Australian Health Ministers’ Advisory Council

Guidance: A joint jurisdictional assessment process for proposals for nationally consistent scheduled medicines authorities for the unregistered health professions

PURPOSE

‘Scheduled medicines’ are substances that are included in a schedule to the current Poisons Standard under the Therapeutic Goods Act 1989 (Cth). The legal authorities to use (prescribe, supply or administer) scheduled medicines are conferred and controlled at the state/territory level under state and territory drugs and poisons laws.

This document provides advice to professional bodies and other interested parties on how the state, territory and Commonwealth governments will jointly consider proposals for nationally-consistent scheduled medicines authorities for classes of person who are not registered as health practitioners under the National Registration and Accreditation Scheme (in this document called ‘unregistered healthcare workers’).

This joint jurisdictional assessment process is intended to foster a national approach to the assessment and conferral of scheduled medicines authorities for the unregistered health professions.

The joint jurisdictional assessment process is intended to promote the quality use of medicines across all states and territories by:

- facilitating national level evidence-informed assessment of proposals for extended use of scheduled medicines by classes of unregistered healthcare worker
- facilitating common national standards across professions for training and clinical practice with respect to the use of scheduled medicines
- facilitating national consistency in core scheduled medicines authorities
- fostering the development and adoption of innovative models of care incorporating expanded scheduled medicines authorities.

It is not intended that this joint jurisdictional assessment process preclude individual states and territories from legislating locally to confer new or amended scheduled medicines authorities on healthcare workers within their respective jurisdictions.

TERMINOLOGY

Each state and territory has its own terminology for the types of legal authorities that can be conferred on an individual. In this document, the terms ‘prescribe’, ‘supply’ and ‘administer’ are defined and used as follows:

- to ‘prescribe’ a medicine means to authorise the supply or administration of the medicine to a patient (for example, an optometrist who writes a prescription for a patient to take to a pharmacy to fill is exercising an authority to prescribe)
- to ‘supply’ a medicine means to provide a medicine to a patient for their later use or administration (for example, a nurse in a hospital in a rural and remote area who is authorised to supply a medicine to a patient to take home for self-administration is exercising their authority to supply)
to ‘administer’ a medicine means to personally apply or introduce the medicine, or personally observe its application or introduction, to the patient’s body (for example, a podiatrist who applies a local anaesthetic to a patient’s foot prior to undertaking a procedure is exercising an authority to administer).

A table of the acronyms and abbreviations used in this document is at Attachment 1.

BACKGROUND

The current Poisons Standard provides a national framework for classifying medicines. However, matters such as which persons are authorised to use these scheduled medicines, and under what circumstances, are determined under state and territory drugs and poisons laws.

While referencing the current Poisons Standard, each state and territory law separately specifies the classes of person who are authorised to use scheduled medicines, as well as the various controls or limits placed on this use, including the types of medicines, type of use, setting, supervision requirements and clinical protocols.

For registered health practitioners, the Health Practitioner Regulation National Law (the National Law) as in force in each state and territory, establishes a national framework for collaborative decision making by jurisdictions. This legislative framework provides a means for state, territory and Commonwealth governments to jointly consider the qualifications and other requirements for safe and competent use of scheduled medicines by registered health practitioners. Under the National Law, the COAG Health Council (sitting as the Australian Health Workforce Ministerial Council) approves a National Board to endorse registered health practitioners as qualified to use a scheduled medicine or class of scheduled medicines.

The Ministerial Council may specify in the approval:

- the class of health practitioners to which the approval relates
- the scheduled medicine or class of scheduled medicines
- the type of activity that the endorsed practitioners are qualified for, that is, to administer, obtain, possess, prescribe, sell, supply or use the scheduled medicine/s.

