Aboriginal and Torres Strait Islander health practice
Chinese medicine
Chiropractic
Dental
Medical
Medical radiation practice
Nursing and Midwifery
Occupational therapy
Optometry
Osteopathy
Pharmacy
Physiotherapy
Podiatry
Psychology

Australian Health Practitioner Regulation Agency

Guide for National Boards

Guide for National Boards developing submissions under the Australian Health Ministers' Advisory Council's *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*

6 February 2018

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Glossary

AHMAC means the Australian Health Ministers Advisory Council, the advisory body of the COAG Health Council.

AHPRA means the Australian Health Practitioner Regulation Agency.

AHMAC guidance means the *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*. It is published on the AHPRA website.

COAG Best practice principles mean the principles outlined in the *Best practice regulation - A guide for ministerial councils and national standard setting bodies* published on the website of the Department of the Prime Minister and Cabinet.

Consultation process for National Boards means the consultation process undertaken by National Boards when developing registration standards and guidelines. It is published on the AHPRA website.

HPPP means the Health Professionals Prescribing Pathway developed by Health Workforce Australia and approved by Health Ministers in 2013.

Ministerial Council means the COAG Health Council comprising ministers of the governments of the participating jurisdictions and the Commonwealth with portfolio responsibility for health.

National Law means the Health Practitioner Regulation National Law Act, as in force in each state and territory.

National Scheme means the National Registration and Accreditation Scheme.

NPS Competencies means the competencies required to prescribe medicines as described in the NPS *MedicineWise Prescribing Competencies Framework*. The framework and competencies are available on the NPS MedicineWise website.

NPS MedicineWise Prescribing Competency Framework means the framework developed by the National Prescribing Service that describes the competencies that health professionals need to prescribe medicines judiciously, appropriately, safely, and effectively in the Australian healthcare system. The framework is available on the NPS MedicineWise website.

OBPR means the Australian Government Department of Prime Minister and Cabinet's *Office of Best Practice Regulation who oversee the Council of Australian Governments Best Practice Regulation: Guide for Ministerial Councils and National Standards Setting Bodies, October 2007*.

Quality Use of Medicines (QUM) means selecting management options wisely; choosing suitable medicines if a medicine is considered necessary; and using medicines safely and effectively. The full definition is in the National Strategy for Quality Use of Medicines.

Regulatory principles mean the Regulatory principles for the National Scheme.

RIS means regulatory impact statement.

Scheduled medicines means substances included in a schedule to the current Poisons Standard within the meaning of the *Therapeutic Goods Act 1989* (Cth).

About this guide

This guide has been developed for use by National Boards when developing a submission to the Ministerial Council seeking approval to endorse health practitioners under section 94 of the National Law or vary an existing endorsement. It provides information on how National Boards may meet the requirements of the Australian Health Ministers Advisory Council's *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* (the AHMAC guidance).

It describes the key stages in both developing the concept and the submission, ministerial approval process, implementation and monitoring. Different entities have different responsibilities at key stages. Key considerations, suggested activities, points of engagement and anticipated outcomes are described for each stage.

When does this guide need to be used?

This guide should be used when the AHMAC guidance applies, that is, when a National Board is developing a proposal for a new endorsement for scheduled medicines or to amend an existing endorsement.

This can be taken to mean to also include any proposed revisions to guidelines associated with an existing endorsement.

Note: This guide needs to be read in conjunction with the AHMAC guidance and other related material listed in this guide.

Governance and regulatory policy framework

The AHMAC guidance and other components and tools when considered together form a governance and policy framework. This supports a consistent, rigorous, and risk-based approach to the safe and effective use of scheduled medicines by registered health practitioners.

By viewing these different components as an overall framework, health practitioners and the National Boards that regulate them, recognise the complexity of the policy context that supports safe prescribing of scheduled medicines.

There are a number of different agencies responsible for each policy area. Some relate specifically to scheduled medicines, other components establish the broader regulatory context. Many of the components that form this framework are built around similar objectives and principles.

The framework is made up of:

- The AHMAC guidance
- the National Law
- regulatory policies including registration standards and guidelines
- accreditation standards
- *Regulatory principles for the National Scheme*
- health professions prescribing pathway
- *NPS MedicineWise Prescribing Competency Framework*, and
- *Quality use of Medicines*.

The core elements of these are summarised in *Appendix A* of this guide.

The AHMAC guidance

The AHMAC guidance sits at the heart of the framework. A copy of the guidance is available on the AHPRA website. It was developed for National Boards recommending Ministerial Council approval of a new or amended scheduled medicines endorsement.

The objectives of the AHMAC 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, and
- facilitate nationally-consistent, core scheduled medicines authorities to enable innovation in health service delivery.

Terminology

The AHMAC guidance includes definitions of common terms including:

- prescribe
- supply
- administer, and
- scheduled medicines.

Other terms such as 'obtain', 'possess', 'sell' and use' have not been defined but should be given their ordinary dictionary meaning. These were deliberately not defined by the working group that developed the AHMAC guidance because of variation across jurisdictions.

A National Board has the option under section 94 of the National Law to include these other terms in the scope of an endorsement. This is not limited by the fact that they are not listed in the AHMAC guidance.

Note: National Boards are advised to use the definitions of 'prescribe', 'supply' and 'administer', as defined in the AHMAC guidance in any registration standards and guidelines related to the endorsement.

A National Board may then define the other terms of 'obtain', 'possess', 'sell' or 'use', in the context of the applicable model if they intend to include them in the scope of an endorsement. These definitions should be listed in the registration standard. No single definition of these terms is included in this guide.

Structure of the AHMAC guidance

Section 14 of the National Law empowers Ministerial Council, on the recommendation of a National Board, to decide that the National Board may endorse the registration of a practitioner as qualified to use a scheduled medicine or class of scheduled medicines.

The AHMAC guidance outlines this process in two parts:

- part A sets out the matters that a National Board should address in making a recommendation, and
- part B sets out how the Ministerial Council proposes to deal with recommendation from a National Board.

Appendix 3 of the AHMAC guidance provides detail on what a National Board needs to include in the submission.

