Australian Government

Department of Health and Ageing

Therapeutic Goods Administration

CONSULTATION DOCUMENT

A PROPOSED MODEL FOR THE

SCHEDULING OF MEDICINES

July 2005

KEY ASPECTS OF THE PROPOSED MODEL FOR SCHEDULING OF MEDICINES

(Note for the purposes of scheduling, medicine means the active ingredient in a therapeutic product)

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 Joint Agency will provide the committee secretariat for both the MSC and the PSC. All scheduling 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 in electronic format. The scheduling standard will essentially be a database which will allow New Zealand to adopt the scheduling entries which are relevant to medicines only.

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), as the cross jurisdictional committee whose role is to take action necessary to bring about the co-ordination of legislative and administrative controls on therapeutic products and poisons. This policy framework will apply equally to the scheduling of medicines and poisons 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.

The NCCTG will continue to operate as a standing sub-committee of the Australian Health Ministers Advisory Council.

Adoption of scheduling decisions

The Agency will make the scheduling decisions (in terms of the entry in the scheduling standard) which will be characterised in the Commonwealth legislation as scheduling recommendations to the States and Territories. These decisions will be reflected in the scheduling standard and adopted into law by the jurisdictions. Scheduling will be given legal effect in New Zealand under New Zealand legislation.

New substances

Initial decisions on the scheduling of a new substance (ie on which a previous scheduling decision has not already been made) will be made as part of the evaluation and approval process for the medicine that contains the substance by the Agency. Before making such a

decision, the Agency will be able to seek advice from the expert advisory committees that advise on the safety of new prescription, over-the-counter or complementary medicines or the MSC (as an expert advisory committee on the scheduling of substances for therapeutic use in humans). These committees will be joint Australia/New Zealand committees whose members are selected on the basis of their technical expertise.

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

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 made for rescheduling.

The Agency must have regard to the advice to be provided by the MSC on rescheduling applications, following input provided to that Committee by any other relevant expert advisory committee/s.

Membership of the Medicines Scheduling Committee

The MSC will be an expert advisory committee of between 10 to 16 members. The Australian States/Territories will be able to nominate one member each and the Agency and New Zealand (as represented by the New Zealand Ministry of Health) will also nominate one committee member each.

These expert members will have requisite expertise in one of more of the following areas:

- The regulation of the scheduling of medicines in an Australian State/Territory or New Zealand;
- Toxicology;
- Practising pharmacist;
- Medical practice;
- Industry issues;
- Consumer issues; or
- Clinical pharmacology.

Following the nomination of these 10 committee members, the Agency will determine whether there is a lack of coverage in any of the required areas of professional expertise. Where this is the case, the Managing Director of the Agency will nominate relevant experts.

The Therapeutic Products Ministerial Council will appoint committee members, based on recommendations from the Agency. The Chair must be a person nominated by the Agency and will be appointed by the Ministerial Council.

This expert advisory committee will:

- provide advice to the Agency in relation to the scheduling of medicines[1] including the broader policy framework;

[1] It is expected that the Agency will also be able to seek the advice of the Medicines Scheduling Committee on the scheduling/rescheduling of prohibited (S9) substances.

- make recommendations to the Agency regarding applications to change the scheduling classification of a medicine, 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 MSC 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, and rescheduling decisions, will be internally reviewable on request of the applicant by a more senior delegate in the Agency on the grounds that the scheduling policy framework was incorrectly applied.