While various classes of unregistered healthcare worker are also authorised to use scheduled medicines under state and territory law, there is no similar national framework for joint consideration of the scope of these authorities or the controls required. In the absence of such a framework, classes of healthcare worker may be authorised to use medicines in some states but not others, and individual healthcare workers may be unable to work to their full scope of practice because their authorities to use scheduled medicines do not travel with them across state and territory borders.

The Australian Health Ministers’ Advisory Council (AHMAC) has decided there is merit in pursuing a national approach to regulatory policy with respect to the conferral of authorities to use scheduled medicines. AHMAC’s aim is to achieve greater national consistency in core scheduled medicines authorities for classes of unregistered healthcare workers.

In the event that it considers legislative changes may be necessary to achieve national consistency, AHMAC may recommend to the Council of Australian Governments Health Council (the COAG Health Council) that state and territory
legislation be amended. In such circumstances, the COAG requirements for regulatory assessment would apply to such proposals. These requirements are set out in the document *Council of Australian Governments Best Practice Regulation: A Guide for Ministerial Council and National Standard Setting Bodies, October 2007* (the COAG Guidelines).  

The following joint jurisdictional assessment process is consistent with the COAG Guidelines.

**JOINT JURISDICTIONAL ASSESSMENT PROCESS**

This joint jurisdictional assessment process sets out:

- the matters that a *sponsoring jurisdiction* should address when bringing forward for national consideration a proposal for a new or amended scheduled medicines authority for a class of healthcare worker
- how AHMAC deals with a proposal for a nationally-consistent scheduled medicines authority or changes to the scope of an existing authority.

A *sponsoring jurisdiction* is a state, territory or Commonwealth health department.

A flow chart providing an overview of the joint jurisdictional assessment process is at Attachment 2.

**Step 1: Preliminary consideration**

A proposal for a nationally-consistent scheduled medicines authority or change to an existing authority may be developed at a jurisdiction’s own initiative, or by an external body such as a professional body or other interested party.

A proposal should consider:

- the public health need to be addressed
- the current arrangements with respect to use of scheduled medicines by the class or classes of healthcare worker
- the proposed change to scheduled medicines authority/ies, including the scheduled medicines or class of scheduled medicines that are proposed for use and the type of use (prescribe, supply or administer)
- the training and continuing competence considered necessary to support safe, competent and effective use of scheduled medicines by the class of healthcare worker
- the guidelines and other system supports considered necessary to ensure safe, competent and effective use of scheduled medicines by the class of healthcare worker
- any other policy or implementation issues.

Where a proposal has been developed by an external body, a state, territory or Commonwealth health department may decide to bring the proposal forward for preliminary consideration. Prior to bringing the proposal forward, the sponsoring jurisdiction should be satisfied that i) it adequately addresses the matters set out above and ii) there is sufficient merit in joint consideration of the proposal.

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1 The COAG Guidelines apply to any decisions of the COAG Health Council which are to be given effect through principal and delegated legislation, administrative directions or other measures which, when implemented, would encourage or force businesses or individuals to pursue their interests in ways they would not otherwise have done.
The sponsoring jurisdiction submits the proposal to the Health Workforce Principal Committee (HWPC) of AHMAC for preliminary consideration. The HWPC assesses the proposal and provides advice to AHMAC.

Following advice from the HWPC, AHMAC may decide that:
- a full submission for joint consideration may be brought forward for national consideration
- the proposed nationally-consistent scheduled medicines authority is not supported and outline the reasons why.

If AHMAC decides that a full submission should be brought forward for national consideration, it may appoint a lead jurisdiction (the sponsoring jurisdiction or another jurisdiction) to progress this work. AHMAC may provide advice to the COAG Health Council at this time.

**Step 2: Public consultation**

If AHMAC has agreed there is merit in further work to develop a proposal for a nationally-consistent scheduled medicines authority, the lead jurisdiction seeks advice from the Office of Best Practice Regulation (OBPR) on whether a Regulation Impact Statement (RIS) is required.

