

## Australian Health Ministers' Advisory Council

### Guidance for National Boards: Applications to the Ministerial Council for approval of endorsements in relation to scheduled medicines under section 14 of the National Law

#### PURPOSE

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This document provides guidance to National Boards concerning the process for, and content of, an application to the Australian Health Workforce Ministerial Council (the Ministerial Council) for approval of the terms of an endorsement for scheduled medicines under section 14 of the *Health Practitioner Regulation National Law Act* (the National Law).

A National Board application may recommend Ministerial Council approval of the terms of a new scheduled medicines endorsement or amendment to the terms of an existing approval. A National Board may also use this process to bring forward for Ministerial Council consideration a proposal for a nationally-consistent scheduled medicine authority that is not subject to an endorsement process.<sup>1</sup>

The objectives of this guidance are to:

- ensure robust, evidence-informed development and assessment of proposals for the use of scheduled medicines
- promote the safe and effective use of scheduled medicines
- facilitate common standards across professions for training and clinical practice with respect to the use of scheduled medicines
- facilitate nationally-consistent, core scheduled medicines authorities to enable innovation in health service delivery.

#### TERMINOLOGY

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Each jurisdiction has its own terminology for the types of legal authorities that can be conferred on an individual.

The National Law captures this different terminology by referring to '**administer, obtain, possess, prescribe, sell, supply or use**'. In this guidance, the terms 'administer', 'supply' and 'prescribe' are defined and used as follows:

- to '**prescribe**' a medicine means to authorise the supply or administration of a medicine to a patient (for example, an optometrist who writes a prescription for a patient to be dispensed by a pharmacist is exercising their 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 a medicine, or personally observe its application or introduction, to the patient's body (for example, a podiatrist who personally applies a local anaesthetic to a patient's foot prior to undertaking a procedure is exercising their authority to administer).

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<sup>1</sup> For example, the scheduled medicines authorities conferred on nurse practitioners.

The terms 'obtain, possess and sell' should be given their ordinary dictionary meaning.

A '**scheduled medicine**' means a substance included in a schedule to the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

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

## **BACKGROUND**

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Under section 14 of the National Law, on recommendation of a National Board, the Ministerial Council is empowered to approve a National Board to endorse the registration of a practitioner 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.

Section 94 of the National Law then provides that a National Board may endorse the registration of a practitioner as qualified to use a scheduled medicine or class of scheduled medicines in accordance with an approval given by the Ministerial Council.

Under section 11 of the National Law, the Ministerial Council may provide policy direction to National Boards, including in relation to administrative processes for approval under section 14.

A Ministerial Council approval under section 14 is a '**regulatory instrument**' within the meaning of the *Council of Australian Governments Best Practice Regulation: A Guide for Ministerial Councils and National Standard Setting Bodies, October 2007* (the COAG Guidelines).

The COAG Guidelines set out the criteria and processes for regulatory assessment of proposed regulatory instruments. The Australian Government Department of Prime Minister and Cabinet's Office of Best Practice Regulation (OBPR) oversees these processes.

The COAG Guidelines state:

The Council of Australian Governments (COAG) has agreed that all governments will ensure that regulatory processes in their jurisdiction are consistent with the following principles:

1. establishing a case for action before addressing a problem;
2. a range of feasible policy options must be considered, including self-regulatory, co-regulatory and non-regulatory approaches, and their benefits and costs assessed;
3. adopting the option that generates the greatest net benefit for the community;
4. in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:
  - a) the benefits of the restrictions to the community as a whole outweigh the costs, and
  - b) the objectives of the regulation can only be achieved by restricting competition;

5. providing effective guidance to relevant regulators and regulated parties in order to ensure that the policy intent and expected compliance requirements of the regulation are clear;
6. ensuring that regulation remains relevant and effective over time;
7. consulting effectively with affected key stakeholders at all stages of the regulatory cycle; and
8. government action should be effective and proportional to the issue being addressed.

The following approval process incorporates the COAG best practice regulation requirements outlined above.

