CONSULTATION DOCUMENT

A PROPOSED MODEL FOR THE SCHEDULING OF POISONS IN AUSTRALIA

July 2005

Background information to proposed model

Poisons legislation in each State/Territory of Australia is currently administered by the relevant State/Territory Department of Health. As it is widely acknowledged that these substances may cause harm if handled or used incorrectly, it is considered appropriate that these portfolios (which have as their primary reason for being, public health and safety) are responsible for maintaining, monitoring and enforcing legislated requirements.

In support of the need to work towards national uniformity on scheduling, the National Drugs and Poisons Schedule Committee (with members represented by the Australian Government and each State/Territory Department of Health) was established to co-ordinate decision making. This Committee is a statutory committee and the arrangements for membership and processes are set out in the therapeutic goods legislation. The current role of the TGA in conjunction with the Office of Chemical Safety, as part of the TGA Group of Regulators, is to provide secretariat support for the Committee and to maintain the decisions of the Committee as included in the *Standard for the Uniform Scheduling of Drugs and Poisons*.

The Therapeutic Goods Administration (TGA) Group of Regulators, which includes the TGA, the Office of the Gene Technology Regulator and the Office of Chemical Safety – incorporating the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), is currently responsible for the regulation of therapeutic products, chemicals and gene technology in Australia.

While the TGA Group of Regulators will cease to exist with the commencement of the joint agency on 1 July 2006, the joint agency will continue to incorporate under its broad administrative umbrella, the Office of the Gene Technology Regulator and the Office of Chemical Safety which includes the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), although these regulators will only operate in Australia. This arrangement was confirmed in the media release issued by the former Parliamentary Secretary for Health, Ms Trish Worth on 10 December 2003, following the signing of the Treaty between Australia and New Zealand to establish a single regulatory agency for therapeutic products.

Therefore, in considering possible new arrangements for the scheduling of poisons, the proposed model takes into account that expertise in the regulation of poisons will continue to be available within the Joint Agency through the Office of Chemical Safety (as continuing to have responsibility for undertaking risk assessments and providing advice on potential public health risks posed by chemicals used in the Australian community). Delegations to make decisions on the scheduling of poisons would only be granted to officers within the Agency with appropriate experience in the regulation of chemicals, who in making these decisions would also be required to take into consideration advice from the expert committee on poisons scheduling.

KEY ASPECTS OF THE PROPOSED MODEL FOR SCHEDULING OF POISONS

Expert Committees

Consistent with the recommendation of the Galbally Review, two expert committees on scheduling are to be established within the Joint Agency framework. The Medicines Scheduling Committee (MSC) will provide advice to the Joint Agency on scheduling matters concerning medicines (ie products for human therapeutic use) and prohibited substances (Schedule 9) and the Poisons Scheduling Committee (PSC) will provide advice to the Joint Agency on scheduling matters concerning poisons (including agricultural/veterinary chemicals and industrial / household chemicals).

Secretariat /Policy

The trans-Tasman Therapeutic Products Agency (the Agency) will provide the committee secretariat for both the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee (PSC). All recommendations for both medicines and poisons will be published in the *Standard for the Uniform Scheduling of Medicines and Poisons* (the scheduling standard), which will be maintained by the committee secretariat. The scheduling standard will essentially be a database which will allow the Australian States and Territories to adopt the scheduling entries which are relevant to poisons and medicines.

Overarching policy guidance and protocols (eg due process, consultation arrangements etc) on scheduling are to be developed, under the oversight of the National Coordinating Committee on Therapeutic Goods (NCCTG). This policy framework will apply equally to the scheduling of medicines and agricultural, veterinary and household chemicals and allow judgment by reviewers (including any expert advisory committees or evaluators / decision-makers within the Agency) to find the best fit for new substances and to facilitate the re-evaluation process of scheduled substances when an application for rescheduling is received or new knowledge or practice emerges.

Adoption of scheduling decisions

The Agency[1] will make the scheduling decisions (in terms of the entry in the scheduling standard) which will be characterised in the Commonwealth legislation as poisons scheduling recommendations ns to the States and Territories. These decisions will be reflected in the scheduling standard and adopted into law by the jurisdictions.

