GUIDELINES FOR USE OF CONFIDENTIAL INFORMATION

<THIS CHAPTER IS UNDER REVIEW>