## **APPROVAL PROCESS**

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The approval process is set out in two parts:

- Part A sets out the matters that a National Board should address in making a recommendation to the Ministerial Council under section 14 of the National Law. These relate to approval of the terms of a new or amended scheduled medicines endorsement for a profession or class of health practitioners within a profession.
- Part B sets out how the Ministerial Council proposes to deal with a recommendation from a National Board under section 14.

A flow chat providing an overview of the approval process is provided at **Attachment 2**.

### **Part A: National Board application**

#### **Step 1: Proposal development and preliminary consultation**

A National Board develops a proposal for a new scheduled medicines endorsement or an amendment to an existing scheduled medicines endorsement. The proposal may be at the National Board's own initiative, or in response to representations from government/s, consumers or a professional association.

The National Board undertakes preliminary consultation on the proposal in accordance with this guidance and any relevant Australian Health Practitioner Regulation Agency (AHPRA) guidelines relating to consultation processes for the development of National Board standards, codes and guidelines.

#### *Preliminary consultation with an expert committee convened by the Australian Health Practitioner Regulation Agency and the National Boards*

Prior to proceeding to the Ministerial Council, a National Board proposal must be considered by an expert committee convened by AHPRA and the National Boards. The expert committee should comprise:

- core members
- co-opted members who bring relevant profession-specific and other clinical care expertise. This should include two jurisdictional nominees proposed by the Health Workforce Principal Committee (HWPC) (a standing committee of AHMAC, the Australian Health Ministers' Advisory Council).

Expert committee membership should comprise the following key skills, knowledge and attributes:

- expertise in applying medicines and poisons legislation
- expertise in jurisdictional processes

- expertise in workforce reform
- understanding of the competencies underpinning the act of prescribing (NPS MedicineWise)<sup>2</sup>
- expertise in the *Quality Use of Medicines*<sup>3</sup>
- expertise in the use and monitoring of scheduled medicines in the clinical setting
- ability to bring a cross-professional perspective
- ability to work constructively in a committee structure and participate in consensus-based decision making
- ability to undertake risk assessments to ensure public safety
- ability to balance the risks and benefits associated with the use scheduled medicines
- expertise in education relating to the therapeutic use of scheduled medicines
- experience in the supply and administration of scheduled medicines
- expertise in development of standards, guidelines and protocols to support practice change
- expertise in quality and safety in healthcare
- expertise in clinical care provision in the profession to which the proposal relates
- expertise in the education of the profession to which the proposal relates.

The expert committee's role is to advise the relevant National Boards on the use of scheduled medicines generally, and on matters relevant to a sponsoring National Board's proposal, including:

- the public health need, if any, addressed by the proposal
- the scheduled medicines or classes of scheduled medicines that are suitable for the class of health practitioner to administer, supply or prescribe
- the training and continuing competence requirements to support safe and effective use of scheduled medicines by the class of health practitioner
- the guidelines and other system supports required to ensure safe and effective use of scheduled medicines by the class of health practitioner
- any other implementation issues.

#### *Preliminary consultation with Office of Best Practice Regulation*

Prior to proceeding to public consultation, a National Board must seek advice from the OBPR on whether a Regulation Impact Statement (RIS) process is required.

A copy of the National Board's submission to the OBPR, and OBPR's response, should be forwarded to the HWPC chair for information.

#### *Preliminary consultation with jurisdictions*

Prior to proceeding to public consultation, a National Board must seek advice from the HWPC.

### **Step 2: Public consultation**

Following review of advice received during the preliminary consultation stage, if a National Board decides to proceed with the proposal, the Board prepares a consultation paper for public release.

<sup>2</sup> As set out in NPS: Better choices, Better health. *Competencies required to prescribe medicines: putting quality use of medicines into practice* (2012). Sydney

<sup>3</sup> Commonwealth of Australia, *The national strategy for quality use of medicines* (2002). Plain English edition, Canberra

If the OBPR has advised the National Board that a RIS process is required, the National Board:

- prepares the consultation paper in the form of a Consultation RIS and seeks OBPR confirmation that it meets COAG best practice regulation requirements
- publicly releases the paper
- conducts a national consultation in accordance with COAG best practice regulation requirements (see the COAG Guidelines for details) and relevant National Board consultation requirements.