New substances

Upon application for approval of a new active constituent to the Australian Pesticides and Veterinary Medicines Authority (APVMA) or notification through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (for industrial / domestic chemicals), the applicant shall address scheduling matters at the same time.

The Agency will make the initial scheduling assessment for a new ‘poison’ as part of the toxicology assessment of a new chemical or product. The Agency summary and initial assessment will be forwarded to the PSC for their advice as an expert advisory committee. The final decision on scheduling will be made by the Agency in accordance with the scheduling policy framework developed by the NCCTG in making scheduling decisions for

[1] The “Agency” is considered to include all staff necessary to perform the agreed functions of the Agency, including any Australian only functions such as the scheduling of poisons.

new substances and included in the final toxicological assessment provided by the Agency to the APVMA.

If the Agency considers for any reason that it is necessary to vary the framework, the matter will be referred through the PSC to the NCCTG for confirmation.

The Director of NICNAS may refer matters relating to the scheduling of an existing industrial chemical (which may also have domestic use) which has not previously been considered for scheduling, to the Agency, including an initial overview of the chemical and a scheduling recommendation.

Rescheduling

Decisions on the rescheduling of substances (ie on which a previous scheduling decision has already been made) will be made by the Agency where an application has been submitted to the APVMA for the rescheduling of an agricultural or veterinary substance. The Agency or the PSC may also initiate reviews of scheduling on their own volition, including reviews initiated by NICNAS for the scheduling of domestic chemicals.

The Director of NICNAS may refer matters relating to the rescheduling of a new industrial chemical which also has domestic use to the Agency, including an initial overview of the chemical and a rescheduling recommendation.

The Agency must have regard to the advice to be provided by the PSC on rescheduling applications.

Membership of the Poisons Scheduling Committee

The PSC will be an expert advisory committee of between 10 to 16 members. The States/Territories will be able to nominate one member each and the Australian Government (as represented by the Agency), NICNAS and the APVMA will also nominate one committee member.

These expert members will have requisite 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;
- Industrial[2] and domestic chemicals;
- Agricultural and veterinary chemicals;
- Clinical aspects of human poisoning;
- Consumer issues;
- Industry issues;
- Occupational health, with expertise preferably also as a medical practitioner.

The NZ Environmental Risk Management Authority (NZERM) should also be invited to nominate a permanent observer (with no voting rights) to the PSC in the interests of furthering closer trans-Tasman ties on the regulation of chemicals.

Following the nomination of the 11 standing committee members, the Agency will determine whether there is a lack of coverage in any of the required areas of professional expertise.

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

Where this is the case, the Managing Director of the Agency will nominate relevant experts.

The Australian Health Minister will appoint committee members, based on recommendations from the Managing Director.

The Chair must be a member nominated by the Australian Government (as represented by the Agency) and will be appointed by the Australia Minister for Health, in consultation with the Minister for Agriculture, Fisheries and Forestry.

All members of the PSC will have equal voting rights. In the case of a tied vote, the Chair will have the deciding vote.

This expert advisory committee will:

- provide advice to the Agency in relation to the scheduling of poisons including the broader policy framework;
- make recommendations to the Agency regarding applications to change the scheduling classification of a poison, with input from other relevant expert advisory committees; and
- be able to review scheduling decisions on new substances, and rescheduling decisions made by the Agency of its own initiative and make submissions on proposed changes to the Agency.