This guide focuses on helping National Boards address the matters outlined in part A of the AHMAC guidance.

It also provides a brief overview of the ministerial approval process and the possible outcomes of this process.

Using this guide

The development of a proposal for endorsement for scheduled medicines needs to be seen as a continuous policy cycle of development, implementation, monitoring and evaluation.

Each of the sections in *Figure 1* below represents a key stage in the process.

The stages are:

- concept development
- National Board submission preparation
- ministerial approval process
- implementation, and
- monitoring.

No two submissions developed under the AHMAC guidance will be the same as the context and scope of the endorsement will vary according to the profession, proposed model(s) of care, the schedules included, and the proposed healthcare setting(s).

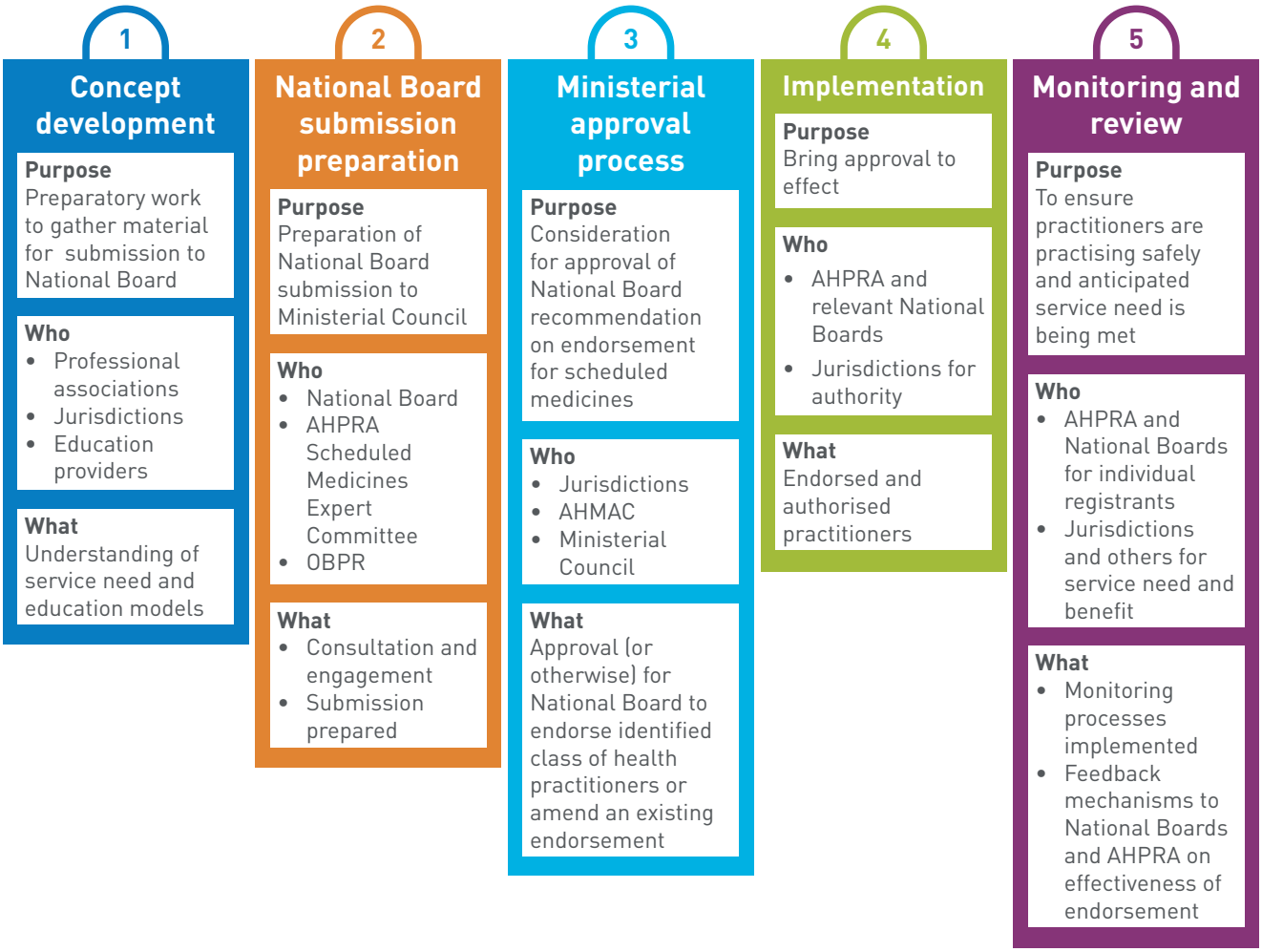
The level of detail in a submission will be commensurate with the scope of the proposed change. For example, an application for a new scheduled medicines endorsement is likely to need more detail than an application to vary the terms of an existing Ministerial Council approval. This guide is deliberately not prescriptive in the structure to accommodate this variance.

Each National Board submission, regardless of the scope of endorsement being recommended, needs to meet the requirements of the AHMAC guidance.

The key considerations and responsibilities, suggested activities, points of engagement and anticipated outcomes for each stage are outlined below.

No estimated timelines are provided for the completion of each stage, or the process as a whole, because of the many variables affecting the time from concept development through to implementation.

Figure 1: Summary of key stages



Stage 1: Concept development

The AHMAC guidance does not refer to this stage as a distinct stage. It is listed here to highlight the extent of the preparatory work that needs to be done before a National Board can properly assess and consult on the regulatory need to progress to seeking approval for an endorsement or an amendment to an existing one.

It is this stage that prepares the groundwork for a profession to integrate prescribing into its scope of practice. This stage is also critical if amendments to an existing endorsement are required.

Key responsibilities

A proposal to introduce an endorsement or amend an existing one may not be the National Board's own initiative. It may be initiated by government(s), consumers and/or professional associations.

Note: Any interested party needs to read the AHMAC guidance to understand the breadth and depth of information needed for National Boards to recommend a proposal for endorsement to the Ministerial Council.