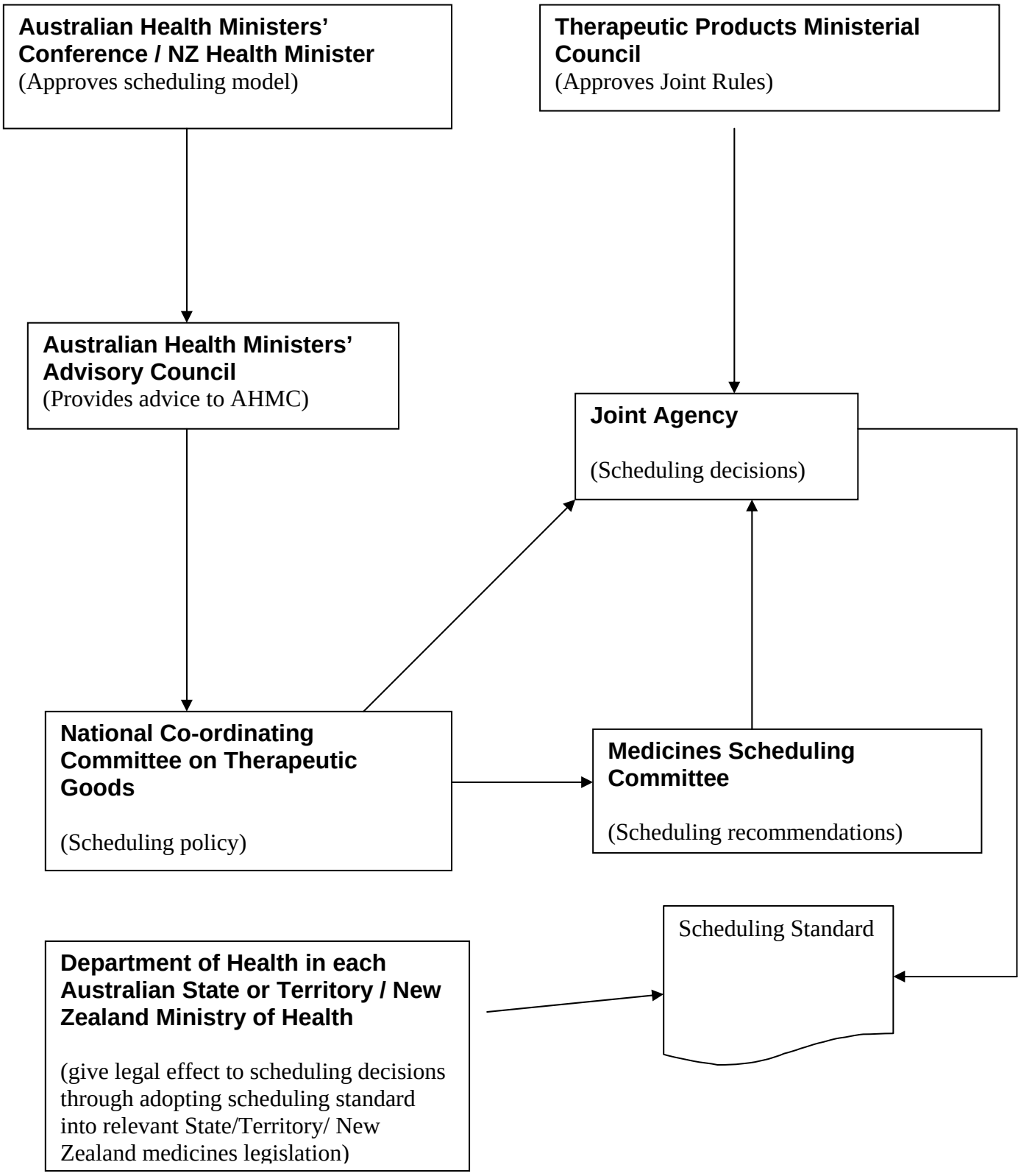
Review of decisions will be made having regard to advice provided by the MSC following input provided to that Committee by any other relevant expert advisory committee, and the submissions of the applicant.

Proposed transitional arrangements

It is proposed that decisions made at the June 2006 NDPSC meeting which have been completed but not yet come into effect will carry over into the new legislation as scheduling decisions with the same date of effect.

Initial scheduling decisions made at the June 2006 NDPSC meeting which have not been completed before the new legislation comes into effect, are to be completed under the therapeutic goods legislation but with the Poisons Scheduling Committee / Medicines Scheduling Committee (as appropriate to the substance) finalising this activity rather than the National Drugs and Poisons Schedule Committee.

Key Bodies in the Scheduling of Medicines



Note – The New Zealand Minister of Health is a member of the Australian Health Ministers Conference. The New Zealand Ministry of Health is also represented on the Australian Health Ministers' Advisory Council. The Therapeutic Products Ministerial Council includes the Australian Health Minister and the New Zealand Minister of Health.

PROPOSED ADMINISTRATIVE PROCESSES TO IMPLEMENT THE MODEL

A. Scheduling of a new medicinal substance

Phase 1: Submission

- It is not intended that there will be separate scheduling application forms. Where an application is made for a product licence for a Class II[2] medicine containing a new chemical entity for therapeutic use, sufficient information will be requested as part of that application to allow for the scheduling of the new chemical entity to also be determined. Similarly, where an application is made to the Agency for the evaluation of a new complementary medicine substance, an integral part of the assessment process is to determine whether the substance should be scheduled (as substances that are scheduled are not permitted in Class I medicines).

- Any member of the MSC may also submit a scheduling proposal for either a new medicine, or for a poison which is proposed to be included in Schedule 9 of the scheduling standard as a prohibited substance.

- Following acceptance of the application/proposal, the initial decision on the scheduling of the new substance (ie on which a previous scheduling decision has not already been made) is to be made by the evaluation stream as part of the evaluation and approval process for the product that contains the substance. The evaluator is to take into consideration the matters referred to in the therapeutic products legislation for scheduling and the scheduling policy framework.