If the OBPR advises that a RIS process is required, the lead jurisdiction:
- prepares a consultation paper in the form of a Consultation RIS and, before releasing the paper publicly, seeks OBPR confirmation that it is in a form that meets COAG best practice regulation requirements
- conducts a national consultation in accordance with the COAG best practice regulation requirements (see the COAG Guidelines for details).

If the OBPR advises that a RIS process is not required, the lead jurisdiction conducts any necessary research and consultations.

**Step 3: Submission development**

The lead jurisdiction prepares a submission for a nationally-consistent scheduled medicines authority or change to an existing authority for a class of healthcare worker.

The lead jurisdiction must ensure that any submission brought forward for joint consideration addresses the matters set out in Attachment 3, namely:
- purpose of submission
- overview of proposal
- legislative arrangements
- details of proposal
- training arrangements
- administrative processes for endorsement
- standard setting and practice monitoring arrangements
- consultations undertaken, including details of any dissenting views.

When the proposal has been initiated by an external body, the lead jurisdiction may work with the external body to prepare the submission. The lead jurisdiction should also ensure that they have consulted with a sufficient range of experts and stakeholders in the development of the submission.
The level of detail in a submission will be commensurate with the scope of the proposed change. For example, an application for a new scheduled medicines endorsement for a class of healthcare worker is likely to require more detail than an application to vary the terms of an existing nationally-consistent scheduled medicines approval.

If the OBPR has advised that a RIS process is required, then a Decision RIS must be prepared and a copy attached to the submission, along with a copy of the OBPR’s assessment of compliance with the COAG best practice regulation requirements. Where material required in the submission is contained in the Decision RIS, it may be referenced rather than repeated in the submission.

**Step 4: Submission assessment**

The lead jurisdiction submits the proposal to the HWPC for consideration. On receipt of the submission, the chair of the HWPC refers the submission to the Scheduled Medicines Subcommittee of HWPC for advice. The HWPC may supplement the membership of the Scheduled Medicines Subcommittee to ensure that it comprises a suitable range of experts to assess the proposal.

In considering its advice to HWPC, the Scheduled Medicines Subcommittee addresses:

1. whether the proposal development has been sufficiently rigorous, including that:
   - the service need is well documented
   - an evidence-based approach has been adopted
   - an integrated, cross-profession approach has been applied, including in relation to determining the qualification requirements, clinical practice standards and guidelines and training and curriculum
   - a sufficient range of experts and stakeholders has been consulted
   - adverse views of stakeholders (if any) have been adequately addressed
   - the proposal is compatible with the *National Medicines Policy* and the *Quality Use of Medicines*
   - the process has complied with COAG best practice regulation requirements (if required).

2. whether the regulatory and other quality control measures proposed are considered sufficient to support safe, competent and effective use of scheduled medicines by the class of healthcare worker, particularly with respect to:
   - curriculum, content and the standard of programs of study that provide competence for an endorsement to prescribe scheduled medicines or other scheduled medicines authority
   - the content and standard of clinical experience required to equip a class of practitioner to be granted a scheduled medicines authority
   - any clinical guidelines and/or protocols necessary to support safe, competent and effective prescribing practice or other scheduled medicines authority
   - continuing professional development needs of healthcare workers to be granted an authority to use scheduled medicines

3. whether the proposal should proceed to AHMAC for consideration and, if so, recommendations concerning:
   - the class of healthcare workers covered by the authority
- the scheduled medicine or class of scheduled medicines
- the nature of the authority that should be conferred under state/territory legislation (obtain, possess, administer, prescribe, sell, supply)
- any additional controls needed, such as clinical or other health service protocols or shared care arrangements, and at what level these controls should be exercised.

**Step 5: Decision**

Following receipt of advice from its Scheduled Medicines Subcommittee, the HWPC may progress the proposal to AHMAC with recommendations for reform. After considering this advice, AHMAC may:

- support the terms of the proposed nationally-consistent scheduled medicines authority
- request further information from the lead jurisdiction or another body prior in order to make a decision
- advise the lead jurisdiction that the proposed nationally-consistent scheduled medicines authority is not supported and outline the reasons why.