Key engagements

The preparatory work at this concept stage requires collaboration across all interested groups:

- health service providers, including jurisdictions
- joint jurisdictional scheduled medicines committee
- professional associations
- individual practitioners
- education providers
- consumers
- accreditation councils, and
- National Boards.

Each of these groups needs to be engaged so the National Board has a solid foundation on which to build future work.

The National Board and AHPRA are in most cases at this stage the enablers and supporters of the work, not the 'doers'. They do need to be engaged at this stage. It is important to remember that it is the Ministerial Council that decides if a class of health practitioners are to be endorsed.

Key considerations

As mentioned in this guide the development of a concept may be initiated by the profession through the professional association or government/s or consumers. The following questions need to be considered by the party who is developing a concept. Any representation to a National Board would be expected to address these issues in some form.

It is the National Board's responsibility at the next stage to address these issues and consult on and assess the regulatory need for an endorsement or an amendment to an existing one before making a recommendation to the Ministerial Council.

By working through these issues at this stage, it is possible to understand the full extent of the effort needed and by whom, as well as the likely timelines.

Area of focus	Considerations
Value	*What is the service need that needs to be met?* *What alternative options have been considered?* *What are the perceived benefits associated with the proposed change? (anticipated improvements in safety, quality, and impact on consumers)* *What is the overall balance of cost-benefit of the proposal?* *How does it align with the COAG Best practice principles?*
Proposed model of prescribing	*What is the proposed model(s) of prescribing? (e.g. autonomous, under supervision, protocol)* *Is an endorsement needed for the model or could local governance arrangements establish it?* *What is the scope of endorsement needed to support this model(s)? (e.g. prescribe, supply, administer)*
Risk	*What are the risks associated with the proposed model(s) and how will they be managed?* *Are there any risks associated with patients not having access to services and medicines?* *Are there particular risks with the setting? Are there other practitioners in close proximity or is the practitioner practising in an isolated practice setting?* *Are there particular risks associated with the patient cohort?* *Are there particular risks associated with the scheduled medicines likely to be prescribed (e.g. schedule 8)?* *What is the risk-benefit ratio of the proposal?*

Area of focus	Considerations
Engagement with other health professionals	*How will the risk of multiple prescribers be managed?* *What systems are in place to support clear communication between practitioners involved in the patient's care?* *Is the profession currently linked into these systems? What will it take to engage?* *What is the likely perceived impact on other professions? Could this be perceived as competition? Is this competition going to add value to patients?* *National Boards will need to describe how these groups have been consulted and their views taken into consideration when developing their submission to Ministerial Council.*
Education	*What are the changes needed in the education of the profession?* *Do current programs prepare students to the level of competence required for the model?* *What are the gaps? What will it take to bridge the gap?* *What is the capacity of the system to absorb additional teaching?* *Will parts of the program need to be removed to accommodate any additional teaching?* *What is the model of education? Postgraduate or entry-level? Access for rural and remote students?* *Does all the profession need to be educated or just some?* *What other disciplines need to be involved in the teaching? How will they be engaged?* *What are the opportunities for multi-profession learning and clinical placements?* *What is the capacity/availability of clinical placement experience?* *Are there accreditation standards in place for the profession? Do they need to be developed?*
Readiness within the profession	*What is the willingness of individuals within the profession to expand their scope of practice into this area?* *Is it likely to affect some or all of the profession?* *What will the costs be to individuals? Cost of education vs remuneration once endorsed? Will there be a perceived value in return?*
Existing examples	*Are there any national or international models of prescribing that can be replicated within the profession? Note that this may not be in the same profession but in other professions in similar settings (e.g. emergency departments, primary care settings).* *What evidence is there of safe prescribing practice of this profession (or similar professions/models)?*

Suggested activities

The following activities and work may support the development of the concept. These are suggestions only as there may be other activities that a profession may use when developing a concept. What is needed will be commensurate with the scope of the proposed change:

- activities that may support understanding and collaboration across the different sectors:
  - stakeholder forums and workshops
  - survey of professional association members
  - discussions with state and territory health departments, and
  - discussions with other related and relevant disciplines within the education sector
- business case(s) that assess the value, impact, and risk of different options, and
- research activities that support an understanding of what has gone before.

Anticipated outcomes

For new endorsements, at the end of this concept development stage there should be an increased understanding amongst the profession, governments, consumers, and the education sector of the need and value of the profession incorporating or integrating prescribing into their scope of practice. Interested parties should be in a position to make a clear representation to the National Board.

It is possible that at the end of this concept development stage it is apparent that there is limited value in a profession moving to incorporate or integrate prescribing in their scope of practice as the costs and risks outweigh the benefit at this point in time.

The sequence of work that needs to be completed and anticipated timelines before a National Board can consult on and assess the regulatory need for an endorsement or an amendment to an existing one should be clear. Some of this work will be well underway or completed before any representation is made to a National Board.

Stage 2: National Board submission preparation

National Boards may have initiated a concept for a new endorsement or variation to an existing one (refer to concept development stage in this guide) or most likely other parties will make a representation to a National Board on the need for the endorsement or the variation.

Note: It is important to remember what an endorsement does. It is an indication that the health practitioner is qualified to use scheduled medicines as described in the endorsement. It does not authorise the practitioner to use the scheduled medicines. This authorisation is provided by, or under, state and territory drugs and poisons legislation.

Key responsibilities

The National Board is responsible for consulting on and assessing the regulatory need for an endorsement or variation to an existing endorsement and then developing a submission recommending the endorsement or variation to Ministerial Council for approval under section 14 of the National Law. The National Board needs to also ask Ministerial Council to approve at the same time any associated registration standard under section 12 of the National Law.

In addition to meeting the requirements of the AHMAC guidance, a National Board must also consider any proposal against the:

- objectives and guiding principles of the National Scheme
- *Regulatory principles for the National Scheme*, and
- *COAG Principles of Best Practice Regulation*.

The National Board needs to develop a registration standard and any associated guidelines to describe the scope of the endorsement and the expected behaviours of the endorsed practitioner. The National Board will consult on these consistent with the Consultation process for National Boards.