If OBPR has advised that a RIS process is not required, the National Board proceeds with its usual consultation processes in accordance with relevant AHPRA guidelines.

### **Step 3: Application to Ministerial Council**

Following completion of the public consultation, the National Board prepares a submission to the Ministerial Council which 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 any dissenting views.

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

The National Board's covering letter applies to the Ministerial Council with a recommendation for approval under section 14(1) of the National Law for endorsement in relation to scheduled medicines.

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 is likely to require more detail than an application to vary the terms of an existing Ministerial Council approval.

### **Part B: Ministerial Council decision**

On receiving an application from a National Board under section 14 of the National Law, the chair of the Ministerial Council refers the application to AHMAC for advice.

AHMAC assesses the application and provides advice to the Ministerial Council. AHMAC may refer the matter to HWPC to seek advice from the Scheduled Medicines Subcommittee of HWPC.

In preparing its advice to the Ministerial Council, AHMAC considers:

1. whether the proposal development has been sufficiently rigorous and has complied with Ministerial Council requirements, 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 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*<sup>4</sup> and the *Quality Use of Medicines*
  - the process has complied with COAG best practice regulation requirements
2. whether the proposed regulatory and other quality control measures are considered sufficient to support safe and effective use of scheduled medicines, particularly with respect to:
    - curriculum, content and the standard of study programs 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 an endorsement for scheduled medicines or other scheduled medicines authority
    - any clinical guidelines and/or protocols required to support safe and effective prescribing practice or other scheduled medicines authority
    - continuing professional development of health practitioners to be granted an authority to use scheduled medicines.
  3. what recommendations should be made to the Ministerial Council as to the terms of an approval under section 14(2) of the National Law, including with respect to:
    - the class of health practitioners
    - 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 required, such as clinical or other health service protocols or shared care arrangements, and at what level these controls should be exercised (such as National Board; state/territory department; service delivery setting)
  4. whether Ministerial Council approval of the application (if granted) is consistent with the guiding principles and objectives of the National Law and any relevant state and territory legislation
  5. what steps should be recommended to give effect to Ministerial Council approval in an efficient manner and how the arrangements should be monitored and evaluated.

Following advice from AHMAC, the Ministerial Council may:

- decide to approve the terms of the scheduled medicines endorsement as recommended by the National Board
- request further information from the National Board or another body prior in order to make a decision
- advise the National Board that the scheduled medicines endorsement is not approved and outline the reasons why.

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<sup>4</sup> Department of Health and Ageing, *National medicines policy*, (2000) Canberra

In approving the terms of a new or amended scheduled medicines endorsement, the Ministerial Council should consider whether:

- the proposal is consistent with the objectives and guiding principles of the National Law and will meet standards for the safe and effective use of scheduled medicines
- 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)*<sup>5</sup> 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 Ministerial Council approval, each minister uses their best endeavours to give effect to the Ministerial Council-approved endorsement and to confer the necessary authorities under the respective state or territory laws. This may require changes to relevant legislation or administrative orders.

The sponsoring National Board takes the necessary administrative actions to give effect to the Ministerial Council approval, including:

- approving new or amended program accreditation standards
- approving changes to qualifications required for endorsement
- establishing or amending administrative arrangements, such as forms to receive and process applications for endorsement
- approving changes to guidelines or clinical protocols
- establishing mechanisms to evaluate the impact of the changed arrangements.