Scheduling Recommendations

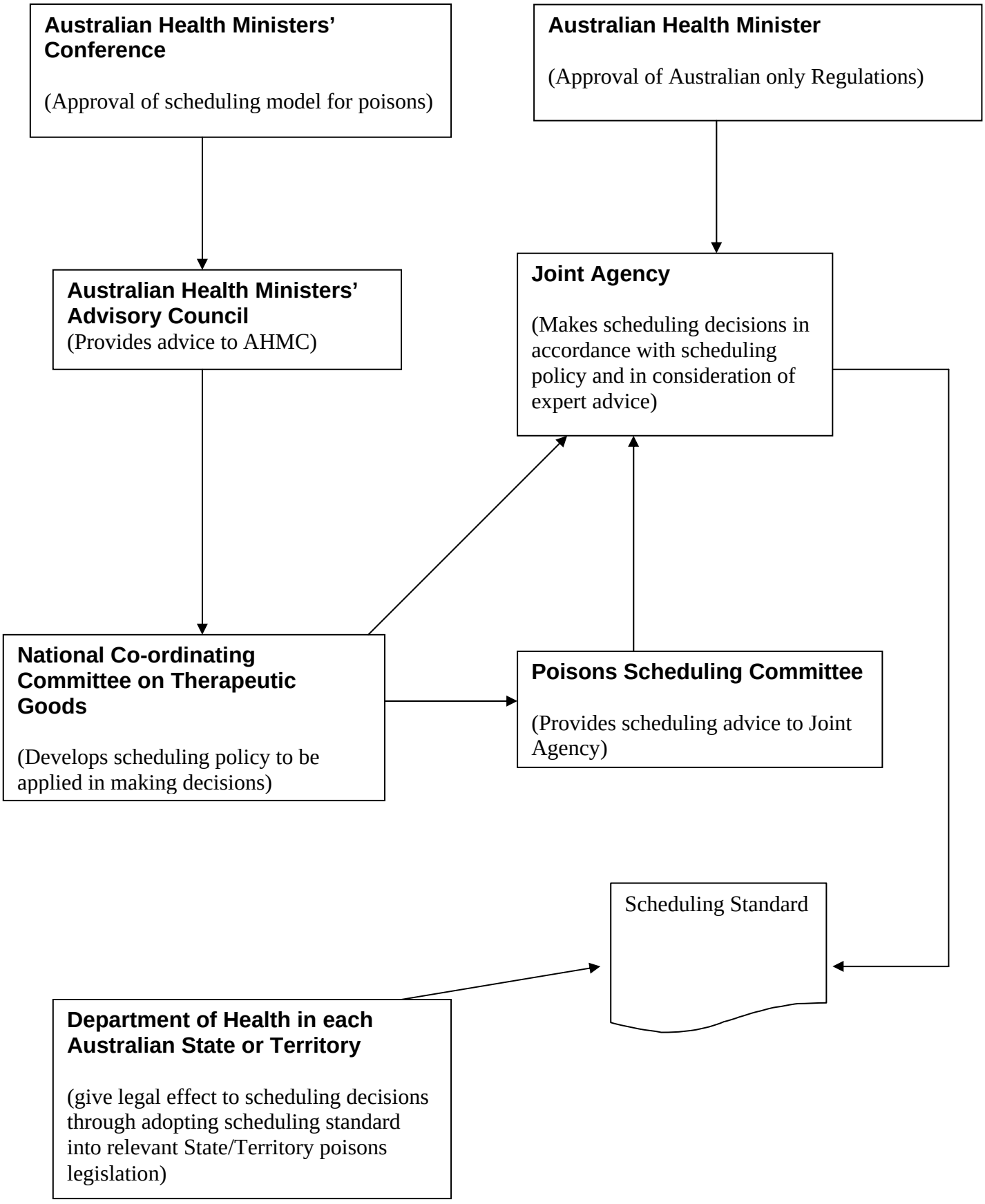
All members of the Poisons Scheduling Committee will have equal voting rights. In the case of a tied vote, the Chair will have the deciding vote.

Review of decisions made by the Agency

All initial scheduling decisions, will be internally reviewable on request of the applicant on the grounds that the decision failed to correctly apply the scheduling policy framework. Rescheduling decisions will be internally reviewable on the grounds that the decision failed to correctly apply the scheduling policy framework on the request of any interested party that made a submission during the consultation period.

Review of decisions will be made having regard to advice provided by the PSC, following input provided to that Committee by any other relevant expert advisory committee, advice from the APVMA and the submissions of the applicant.