Key engagements

Stakeholders

The development of a submission to recommend an endorsement needs early and regular engagement and consultation with a range of stakeholders. This includes:

- health service providers, including jurisdictions
- joint jurisdictional scheduled medicines committee
- professional associations
- individual practitioners
- education providers
- accreditation authorities, and
- consumers.

Expert committee

The AHMAC guidance requires AHPRA and the National Boards to establish an expert committee for scheduled medicines. The terms of reference (TOR) for this committee are available on AHPRA website. The process for engagement with National Boards is at *Appendix B*.

Office of Best Practice Regulation (OBPR)

National Boards need to engage with the OBPR during the preliminary consultation stage for an assessment of the regulatory impact of any regulatory proposal. OBPR may need the National Board to develop a consultation RIS and a decision RIS. AHPRA will advise any National Board how best to meet this requirement on a case by case basis.

Key considerations

In addition to the key principles listed above and the key considerations listed in the concept development stage of this guide, National Boards need to focus on the following areas.

Area of focus	Considerations
Scope of endorsement	*The nature of any clinical governance arrangements required to support the endorsed practitioner (e.g. drug therapy protocols, shared care arrangements) and who is responsible for developing these if new, or what is already in place (e.g. therapeutic guidelines)* *How does the proposal support the Quality Use of Medicines?* *Does the endorsement accommodate the different models that may be required in the one profession?* *Is the proposed scope of the endorsement appropriate for the profession? E.g. prescribe, supply, administer etc.* *Does the proposed scope of the endorsement allow it to remain relevant over time?*
Education	*How will the education model support a range of prescribing models and practices over time?* *How will the education model enable registered practitioners to become endorsed?* *Have appropriate accreditation standards been developed and approved or are they being developed?*
Cross-professional approach	*The HPPP provides a model for consistency, where practicable, across professions with regard to setting qualifications, clinical practice standards and guidelines, education and curriculum, and systems to support the quality use of medicines.* *How does the Board's proposal support this approach?* *Has the Board adopted the template registration standard and guidelines where practicable?*

Area of focus	Considerations
Legislative arrangements	*What current legislative arrangements exist to authorise the endorsed practitioner to use and prescribe the scheduled medicines within the scope of the endorsement?* *What needs to change? (Noting that this is the responsibility of the government in each jurisdiction)*
Continuing professional development (CPD) and recency of practice (ROP) requirements	*Each National Board establishes a registration standard to describe the CPD and ROP requirements for the profession. These are described in generally broad terms to accommodate the range of practice across the whole of the profession.* *Practitioners, including endorsed practitioners, are expected to meet the requirements as they apply to their individual scope of practice.* *Do the risks associated with the model of endorsement require additional CPD requirements (e.g. cardiopulmonary resuscitation (CPR) requirements for endorsed practitioners in primary care settings being able to respond to adverse events)?* *If additional requirements are needed, are they currently listed in the CPD or ROP registration standards or do they need to be amended? If so, consideration needs to be given to the timing of these amendments so that the revised standard(s) can be in place for the implementation of the registration standard for endorsement.*
Implementation	*What are the associated fees for endorsement?* *What are the internal system and process changes needed for AHPRA to manage applications for endorsement and renewal of endorsement?* *What, if any, profession specific expertise will be needed to assess applications? What governance structures need to support these?* *What is the communication strategy to support the implementation? Who are the interested and impacted stakeholders, including consumers?* *What if any transition arrangements need to be put in place?* *What are the anticipated timelines for implementation?* *If it is anticipated that the preparatory work required to support the implementation is not going to be complete by the time Ministerial Council makes its decision, then the National Board needs to include a later date in the registration standard.* *This is to satisfy the requirements of section 40(4) of the National Law.*

Area of focus	Considerations
Monitoring	*How will the Board monitor the safe use of scheduled medicines by endorsed practitioners?* *What review period for the registration standards would be reasonable for the endorsement? This is something that National Boards would consult on. This review period will be influenced by the nature of the changes (i.e. whether it is a new endorsement or amended)* *Although it is not the responsibility of the Board to ensure the service need is met, who are the stakeholders the Board needs to engage with to get feedback on the adequacy and effectiveness of the endorsement to ensure the endorsement remains relevant overtime?*

Suggested activities

National Boards need to carry out a range of activities, often beyond the normal levels, to be in a position to meet the requirements of the AHMAC guidance, including:

- engagement:
  - AHPRA Scheduled Medicines Expert Committee
  - establishing a working group for the duration of the development work
  - conducting stakeholder forums to assess the understanding and readiness of the profession and education sector
  - liaison with the accreditation authority for the profession to ensure accreditation standards are in place and approved programs of study available, and
  - with jurisdictions to understand governments' support for any recommendation coming forward (see information on jurisdictions in ministerial approval section of this guide)
- development of registration standard and associated guidelines:
  - template registration standards and guidelines have been developed to support consistency in structure and content of the regulatory instruments that enable endorsements for scheduled medicines. These template documents are only indicative and may be adjusted by National Boards (refer to *Appendices C and D*).
- consultation on proposal and associated registration standard and guidelines:
  - in line with the Consultation process for National Boards, and
  - in the form of a consultation RIS (if needed by OBPR)
- approval of any associated guidelines under section 39 of the National Law
- development of a submission for Ministerial Council that addresses the requirements of the AHMAC guidance and describes how it aligns with the objectives and principles outlined above.

Anticipated outcomes

At the end of this stage the National Board should be in a position to describe:

- the demonstrated service need and considered options
- the class of health practitioner the endorsement applies to
- the scope of a new endorsement or nature of amendment sought to an existing endorsement
- the education pathways for endorsement, including those for overseas-trained practitioners with relevant qualifications and experience
- any supervised practice requirements (this may or may not be in addition to supervised practice carried out in the qualification leading to endorsement)
- the risks associated with the endorsement and how these have been minimised
- any specific CPD and ROP requirements (if any) as described in the relevant registration standards
- how the views of stakeholders were gathered and considered in the development of the recommendation
- a high-level implementation strategy for the endorsement including the communications plan, and
- how National Boards will monitor the safe practice of endorsed practitioners.