AHMAC may make a recommendation to the COAG Health Council about any changes required to state and territory drugs and poisons legislation to give effect to the proposed nationally-consistent scheduled medicines authority.

In approving the terms of a new or amended nationally-consistent scheduled medicine authority, the COAG Health Council should consider whether:

- the proposal is compatible with *Quality Use of Medicines, a key objective of the National Medicines Policy*
- there has been sufficient consultation with key stakeholders during development of the proposal, an appropriate range of experts has been consulted and any dissenting views have been canvassed and responded to
- a cross-profession perspective has been applied in the development of the proposal, that is, the proposal complies with the *Health Professionals Prescribing Pathway* (HPPP) and, as far as practicable, reflects consistency across professions with respect to: setting qualification requirements; clinical practice standards and guidelines; training and curriculum; and systems support for quality use of scheduled medicines
- the COAG best practice regulation requirements have been met.

Following COAG Health Council approval, each Minister is expected to use their best endeavours to give effect to the decision and to confer the necessary authorities under the respective state or territory laws. This may require changes to relevant legislation or administrative orders.
**Attachment 1: Acronyms and abbreviations**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHMAC</td>
<td>Australian Health Ministers’ Advisory Council</td>
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<td>AHPRA</td>
<td>Australian Health Practitioner Regulation Agency</td>
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<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
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<tr>
<td>COAG Guidelines</td>
<td>Council of Australian Governments <em>Best Practice Regulation: A Guide For Ministerial Councils and National Standard Setting Bodies, October 2007</em></td>
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<tr>
<td>HPPP</td>
<td>Health Professionals Prescribing Pathway</td>
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<tr>
<td>HWPC</td>
<td>Health Workforce Principal Committee</td>
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<td>Ministerial Council</td>
<td>Australian Health Workforce Ministerial Council</td>
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<td>National Law</td>
<td><em>Health Practitioner Regulation National Law Act</em></td>
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<tr>
<td>OBPR</td>
<td>Office of Best Practice Regulation</td>
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<td>RIS</td>
<td>Regulation Impact Statement</td>
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</table>
Attachment 2: Process for assessing proposals for nationally-consistent scheduled medicines authorities for the unregistered health professions

Step 1: Preliminary consideration
A sponsoring jurisdiction submits a proposal to the Health Workforce Principal Committee (HWPC) for preliminary consideration. HWPC provides advice on the proposal to the Australian Health Ministers' Advisory Council (AHMAC). AHMAC may decide that a submission for joint consideration be brought forward and appoint a lead jurisdiction to progress the work.

Step 2: Public consultation
The lead jurisdiction seeks advice from the Office of Best Practice Regulation on whether a Regulation Impact Statement (RIS) is required:
- If a RIS is required, a Consultation RIS and national consultation are undertaken in accordance with the Council of Australian Governments Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies, October 2007
- If a RIS is not required, the lead jurisdiction conducts any necessary research and consultation.

Step 3: Submission development
The lead jurisdiction prepares a submission for nationally-consistent scheduled medicines authorities or change to an existing authority for a class of healthcare worker.

Step 4: Submission assessment
The lead jurisdiction submits the proposal to HWPC for consideration. The submission is referred to the Scheduled Medicines Subcommittee of HWPC for advice.

Step 5: Decision
HWPC may refer the proposal to AHMAC with recommendations for reform. After considering HWPC’s advice, AHMAC may decide to support the proposal and recommend to the COAG Health Council any changes required to state and territory drugs and poisons legislation to give effect to the proposed nationally-consistent scheduled medicines authorities. The COAG Health Council may then approve the new or amended nationally-consistent scheduled medicine authority.