Phase 2: Advice from Expert Advisory Committees

- The evaluator may refer an overview report on the product licence / complementary substance application to the relevant expert advisory committee[3] which has responsibility for providing advice on the type of product/substance being evaluated. The Agency overview may also include an initial recommendation on the scheduling of the new substance, in accordance with the scheduling policy framework.

- Where the advice of an expert committee is sought, the applicant will also receive a copy of the Agency overview before the expert advisory committee meeting. The overview is to be provided to allow the applicant a final opportunity to address any outstanding scheduling issues identified in the overview.

- Where the expert committee has been asked for advice on scheduling issues, the committee is to provide a recommendation to the Agency on the recommended schedule.

[2] Class I and Class II medicines equate to listed and registered medicines respectively under the current Australian system.

[3] Being the successor trans-Tasman expert committees to the Australian Drug Evaluation Committee, the Medicines Evaluation Committee and the Complementary Medicines Evaluation Committee

Public Consultation

- Where the scheduling decision is unlikely to be contentious[4], the Agency may decide not to proceed to public consultation on certain substances. Where the Agency makes this decision, the application will be referred, as a separate process, to the MSC for advice on whether any of the appendices to the scheduling standard need to be changed.

  (Note: the aim would be for any changes required to the scheduling standard to be made simultaneously (ie the schedule entry and any changes to the appendices), however, where this is not possible due to timing issues, it may be necessary for these to be separate processes.)

- If the application meets the criteria for consultation, the Agency may refer the application to the Scheduling Secretariat to commence the public consultation process. Where it is not clear whether consultation would be in the public interest, the Agency may await the advice of the expert advisory committee before making this decision.

Urgent scheduling

- Where the Agency is satisfied that it would be in the public interest to consult on a scheduling matter for a new medicine, but considers that in the interests of public health and safety, urgent scheduling of the medicine is necessary, the Agency may make a scheduling decision without public consultation. The Agency must review the decision as a soon as practicable after making the decision.

  (Note: it would generally be expected that the need for urgent scheduling would be limited to proposals from the MSC or the PSC for inclusion of substances in Schedule 9 (as prohibited substances which are of serious risk to public health and safety).)

Phase 3: Consultation

- For new substances which are evaluated by the non-prescription regulatory streams or are of public / industry sector interest, the scheduling proposal[5] will be published in the pre-meeting MSC notice on the Agency website and "registered interested parties" who have subscribed to the listserver[6] advised.

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

[4] An application for a product containing a new substance accepted for evaluation by the prescription medicines evaluation stream will normally be clearly consistent with inclusion of that substance in either Schedule 4 or Schedule 8. In such cases public consultation may not be necessary.

[5] Including the name of the applicant, name of the substance, proposed schedule and any other relevant details not considered to be commercial-in-confidence (refer Scheduling Policy Framework for further details).

[6] 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 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 4: Recommendation from Medicines Scheduling Committee

- Where public consultation is sought, the Agency will refer the overview report and any submissions received from the public consultation process to the MSC**.** 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 Australian Drug Evaluation Committee (ADEC) considerations.)

- In considering the scheduling application, the overview report and any further submission from the applicant or other interested parties, the MSC 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.

- A summary of the MSC recommendations is posted on the Agency website immediately after the meeting (ie 1-2 weeks after the meeting)[7]. This summary is posted immediately after the MSC meeting to give quick advice of the recommendations made by MSC to the Agency. This summary does not represent the decisions of the Agency. Reasons underlying these recommendations will be available after Members ratify the Minutes.

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

Phase 5: Initial Decision

- The Agency[8] makes an initial scheduling decision giving due regard to the recommendation of any expert advisory committee, any submissions received and the scheduling policy framework established by the NCCTG.

Default for prescription medicines

- In the case where a product licence has reached the final approval stage prior to the scheduling decision being made by the Agency and the product has been evaluated by the prescription medicines regulatory stream, the product licence may still be issued

[7] This process is consistent with other expert advisory committees.
[8] Under the new legislation, officers in certain positions within the Agency would be delegated the power to decide on the scheduling of substances for medicines.

on the basis that the product will be considered to be Schedule 4 until such time as the initial scheduling decision is made[9].

Phase 6: 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 7: Internal Review

- A notice of intent by the applicant to seek an internal review to a scheduling decision should be lodged with the Agency within 10 working days of the date the initial decision is published on the website. The submission should 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 Agency website stands as the decision until the review is finalised. A product licence may be approved before the request for an internal review has been finalised on the basis that the initial decision stands until it is confirmed or set aside and another decision made.