This should be reflected in:

- the cover letter to Ministerial Council
- a decision RIS (if needed by OBPR)
- a registration standard recommended to Ministerial Council, and
- guidelines associated with the endorsement approved by the National Boards.

Further detail about the matters that need to be addressed in the National Board submission to Ministerial Council is set out in Attachment 3 to the AHMAC guidance.

Stage 3: Ministerial approval process

By the end of the concept development and proposal drafting stages, National Boards should be in a position to meet the requirements of the AHMAC guidance and make a recommendation to the Ministerial Council for approval.

The usual established government engagement and approval processes for approval of National Board registration standards apply to submissions for endorsement for scheduled medicines with some additional considerations.

Key responsibilities

Under section 14 of the National Law, National Boards make recommendations to the Ministerial Council to decide if the National Board can endorse the registration of practitioners as being qualified to use scheduled medicines in the scope of the endorsement. This may apply when changes to an existing endorsement are proposed.

Ministerial Council may approve the associated registration standard for the endorsement under section 12 of the National Law.

AHMAC assesses the application and provides advice to the Ministerial Council.

Key engagements

In addition to the usual engagement process through the jurisdictions, the National Boards may need to engage with the joint jurisdictional scheduled medicines committee established under Part B of the AHMAC guidance.

Key considerations

Part B of the AHMAC guidance lists the considerations of AHMAC when preparing its advice to the Ministerial Council. These align with the requirements of the National Boards under the guidance.

Key activities

The usual government approval processes apply for applications for endorsement for scheduled medicines.

If the Ministerial Council decides to approve a new endorsement or vary an existing one, each Minister uses their best endeavours to give effect to the Ministerial Council-approved endorsement by conferring the necessary authorities under the respective state or territory laws. This may require changes to relevant legislation or administrative orders.

Anticipated outcomes

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 in order to make a decision, and/or
- advise the National Board that the scheduled medicines endorsement is not approved and outline the reasons why.

This advice will be provided in writing to the National Board.

If the Ministerial Council requests further information or advises that the endorsement is not approved, then the National Board may need to return to an earlier stage in this cycle – potentially the concept development stage.

Stage 4: Implementation

If the endorsement is approved, the National Board needs to work with AHPRA to take the necessary administrative actions to give effect to the Ministerial Council approval.

National Boards are expected to provide a high level overview of the implementation strategy and associated communications plan. This needs to be described in more detail if the endorsement is approved.

Key engagements

The implementation plan should identify the key internal and external stakeholders that the National Board needs to work with and inform of any changes. At a minimum this would include:

- individual registrants
- education providers
- the accreditation authority
- state and territory governments
- relevant health service providers
- professional associations
- AHPRA, and
- relevant delegated decision-making bodies.

Key responsibilities

The National Board and AHPRA need to work together to ensure the necessary governance structures, resources, systems and processes and communication material are in place to support the implementation of the endorsement in the event the Ministerial Council approval is granted.

National Boards and AHPRA do not have responsibility for:

- giving effect to the Ministerial Council-approved endorsement by conferring the necessary authorities under the respective state or territory laws
- developing the necessary health system requirements, including local level clinical governance structures to enable the endorsed and authorised practitioner to develop, or
- integrating endorsed and authorised practitioners into health funding systems including the Pharmaceutical Benefit Scheme (PBS) and Medicare Benefits Schedules (MBS).

Key considerations

As part of the submission to the Ministerial Council, National Boards need to provide a high-level overview of the implementation strategy and communication plan. The key considerations to be considered are listed in the National Board submission preparation section of this guide.

When the Ministerial Council approves a registration standard, it comes into effect on the day of the approval or a later date stated in the registration standard. National Boards therefore need to be cognisant of the anticipated timelines for implementation. If the preparatory work is not going to be completed in time for the Ministerial Council approval, then the Board needs to have included a later date in the registration standard.

This later date is then the date the registration standard takes effect.

Consideration also needs to be given to coordinating the implementation of revised CPD and ROP standards if applicable.

Suggested activities

National Boards and AHPRA need to complete a range of activities to support the implementation of the endorsement across the key areas of:

- governance structures to support decision-making including delegated decision-makers
- resources needed to support assessment of applications including access to profession specific advice if required
- system and process requirements to support the implementation, and
- communication material targeted at:
  - individual registrants applying for endorsement
  - endorsed practitioners
  - employers of endorsed and non-endorsed practitioners
  - jurisdictions
  - professional indemnity insurance (PII) providers, and
  - consumers.

Each of these groups (except for endorsed practitioners if the endorsement is new) will have had the opportunity to contribute to or have been directly engaged at different stages of the consultation process.

Anticipated outcomes

Following the implementation of the endorsement it is expected that:

- the systems, processes and resources are in place to support the effective, efficient and transparent processing of applications for endorsement
- applicants for endorsement understand what is required of them
- endorsed registrants understand what is expected of them
- health service providers understand requirements for endorsement (noting that the information published on the concept design stage provides background for services looking to implement a new service model), and
- consumers understand both what National Boards require of an endorsed practitioner, how to identify an endorsed practitioner and how they can make a complaint if they have any issues.

Stage 5: Monitoring and review

The final stage in the development and implementation of an endorsement is monitoring of the effectiveness of the endorsement, the safe practice of endorsed practitioners and the relevance of the standards over time.

Key responsibilities

Under the AHMAC guidance, National Boards and AHPRA are responsible for monitoring the safe and effective use of scheduled medicines by endorsed practitioners.

National Boards and AHPRA are not responsible for monitoring the broader system and service level impacts of the implementation of the endorsement. They would look to engage with stakeholders responsible for this monitoring to inform any review of the scope of an endorsement to ensure that the endorsement remains relevant and effective over time.

National Boards and AHPRA will liaise with the relevant state and territory drugs and poisons department to support compliance with local authorising legislation.

Key considerations

The processes in place in the National Scheme for the management of complaints against health practitioners apply equally to endorsed health practitioners. The powers for the decisions available to National Boards are described in the National Law. This includes the powers available to a National Board to monitor conditions.