Key Bodies in the Scheduling of Poisons



PROPOSED ADMINISTRATIVE PROCESSES TO IMPLEMENT THE MODEL

A. Scheduling of a new poison

Phase 1: Submission

- Where an application is made to the Australian Pesticides and Veterinary Medicines Authority (APVMA) for approval of an agricultural or veterinary product containing a new active constituent, the APVMA will refer the application to the Agency for consideration.

- Where either a notification is made through NICNAS for a new industrial chemical (which may also have a domestic use) or NICNAS initiates an existing chemical review of a chemical which has not been previously considered for scheduling, the Director of NICNAS may refer the matter of the scheduling of the chemical to the Agency.

- The initial decision on the scheduling of the new substance (ie. on which a previous scheduling decision has not already been made) will be made by the Agency, in accordance with the matters referred to in the Australian Regulations relevant to scheduling and the scheduling policy framework.

Phase 2: Consultation

- The scheduling proposal[3] will be published in the Gazette on the Agency website and "registered interested parties" who have subscribed to the listserver[4] advised of the gazettal.

- This provides an opportunity for interested stakeholders to make written comment on scheduling proposals to be considered by the PSC and the Agency. Approximately four weeks is available for the preparation of comments. Closing dates would be published on the Agency website. Provided that the submission is directly relevant to the scheduling matter it will be considered.

- The Agency must publish on the Agency's website, or where publication is not practical, make available, all public submissions that it is required to consider (other than information which is accepted as being commercial-in-confidence).

Phase 3: Initial decision and advice from Poisons Scheduling Committee

[3] Note: information which may be released for public consultation includes the substance name, the applicant and the proposed schedule. Certain information including sales data, product formulation details and manufacturing process will be defined as commercial-in-confidence and will not be available to the public.
[4] It is proposed that interested parties will be able to subscribe to a list which will receive automatic notification to their nominated e-mail address.

- The Agency will refer an overview report and any submissions received from the public consultation process to the PSC**.** The Agency overview will include an initial recommendation on the scheduling of the new substance, in accordance with the scheduling policy framework and may consider whether the substances should be included in an appendix to the scheduling standard. The applicant will also receive a copy of the Agency overview before the expert advisory committee meeting.

  (Note it is proposed that the overview be provided to the applicant to allow the applicant a final opportunity to address any outstanding issues identified in the overview – similar to the process already in place for the NICNAS chemical review program.)

- In considering the scheduling application, the overview report, submissions from interested parties and any further submission from the applicant, the PSC will provide a recommendation to the Agency on the recommended schedule (if any) and whether there is a need to change any appendix to the scheduling standard.

Phase 4: Initial Decision

- The Agency[5] makes a scheduling decision giving due regard to the recommendation of the PSC, any submissions received and the scheduling policy framework established by the NCCTG.

Phase 5: Communication

- The initial decision is published on the Agency website with a statement of reasons for the decision. Those who have made written submissions to the Agency or have registered on the listserver are advised of the posting.

Phase 6: Internal Review

- A notice of intent by the applicant to seek an internal review to a scheduling decision must be lodged with the Agency within 10 working days of the date the initial decision is published on the Agency website. The submission must be received by the Agency within the following 20 working days. If a notice of intent to seek an internal review is received, the status of the substance on the website stands as the decision until the review is finalised.

- This is an opportunity for the applicant to seek an internal review to object to the initial decision. A review must be made on the basis that the initial decision was not made in accordance with the scheduling policy framework. Financial or commercial reasons are not acceptable grounds to seek a review. If the applicant wishes to submit further data then a new application should be lodged.

- The Agency (being an officer who was not the delegate who made the initial scheduling decision) makes a decision on whether the request includes sufficient

[5] Under the new Australian-only Regulations, officers in certain specified positions within the Agency would be delegated the power to decide on the scheduling of poisons.

grounds for warranting an internal review. Where the decision is to proceed with an internal review, the Agency must publish on the Agency's website the details of the request of the review and may seek further advice of the PSC before making a final decision. The Agency considers the basis for the initial decision, the advice of the PSC, the evidence submitted in support of the request and will either confirm or set aside the initial decision. The Agency advises the applicant of the outcome.