- This is an opportunity for the applicant to seek an internal review to object to the initial decision recommendation. An internal 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 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 for review and may seek the advice of the MSC before making a final decision.

- The Agency considers the basis for the initial decision, the advice of the MSC, the evidence submitted in support of the request and will either confirm or set aside the initial decision.

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

[9] This default will need to be implemented through State/Territory legislation. The reason for providing for a default is to ensure that product licensing is not delayed due to outstanding scheduling decisions. However, given that there are 255 working days for the prescription medicine stream to evaluate an application for a Class II medicine and there is a high likelihood that a new substance accepted for evaluation by the prescription medicines evaluation stream will meet the factors for inclusion in either Schedule 4 or Schedule 8, it is reasonable to expect that in most instances, scheduling would be resolved within this period.

Phase 8: 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 Agency website, following the lapse of the 10 working day period for an internal review request to be lodged.

Phase 9: Notification

- Notification of amendments to the scheduling standard together with the date of effect will be published in the Agency Gazette[10] 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[11]. Hardcopies will also be published as "unofficial" copies of the scheduling standard, together with regular updates on a subscription basis.

- The Australian States and Territories and New Zealand[12] will adopt into their legislation, the electronic scheduling standard maintained by the Agency. The scheduling standard is to be available to stakeholders for searching and printing on the internet. Scheduling of new substances is to be given legal effect through Australian State/Territory[13] and New Zealand legislation by the effective date specified in the Gazette notice.

Phase 10: Feedback

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

[10] This period has been nominated to bring forward the date of effect for new scheduling entries (as nominated in the notice) and rescheduling amendments (6 months from the date of gazettal). 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 or New Zealand Government Gazettes.
[11] 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
[12] New Zealand is to only adopt medicines in Schedules 2, 3, 4 and possibly 8 of the scheduling standard.
[13] Legislation in some States/Territories will require amending to implement automatic adoption of amendments.

A. Rescheduling of a medicinal substance which is included in the scheduling standard

Phase 1: Submission

- A new application form for the rescheduling of a medicine in the scheduling standard is to be developed. While applications usually come from sponsor companies, anybody may make a submission to the Agency for the rescheduling of a medicine. A rescheduling proposal can also be initiated by a member of the MSC.

- The application form will clearly outline the information required and which 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.

- Applications for rescheduling are reviewed by the Agency and an overview report including a scheduling proposal is prepared.

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 MSC. 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 MSC 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 public submissions (other than information which is commercial-in-confidence) that it is required to consider.

- Comments are forwarded to Committee members together with the original application and the overview report. The Committee may also seek advice on rescheduling matters from other people (including other expert advisory committees), where appropriate. A representative from the relevant evaluating area/s of the Agency may attend the MSC meeting as an observer, to facilitate a shared understanding of scheduling considerations for that agenda item.

Phase 3: Recommendation by Medicines Scheduling Committee

- A summary of the scheduling recommendations (including any recommended changes to the appendices of the scheduling standard) is posted on the Agency website immediately after the meeting (ie 1-2 weeks after the meeting)[14]. This summary is posted immediately after the MSC meeting to give quick advice of the recommendations made by MSC to the Agency. This summary does not represent the decisions of the Agency. Reasons underlying these recommendations will be available after 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 MSC or refers the advice of the MSC to another relevant expert advisory committee for comment[15].

- If the advice from the MSC is to 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.

Phase 5: Communication

- The initial decision[16] of the Agency (which includes a decision not to make an amendment to the current scheduling status of the substance) 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 Committee or have registered on the web server receive an e-mail advising that the decision has been published in the Agency Gazette.

[14] This process is consistent with other expert advisory committees.
[15] 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.
[16] A decision is taken to include a decision not to make an amendment to the current scheduling status of the substance

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 medicine is updated on the Agency website as being subject to an internal review.

- This is an opportunity for an 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 on the Agency's website the details of the request for review and the request is submitted through the Scheduling Secretariat for consideration at the next meeting of the MSC. Within a target timeframe of 7 working days of receiving the ratified minutes of the MSC meeting at which the request was considered**,** the Agency reconsiders the further advice of the MSC 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.

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 Agency 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 (eg 6 months from the date of publication) will be published in the Agency Gazette on the Agency website every month. The Australian States and Territories and New Zealand would adopt by reference[17] the scheduling standard published electronically by the Agency which would also be made available for searching and printing via the

[17] Some State/Territory legislation will require amending to implement automatic adoption of amendments

internet. Scheduling of new substances is to be given legal effect through Australian State/Territory and New Zealand legislation by the effective date specified in the Gazette notice. “Unofficial” hardcopies (with regular updates) will also be available 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 MSC for the next available meeting for information.

SCHEDULING OF A NEW MEDICINE