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<sup>5</sup> Health Workforce Australia, *Health professionals prescribing pathway (HPPP) Project. Final report (2013)*

## Attachment 1: Acronyms and abbreviations

AHMAC	Australian Health Ministers' Advisory Council
AHPRA	Australian Health Practitioner Regulation Agency
COAG	Council of Australian Governments
COAG Guidelines	Council of Australian Governments <i>Best Practice Regulation: A Guide For Ministerial Councils and National Standard Setting Bodies, October 2007</i>
HPPP	Health Professionals Prescribing Pathway
HWPC	Health Workforce Principal Committee
Ministerial Council	Australian Health Workforce Ministerial Council
National Law	<i>Health Practitioner Regulation National Law Act</i>
OBPR	Office of Best Practice Regulation
RIS	Regulation Impact Statement

**Attachment 2: Process for an application to the Ministerial Council for approval of the terms of a scheduled medicines endorsement under section 14 of the National Law**

**Part A: National Board application**

**Step 1: Proposal development and preliminary consultation**

National Board develops proposal and undertakes preliminary consultation with Australian Health Practitioner Regulation Agency (AHPRA) expert committee, Health Workforce Principal Committee, Office of Best Practice Regulation and any other relevant stakeholders.



**Step 2: Public consultation**

National Board undertakes public consultation:  
if a regulation impact statement (RIS) is required, Consultation RIS and national consultation undertaken in accordance with *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, consultation carried out in accordance with the AHPRA guidelines relating to consultation processes for the development of National Board standards, codes and guidelines.



**Step 3: Application to Ministerial Council**

National Board prepares and submits an application to the Ministerial Council in accordance with these guidelines, which includes a recommendation for approval under section 14(1) of the National Law for an endorsement in relation to scheduled medicines.

**Part B: Ministerial Council decision**

**Assessment of application**

Ministerial Council refers the application to the Australian Health Ministers' Advisory Council for advice.



**Decision**

Ministerial Council makes a decision on whether to approve the application or to request further information.



**Implementation of decision by states and territories and the National Board**

## **Attachment 3: Application guidelines for National Boards**

### **Section 14 approval of endorsement in relation to scheduled medicines**

#### **Australian Health Workforce Ministerial Council**

A National Board application to the Ministerial Council for approval under section 14 of the *Health Practitioner Regulation National Law Act* for endorsement in relation to scheduled medicines should address the matters outlined below. National Boards may need to seek the input of jurisdictions in addressing some aspects of the proposal.

#### **1. Purpose of submission**

- 1.1 Identify what the National Board is asking the Ministerial Council to approve, including whether the proposal is seeking Ministerial Council approval for the Board to grant a new scheduled medicines endorsement for the profession or to vary an existing scheduled medicine endorsement.
- 1.2 If the submission is seeking a variation to the terms of an existing Ministerial Council approval, for example, a change from a list of drugs to a list of classes of drugs, identify the scope of the approval that currently applies 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 endorsed health practitioners; 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 approve, that is:
  - the class of health practitioner to which the endorsement is proposed to be available
  - the nature of the proposed endorsement, that is, administration, supply or prescribing of scheduled medicines
  - the proposed boundaries or limits of the proposed endorsement, 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 health practitioner to use the scheduled medicines, particularly:
- how the class of health practitioner is identified under the relevant law of each jurisdiction (if applicable)
  - what the class of health practitioner 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 health practitioner within the profession) and the limits of this scope of practice, including how scheduled medicines are currently used.
- 4.2 Describe i) the service need that is intended to be met by endorsed and authorised health practitioners<sup>6</sup> and ii) the practice settings within which they work.
- 4.3 If the proposed endorsement is to apply differentially to a number of classes of health practitioner within a profession, identify these classes of health practitioner 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 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 health practitioner, define the list/classes of medicine for each class of health practitioners, 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 health practitioner any proposed limits on the use of scheduled medicines included on the list.
- 4.6 Describe the expected changes to the scope of practice, if the application were to be approved, 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 the risks associated with the proposal and how these risks are intended to be managed. Include, for example:
- a summary of the available research documenting known risks associated with the proposed extended use of scheduled medicines for each class of health practitioner
  - 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

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<sup>6</sup> The term 'endorsed' refers to a scheduled medicines endorsement placed on a practitioner's registration under section 94 of the National Law. The term 'authorised' is used to refer to the authorities conferred under state and territory drugs and poisons legislation to administer, supply or prescribe scheduled medicines and may or may not require a scheduled medicines endorsement.