States and territories use best endeavours to give effect to the decision
Attachment 3: Submission guidelines
Australian Health Ministers’ Advisory Council
Scheduled medicines authorities for the unregistered health professions

A submission to the Ministerial Council for consideration of a proposal for nationally-consistent scheduled medicines use by a class of healthcare worker should address the matters outlined below.

1. Purpose of submission

1.1 Identify what the Ministerial Council is being asked to support and whether the proposal is seeking Ministerial Council support for i) a nationally-consistent scheduled medicines authority for a class of healthcare worker or ii) to vary an existing scheduled medicines authority.

1.2 If the submission is seeking to vary the terms of an existing nationally-consistent authority (for example, a change from a list of drugs to a list of classes of drugs), identify the current arrangements and the nature of the amendment sought.

2. Overview of proposal

2.1 Outline: the rationale for the proposal; the service need that is intended to be met by the scheduled medicines authorised healthcare workers; how this service need is currently being met; and any changes in circumstances or context that have prompted the proposal.

2.2 Outline what the Ministerial Council is requested to support, that is:

- the class of healthcare worker to which the nationally-consistent authority is proposed to be available
- the nature of the proposed authority, that is, to administer, supply or prescribe scheduled medicines
- boundaries or limits of the proposed authority, for example:
  - the relevant schedules
  - a specified scope of practice (if applicable)
  - a specified type of health facility approved by XXXX (specify position of person who is to approve) (if applicable)
  - an approved list of drugs or list of classes of drugs (if applicable)
  - approved drug therapy protocols or other health service protocols (if applicable)
  - a shared care protocol, health service protocol or standing order (if applicable).
3. Legislative arrangements

3.1 Specify the current legislative arrangements that apply under state and territory drugs and poisons legislation for authorising the class of healthcare worker to use scheduled medicines, particularly:
   - how the class of healthcare worker is identified under the relevant law of each jurisdiction (if applicable)
   - what the class of healthcare worker is currently authorised to do in each jurisdiction with respect to the use of scheduled medicines (if applicable).

4. Details of proposal

4.1 Describe the existing general scope of practice of the profession (or, where relevant, the class of healthcare worker within the profession) and the limits of this scope of practice, including how scheduled medicines are currently used.

4.2 Describe the service need that is intended to be met by the authorised healthcare workers and the treatment settings within which they work.

4.3 If the proposed nationally-consistent authority is to apply differentially to a number of classes of healthcare worker within a profession, identify these classes of healthcare worker separately and outline how these groupings are identified and labelled, that is, the taxonomy or method of categorisation and the rationale for this.

4.4 Identify the list of scheduled medicines or standard classes of scheduled medicine for which the nationally-consistent authority is being sought. Medicines should be identified in a manner that is consistent with the current Poisons Standard under the *Therapeutic Goods Act 1989* (Cth). If the proposal relates to more than one class of healthcare worker, define the list/classes of medicine for each class of healthcare worker, and identify if only certain preparations or presentations are applicable for specific scheduled medicines or classes of scheduled medicines.

4.5 Define for each class of healthcare worker any proposed limits on the use of scheduled medicines included in the list.

4.6 Describe expected changes, if the application were to be approved, to the scope of practice within each type of relevant setting.

4.7 Identify any precedents that exist within participating jurisdictions, or internationally, for the proposed extended use of scheduled medicines, and provide a summary of the results of any evaluation or research that has been undertaken in relation to these precedents.

4.8 Outline any risks associated with the proposal and how they are intended to be managed. Include, for example:
   - a summary of the available research that documents known risks associated with the proposed extended use of scheduled medicines for each class of healthcare worker
   - the potential risks associated with multiple prescribers, such as where patient comorbidities may be triggered or exacerbated in response to drug interactions
   - non-clinical risks such as acceptance of a proposed change in practice by other stakeholders or impact on the viability of other health practitioners
   - the circumstances (if any) in which it is appropriate to prescribe only in a shared care arrangement with the primary healthcare provider in relation to a comorbidity or comorbidities.