National Boards and AHPRA need to ensure that there is access to the expertise needed to properly investigate the practice of an endorsed practitioner. This may involve engaging with professions other than the profession of the endorsed practitioner.

In addition to managing complaints against individual practitioners, National Boards and AHPRA can establish reporting mechanisms so that any emerging trends across the cohort of endorsed practitioners can be identified. This creates opportunities to monitor for the safe practise across all professions with an endorsement.

The *COAG Best practice principles* require National Boards to ensure the endorsement remains effective and relevant overtime.

Suggested activities

National Boards and AHPRA need to:

- ensure that the management of complaints against endorsed practitioners is integrated into established processes
- establish governance structures needed to support access to the necessary expertise to investigate complaints against endorsed health practitioners
- establish reporting mechanisms to monitor the safe use of the scheduled medicines by a cohort of endorsed practitioners in the profession and across professions
- liaise with state and territory drugs and poisons units to support compliance with authorising legislation and regulations
- establish a review date for the endorsement, and
- engage with relevant stakeholders to review the effectiveness of the endorsement overtime.

Anticipated outcomes

Through the establishment of the required processes, systems and engagement it is anticipated that National Boards and AHPRA can monitor:

- the safe practice of individual practitioners and cohorts of endorsed practitioners in and across professions, and
- the relevance and effectiveness of the endorsement over time.

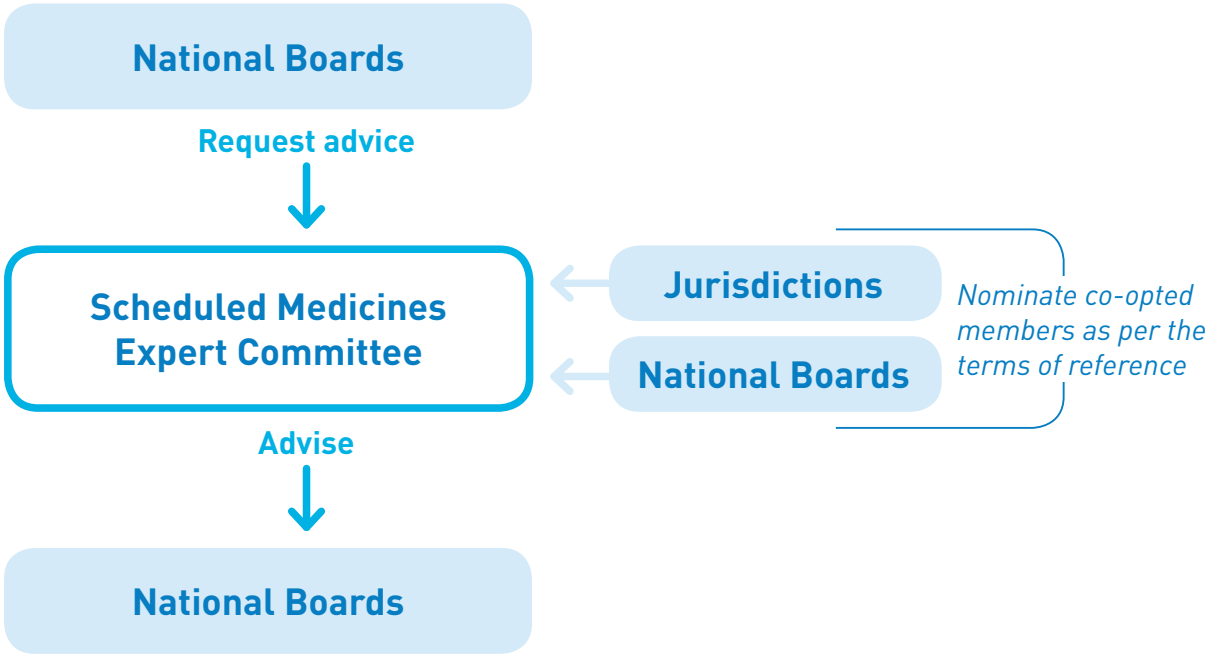
Appendix A: Summary of governance and policy framework

The following table summarises the key documents that when considered together form a governance and policy framework to support the safe and effective use of scheduled medicines by registered health practitioners. The AHMAC guidance is at the heart of this framework.

Document	Approver/Owner	Purpose	Principles/Objectives
AHMAC guidance	Australian Health Ministers' Advisory Council (AHMAC)	The AHMAC guidance provides guidance to National Boards concerning the process for, and content of, an application to the Ministerial Council for approval of the terms of an endorsement for scheduled medicines under section 14 of the National Law.	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, and • facilitate nationally-consistent core scheduled medicines authorities to enable innovation in health service delivery.
National Law	State and territory parliaments	Establishes the National Scheme.	Section 3 of the National Law outlines the objectives and guiding principles of the National Scheme.
Regulatory policies including registration standards and guidelines	National Board develops and Ministerial Council approves registration standards National Boards develop and approve codes and guidelines	Registration standards for endorsement for scheduled medicines describe the education pathways, the scope of an endorsement approved by Ministerial Council and any other requirements for endorsement. Other registration standards developed by the National Board may link to the endorsement, including standards for CPD and ROP. Guidelines for use of scheduled medicines approved by National Boards provide guidance to endorsed practitioners.	Must align with the principles and objectives of the National Scheme.
Accreditation standards	Developed by accreditation authority for the profession Approved by the National Board for the profession	It is the standard used to assess whether a program of study, and the education provider that provides the program of study, provide those who complete the program with the knowledge, skills and professional attributes necessary to practise the profession in Australia. In this case relating to the endorsement.	Must align with that of the National Scheme.
Regulatory principles for the National Scheme	National Boards and AHPRA	The regulatory principles underpin the work of the National Boards' and AHPRA in regulating Australia's health practitioners in the public interest. They shape AHPRA and the National Boards' thinking about regulatory decision-making and have been designed to encourage a responsive, risk-based approach to regulation across all professions.	As listed. Note that they apply to all areas of National Boards' and AHPRA work including the development of regulatory policy.