- The Agency must make a decision on the outcome of the review within a target timeframe of 30 working days after the date of the next PSC meeting (following acceptance of the request).

Phase 7: Confirmation

- The Agency must publish a notice on the Agency website to formally notify the outcome of those decisions which have been the subject of an internal review.

- Where there has been no request for an internal review the initial decision of the Agency is confirmed on the website, following the lapse of the 10 working day period for an internal review request to be lodged.

- The final decision on scheduling is to be included in the toxicological assessment provided by the Agency to the APVMA.

Phase 8: Notification

- Notification of amendments to the scheduling standard together with the date of effect will be published in the Agency Gazette6 on the Agency website every month. The scheduling standard will be published electronically on the Agency website and entries updated as the date of effect falls due[7]. Hardcopies will also be published as "unofficial" copies of the scheduling standard, together with regular updates as a service to users.

- The Australian States and Territories will adopt the scheduling standard (as published electronically by the Agency, from time to time) into their poisons legislation by reference. Scheduling of new substances is to be given legal effect through Australian State/Territory legislation by the effective date specified in the Gazette notice.

Phase 9: Feedback

- Details of the substance and the decision are referred to the Scheduling Secretariat for inclusion in the agenda papers of the PSC for the next available meeting for information.

[6] It is intended that scheduling decisions will be published in a Joint Agency Gazette on the Agency Website rather than the current arrangements using the Australian Government Gazette.
[7] Although to be notified via a monthly electronic gazette, co-ordination of the dates of effect to three times a year is under consideration in order to assist States and Territories in adoption of the scheduling decisions

B. Rescheduling of a poison which is included in the scheduling standard

Phase 1: Submission

- Applications for rescheduling of existing substances should be submitted to the APVMA (ag/vet chemical) or NICNAS (industrial/domestic chemical) which will forward the application to the Agency (ie through the Scheduling Secretariat). A copy of the application will be provided to the area of the Agency which, at that time, has responsibility for toxicological assessments of poisons.

- An application form for rescheduling of an existing substance will clearly outline the information required and what aspects of this information may be released for public consultation, including the substance name, the applicant, the current and proposed schedule, risk of misuse/abuse, adverse event data and the public benefit. Certain information including sales data, product formulation details and manufacturing process will be defined as commercial-in-confidence and will not be available to the public. Applicants will be required to provide an electronic copy of the information included in the application (minus any commercial-in-confidence details) for inclusion on the Agency website as part of the consultation process.

- The rescheduling application is reviewed by the Agency and an overview report including a scheduling proposal is forwarded to the PSC along with the application. A representative from the relevant area of the Agency may attend the PSC as an observer, to facilitate a shared understanding of scheduling considerations for that agenda item.

- The applicant will also receive a copy of the Agency overview report before the PSC meeting.

  (Note it is proposed that the overview be provided to the applicant to allow the applicant a final opportunity to address any outstanding issues identified in the overview – similar to the process already in place for the NICNAS chemical review program.)

- A member of the PSC may also initiate a scheduling proposal.

Phase 2: Consultation

- All details included in applications (other than those accepted to be commercial-in-confidence) are placed on the pre-meeting agenda for the next meeting of the PSC. For the purposes of scheduling, commercial-in-confidence information is defined as information which would be generally protected under Intellectual Property legislation and will not be made available to the public. The PSC agenda and closing date for submissions will be posted on the Agency website and sent to "registered interested parties" with an invitation for public submissions with a closing date of not

less than four weeks after publication. The meeting must not take place until at least two weeks after the closing date.

- This provides an opportunity for interested stakeholders to provide written comment on scheduling proposals to be considered by the Agency. Approximately four weeks is available for the submission of comments. The Agency must publish on the Agency's website, or where publication is not practical, make available, all submissions, other than information which is considered to be commercial-in-confidence, that it is required to consider.

- Comments are forwarded to PSC members with other agenda material before each meeting. The Committee may also seek advice on rescheduling matters from other people (including other expert advisory committees), where appropriate.