- the circumstances (if any) in which it is appropriate to prescribe only in a shared care arrangement with the primary healthcare provider for the comorbidity or comorbidities.
- 4.9 Summarise the benefits associated with the proposed change (for instance anticipated improvements in safety, quality, efficiency, efficacy of service delivery), and identify the extent of work done to document these benefits (for example for patients/consumers, health practitioners or service managers).
  - 4.10 Identify the extent of work done to weigh the risks and benefits of the extended use of scheduled medicines.
  - 4.11 Summarise the reasons why the National Board considers the proposed extended use of scheduled medicines to be safe, effective and appropriate for the profession (or class of health practitioner within the profession) in the settings proposed.

## 5. Training arrangements

- 5.1 Describe the proposed training and clinical supervision required for an endorsement, and how the training is proposed to be delivered: undergraduate/postgraduate, single/multiple site.
- 5.2 Describe the proposed process (including the consultation with, and input from, experts in 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.<sup>7</sup>
- 5.4 Describe how the proposed training curriculum will ensure that health practitioners 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 health practitioners or a class of health practitioners for the proposed endorsement.
- 5.6 In the case of a change to an existing Ministerial Council approval, specify the additional training/retraining and/or supervision requirements (if any) that will apply to existing endorsed health practitioners to ensure they are competent for the expanded scope of practice.
- 5.7 Describe the continuing professional development requirements that will apply to health practitioners in order to renew the proposed scheduled medicines endorsement and how compliance with continuing professional development will be monitored to ensure ongoing competence.

## 6. Administrative processes for endorsement

- 6.1 Outline the proposed endorsement process for new and existing practitioners and the proposed implementation plan for introduction of the new arrangements.
- 6.2 Outline how information on the endorsements that apply to classes of health practitioner will be communicated to the public and other health practitioners.
- 6.3 Provide an extract (or sample) from the relevant register that shows how information on the terms of the endorsement will be made publicly available.
- 6.4 Outline how the National Board communicates, or proposes to communicate, its requirements to potential applicants for endorsement and existing endorsed health practitioners.

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<sup>7</sup> NPS: Better choices, *Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice* (2012). Sydney

- 6.5 Attach details of National Board policy or guidelines provided, or proposed to be provided, to individual applicants for endorsement, including the application form (or draft).
- 6.6 Identify how the National Board proposes to ensure that the assessment of individual applicants for endorsement is rigorous, transparent, nationally consistent, fair and efficient.
- 6.7 Outline how the National Board proposes to deal with applications for endorsement from overseas-trained practitioners, who do not hold approved qualifications, in order to assess the equivalence of their qualifications for scheduled medicines competencies.
- 6.8 Identify how the National Board manages or proposes to manage a refusal to endorse, or a decision to attach conditions to an endorsement.
- 6.9 Provide a copy of the proposed fee schedule for scheduled medicines endorsement.

## **7. Standard setting and practice monitoring arrangements**

- 7.1 Identify any guidelines, or proposed guidelines, issued to support quality use of scheduled medicines by endorsed health practitioners, and outline changes made, or proposed, to existing guidelines and procedures.
- 7.2 Identify other national, state or territory guidelines that apply to endorsed health practitioners' practice and how these will be communicated to applicants for endorsement, endorsed health practitioners, employers and consumers.
- 7.3 Identify how the principles of Quality Use of Medicines have been applied or adopted in the National Board's 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 National Board's strategy for monitoring the safe and effective use of scheduled medicines by endorsed health practitioners and for communication with endorsed health practitioners and their employers (where relevant).
- 7.5 Identify how the National Board expects to become aware of poor practice with respect to the use of scheduled medicines, and what procedures it has adopted, or proposes to adopt, to address instances of poor practice with respect to use of scheduled medicines.
- 7.6 Outline how the National Board proposes to monitor compliance with any conditions or notations placed on an endorsement.

## **8. Consultations undertaken**

- 8.1 Outline the stakeholders affected by the proposal.
- 8.2 Provide details of the consultations undertaken by the National Board 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 AHPRA's expert committee advice on the proposal and outline how any issues raised or recommendations made by the expert committee have been addressed by the National Board.