Document	Approver/Owner	Purpose	Principles/Objectives
Health professionals prescribing pathway (HPPP)	Standing Council on Health	Developed by the former Health Work Australia to provide a nationally consistent approach to the prescribing of medicines by health professionals registered under the National Scheme other than medical practitioners.	The HPPP is based on the following principles: • The health, wellbeing and safety of the person taking a medicine must be maintained at all times. • Health professionals who prescribe are accountable for their actions. • Health professionals authorised to prescribe, carry out prescribing in their individual and professional scope of practice and maintain the level of professional competence and ethical standards (including the separation of commercial interests) expected of their profession. • Health professionals who prescribe commit to the safe and effective use of medicines as described by the *National Medicines Policy*. • Health professionals involved in prescribing work in partnership with the person taking a medicine, their carers and other members of the healthcare team.
NPS MedicineWise Prescribing Competencies Framework	NPS MedicineWise	The Prescribing Competencies Framework describes the competencies that health professionals need to prescribe medicines judiciously, appropriately, safely and effectively in the Australian healthcare system.	This *Prescribing Competencies Framework* contributes to achieving the quality use of medicines objective of the National Medicines Policy by describing the competencies needed to prescribe medicines judiciously, appropriately, safely and effectively in the Australian healthcare system. The competencies describe the knowledge, skills and behaviours of practitioners who perform their work to an acceptable standard across the range of contexts in which they are reasonably expected to practice. The framework describes foundation competencies for autonomous prescribing. It should be used in association with other competency frameworks and standards developed for individual professions. This *Prescribing Competencies Framework* is not a curriculum; however, it provides a useful guide for the development or revision of prescribing curricula.
Quality use of medicines	Department of Health	Quality Use of Medicines (QUM) is one of the central objectives of the National Medicines Policy.	QUM means: • selecting management options wisely • choosing suitable medicines if a medicine is considered necessary, and • using medicines safely and effectively. The goal of the National Strategy for QUM is to make the best possible use of medicines to improve health outcomes for all Australians.

Appendix B: Process for engagement for Scheduled Medicines Expert Committee



Appendix C: Template registration standard

Text highlighted should be modified depending on the profession, the education and training, the class of practitioner and scope of the endorsement.

Registration standard: Endorsement for scheduled medicines

Effective from [date]

This registration standard describes how a [name of profession] can qualify for endorsement for scheduled medicines, the scope of this endorsement and what the [name of National Board] expects of practitioners with this type of endorsement.

Does this standard apply to me?

This registration standard applies to [class of practitioner]:

- applying[1] for endorsement for scheduled medicines, and/or
- whose registration is endorsed for scheduled medicines.

Scope of endorsement

See Note 1

An endorsed [class of practitioner] is qualified to [administer, obtain, possess, prescribe, sell, supply and/or use (delete as applicable)] [scheduled medicines or class of scheduled medicines (e.g. schedule and/or route)] for the purposes of practice of [name of profession].

How can I qualify for endorsement?

See Note 2

You can qualify for endorsement through one of the following pathways:

- holding an approved qualification that includes the required therapeutic components
- holding an approved qualification that includes the required therapeutic components and completing a period of supervised practice required by the Board, and
- another qualification that the Board assesses as substantially equivalent to, or based on similar competencies to, an approved qualification that includes the required therapeutic components.

[Supervised practice]

You also need to complete a period of supervised practice [broad details of requirements for supervised practice].

The Board [name of guideline] provides guidance on how this supervised practice is to be completed.

[What other requirements must I meet to be endorsed?]

See Note 3

[details of additional requirements]

What must I do when I am endorsed?

See Note 4

Guidelines

The [name of guidelines] provide more information about what the Board expects of you when you are endorsed. You are expected to understand and apply these guidelines together with this registration standard.

State or territory authority

The endorsement of your registration indicates that you are qualified to [administer, obtain, possess, prescribe, sell, supply and/or use] the [scheduled medicine or class of medicines] specified in the endorsement but does not authorise you do to so.

The authorisation for you to [administer, obtain, possess, prescribe, sell, supply and/or use (delete as applicable)] the [scheduled medicine or class of medicines] in a state or territory will be provided by or under legislation of the state or territory.

You must [administer, obtain, possess, prescribe, sell, supply and/or use (delete as applicable)] the [scheduled medicine or class of medicines] in the scope of this state or territory authority at all times.

1 Applications for endorsement may be made by those [name of profession] who hold registration with the Board or are applying for registration at the same time as the endorsement. Registration must be granted before the endorsement application can be granted.

Wording to appear on the Register of [name of profession]

Endorsed as qualified to [administer, obtain, possess, prescribe, sell, supply and/or use (delete as applicable)] [scheduled medicines or class of scheduled medicines] for the purposes of the practice of [name of profession].

Authority

See Note 5

The Ministerial Council has decided that the Board may endorse [class of practitioner] to the extent described in this registration standard.

This standard has been approved by the Ministerial Council under section 12 of the National Law on [date].

Registration standards are developed under section 38 of the National Law and are subject to wide-ranging consultation.

Definitions

See Note 6

Approved program of study for a health profession or for endorsement of registration in a health profession, means an accredited program of study:

a. approved under section 49(1) by the National Board established for the health profession, and

b. included in the list published by the National Agency under section 49(5).

Ministerial Council means Australian Health Workforce Ministerial Council.

National Law means the Health Practitioner Regulation National Law as in force in each state and territory.

Review

This standard for endorsement of registration will be reviewed from time to time as necessary. The Board will review this standard at least every [three or five] years.

This standard replaces the previous registration standard dated [date of previous standard].

Notes

Note 1: Scope of endorsement

The National Board needs to describe the scope of the endorsement for approval by Ministerial Council.

There are three parts to the Ministerial approval:

- the class of the practitioner
- the scheduled medicine or class of scheduled medicines, and
- whether the endorsement is to administer, obtain, possess, prescribe, sell, supply and/or use.

A range of factors, including the anticipated service need being met by the endorsement, determine the scope of the endorsement.

There needs to be consistency between what is approved by Ministerial Council with respect to the scheduled medicines for the endorsement and what is subsequently listed by the National Board in its registration standard.