4.9 Summarise the benefits associated with the proposed change (for instance, anticipated improvements in safety, quality, efficiency, or efficacy of service delivery)
and identify the extent of work done to document these benefits (for example, for patients/consumers, for healthcare workers or service managers).

4.10 Identify the extent of work done to weigh the risks and benefits of the extended use of the scheduled medicines.

4.11 Summarise the reasons why the proposed extended use of scheduled medicines is considered safe, effective and appropriate for use by the class of health care worker in the settings proposed.

5. Training arrangements

5.1 Describe the proposed training and clinical supervision required for the nationally-consistent authority, and how the training is proposed to be delivered: undergraduate/postgraduate and single/multiple site.

5.2 Describe the proposed process (including consultation with, and input from, experts in the use of scheduled medicines in the field) for establishing or extending/varying the programs of training (both didactic and clinical).

5.3 Describe how the proposed training curriculum meets the National Prescribing Service MedicineWise Prescribing Competency Framework.

5.4 Describe how the proposed training curriculum will ensure that healthcare workers are competent to deal with any adverse event associated with the administration of a scheduled medicine.

5.5 Describe the proposed accreditation arrangements that will apply to programs that qualify the class of healthcare worker for the proposed nationally-consistent authority.

5.6 In the case of a change to an existing Ministerial Council decision, specify the additional training/retraining and/or supervision requirements (if any) that will apply to existing authorised healthcare workers to ensure they are competent for the expanded scope of practice.

5.7 Describe the continuing professional development requirements that will apply to healthcare workers in order to renew the proposed scheduled medicines authority, and how compliance with continuing professional development will be monitored to ensure ongoing competence.

6. Administrative processes for authorisation

6.1 Outline the proposed authorisation process for new and existing healthcare workers and the proposed implementation plan for introduction of the new arrangements.

6.2 Outline how information on the authorisation that applies to classes of healthcare worker will be communicated to the public and other health practitioners.

6.3 Outline how information on the terms of the authority will be made publicly available.

6.4 Identify how assessment of individual applicants for authorisation will be rigorous, transparent, nationally consistent, fair and efficient.

6.5 Outline how applications for a nationally-consistent authority from overseas trained practitioners will be assessed.

6.6 Identify how refusal to grant an authority will be managed.

6.7 Identify any fees to be charged for granting an authority.

7. Standard setting and practice monitoring arrangements

7.1 Identify any guidelines, or proposed guidelines, that have been issued to support quality use of scheduled medicines by authorised healthcare workers, and outline changes made, or proposed, to existing guidelines and procedures.
7.2 Identify other national, state or territory guidelines that apply to an authorised healthcare worker’s practice, and how these will be communicated to applicants for authorisation, authorised persons, employers and consumers.

7.3 Identify how the principles of Quality Use of Medicines have been applied or adopted in the proposed arrangements, and how clinical guidelines have been applied so that the care available is equivalent regardless of the profession involved.

7.4 Outline the strategy for monitoring the safe and effective use of scheduled medicines by authorised healthcare workers, and for communication with authorised healthcare workers and their employers (where relevant).

7.5 Identify how poor practice with respect to use of scheduled medicines will be identified, and how this will be dealt with.

7.6 Outline how monitoring of compliance with conditions or notations placed on an authority (if any) will be managed.

8. Consultations undertaken

8.1 Outline stakeholders affected by the proposal.

8.2 Provide details of the consultations undertaken, including:

- who was consulted, when and how
- results of consultation and key issues raised
- nature of alternative or opposing views expressed
- how alternative or opposing views have been taken into account in the application and recommendation.

8.3 Provide a summary of research undertaken and experts consulted in developing the application.

8.4 Attach minutes of any expert committee advice on the proposal, and how issues raised or recommendations made by the expert committee have been addressed.