Phase 3: Recommendation by Poisons Scheduling Committee

- A summary of recommendations is posted on the Agency website immediately after the meeting (ie 1-2 weeks after the meeting)[8]. This summary is posted immediately after the PSC meeting to give quick advice of the recommendations made by PSC to the Agency. This summary does not represent the decisions of the Agency. Reasons underlying these recommendations will be available after PSC members ratify the minutes.

- The ratified minutes are forwarded to the Agency within a target timeframe of 6 weeks of the meeting.

Phase 4: Decision

- Within a target timeframe of 7 working days of receipt of the ratified minutes, the Agency (being a delegate independent of the initial recommendation regarding the rescheduling application) either accepts or declines the recommendations of the PSC or refers the advice of the PSC to another relevant expert advisory committee for comment[9].

- If the advice from the PSC is to make a scheduling amendment other than in accordance with the application, the Agency must call for further submissions from any party affected by this decision before deciding whether to accept this advice.

[8] This process is consistent with other Agency expert advisory committees

[9] The ability for a committee to seek advice from other persons and for the Agency (or their delegate) to seek comment on the advice from an expert committee from another committee is consistent with the current legislation regarding expert advisory committee procedures. However, it would generally be expected that the PSC would seek advice from other expert advisory committees if necessary.

Phase 5: Communication

- The initial decision[10] of the Agency with a statement of reasons for the decision is sent to the applicant and posted on the Agency website. If after a period of 10 working days of the date of notification to the applicant, no request for an internal review is received, the notification of an amendment to the scheduling standard is published in the Gazette on the Agency website together with the date of effect, generally being 6 months from the date of the notification.

- Those persons who have made written submissions to the PSC or have registered on the web server receive an e-mail advising that the decision has been published in the Agency Gazette.

Phase 6: Internal Review

- A notice of intent to seek an internal review to a rescheduling decision must be lodged with the Agency within 10 days of the date of notification to the applicant. A request for an internal review can only be made by the applicant or a party who lodged an initial submission (ie an interested party) and must be received by the Agency within the following 20 working days. If a request for an internal review is received, the initial decision for that poison is updated on the Agency website as being subject to an internal review.

- This is an opportunity for any interested party to seek an internal review to object to the initial decision on the grounds that it was not made in accordance with the scheduling policy framework. Financial or commercial reasons are not acceptable grounds to seek a review. New data will not be accepted at this stage as it is expected that all relevant data would have been submitted as part of the consultation phase.

- Where more than one request for a review is received, the requests will be dealt with collectively.

- The Agency (being a delegate independent of the initial decision making process) decides whether the request/s includes sufficient grounds for warranting an internal review. Where the decision is to proceed with an internal review, the Agency must publish the details of the request for review on the Agency's website and the request is submitted through the Scheduling Secretariat for consideration at the next meeting of the PSC. Within a target timeframe of 7 working days of receiving the ratified minutes of the PSC meeting**,** the Agency reconsiders the further advice of the PSC and the evidence submitted in support of the request and will either confirm or set aside the initial decision.

- The Agency advises the applicant of the outcome.

[10] A decision is taken to include a decision not to make an amendment to the current scheduling status of the substance

Phase 7: Confirmation

- The Agency must publish a notice on the Agency website to formally notify the outcome of those decisions which have been the subject of an internal review.

- Where there has been no request for an internal review the initial decision of the Agency is confirmed on the website, following the lapse of the 10 working day period for an internal review request to be lodged.

Phase 8: Notification

- Notification of amendments to the scheduling standard together with the date of effect (generally being 6 months from the date of publication) will be published in the Gazette on the Agency website every month. The Australian States and Territories will adopt by reference the scheduling standard which will be published electronically on the Agency website and updated as the date of effect of any decisions to change the standard falls due. "Unofficial" hardcopies will also be available with regular updates as an additional service to stakeholders.

Phase 9: Feedback

- Details of the substance and the decision are referred to the Scheduling Secretariat for inclusion in the agenda papers of the PSC for the next available meeting for information.

SCHEDULING OF A NEW POISON