From a policy perspective, there are advantages in structuring a standard around classes of scheduled medicines compared to a list of individual medicines as this helps to future proof the standard. The advantages of this approach may be outweighed by risks.

Note 2: How do I qualify for endorsement?

It is expected this section will list a number of pathways as relevant to the profession. This reflects the way in which particular professions educate and train practitioners for endorsement.

This may be by completing an approved program that leads to general registration that also includes the required therapeutic components and thus leading to endorsement as well.

Or

Completing an approved postgraduate program that includes the required therapeutic components as a registered practitioner.

Or

Either of the above with the completion of a supervised practice component in addition to the completion of the qualification.

Step 2 of the *Health Professions Prescribing Pathway* (obtain recognition from the National Board of the competence to prescribe) states:

To support consistency between National Boards, registration standards to endorse a registered health professional to prescribe medicines should include three elements necessary for endorsement to be conferred:

1. The approved qualifications or assessments that will be used to recognise the competence of the health professional.
2. The supervised practice requirement that is required to be completed for a registered health professional to be endorsed, noting that this may be included in (1).
3. The imposition of restrictions for endorsement to prescribe, commensurate with the level of risk of the health professionals prescribing practice. Different models of prescribing may be instructive in terms of the level of education required.

Qualifications

The description of the qualifications would be broad in the registration standard as the details of the qualifications would be listed on the list of approved programs for the profession.

The National Board may publish criteria to assess equivalence of qualifications. It is expected that the level of competence attained through the non-approved qualification would be as described in the NPS *Competencies required to prescribe medicines* as this is the level expected through an approved qualification.

Supervised practice

A period of supervised practice may be needed if this is not included in an approved qualification or for another reason required by the National Board to assure itself of the level of competence of the applicant.

As a matter of principle the registration standard would describe the requirements for supervised practice in broad terms while associated supportive material would provide more information about how the practitioner can meet these requirements (e.g. duration, practise type and/or supervisor requirements).

Any guideline developed and approved by a National Board is done so through wide-ranging consultation.

Note 3: What else must I do to be endorsed?

This section allows the National Board to describe other requirements that it may have for a practitioner to be endorsed e.g. completion of case studies, completion of a number of years practising the profession before applying for endorsement.

This should be informed by a range of factors including the model of prescribing, the profession and the stage of transition in the profession for endorsing practitioners for scheduled medicines.

Note 4: What must I do when I am endorsed?

It is anticipated that a National Board would develop guidelines to support the registration standard.

Though the National Board can approve these guidelines it is expected that they would be developed and consulted on at the same time of the registration standard and included for information in any submission to Ministerial Council for approval of a registration standard.

The guidelines could be reviewed and amended by the National Board separate to the registration standard.

Note 5: Authority

There are two things that a National Board must ask of Ministerial Council before the National Board can endorse a class of practitioners for scheduled medicines.

The first is for the Ministerial Council to decide under section 14 that the National Board may endorse the class of practitioner and the scope of this endorsement.

The second is for the Ministerial Council to approve the registration standard under section 38.

Note 6: Definition

The terms administer, obtain, possess, prescribe, sell, supply or use are terms that are generally defined in state and territory legislation and regulations. This may at times vary across jurisdictions.

The work of jurisdictions on consistent scheduled medicines authorities will be monitored to see if there are common definitions to be developed.

It is not anticipated that the registration standard would define these terms but rather that guidance, such as that developed through jurisdictions, would provide clarity and consistency in the meaning of these terms.

Appendix D: Template guidelines for use of scheduled medicines

Text highlighted should be modified depending on the profession, the education and training, the class of practitioner and scope of the endorsement.

INDICATIVE ONLY

Template [Guidelines for use of scheduled medicines]

Any guidelines for use of scheduled medicines developed using this template should be drafted in consideration of the Australian Health Minister's Advisory Council *Guidance for National Boards: Applications to the Ministerial Council under section 14 of the National Law*.

The AHMAC guidance promotes the safe and effective use of scheduled medicines. The Australian Health Practitioner Regulation Agency (AHPRA) has developed a guide to support National Boards developing a submission to Ministers under the AHMAC guidance. These documents are published at [hyperlink].

Many of the requirements listed in the AHMAC guidance suggested in the AHPRA guide may be addressed through the content of *Guidelines for use of scheduled medicines*.

The template outlines the broad sections and suggested content. Not all sections are relevant to all professions as the context and scope of the endorsement will vary according to the profession, proposed model(s) of care, the schedules included and the proposed healthcare setting(s). Sections not considered relevant should be deleted.

The intent of developing a template is to provide consistency in the structure and key information across all professions developing guidelines.

Guidelines for use of scheduled medicines would generally be developed in conjunction with registration standard for endorsement for scheduled medicines. In this case, the registration standard would address certain identified matters and govern decision-making, while the guidelines provide guidance on how practitioners carry out functions. Guidelines are applications of registration standards and are not documents which set out primary eligibility requirements. A code or guideline should not stipulate matters that should be the subject of registration standards (e.g. qualification pathways).

Guidelines may also be developed by a National Board when a practitioner group prescribes scheduled medicines without endorsement (e.g. dentists) to provide guidance to practitioners on how they should carry out this function to support the safe and effective use of scheduled medicines. References to any relevant registration standard would need to be removed in such a case.

Effective from: [date]

Introduction

These guidelines provide information about how to meet the [name of National Board]'s requirements when you are applying for endorsement for scheduled medicines and when endorsed. You are expected to understand and apply these guidelines together with the *Endorsement for scheduled medicines registration standard*.

The public have the right to access safe and effective use of scheduled medicines from [name of profession] who are educated and competent to [[administer, obtain, possess, prescribe, sell, supply and/or use (delete as applicable)]] them.

Do these guidelines apply to me?

These guideline apply to [class of practitioner]:

- applying[2] for endorsement for scheduled medicines, and/or
- whose registration is endorsed for scheduled medicines.

What must I do?

You must meet the requirements of the *Endorsement for scheduled medicines registration standard*.

2 Applications for endorsement may be made by those [name of profession] who hold registration with the Board or are applying for registration at the same time as the endorsement. Registration must be granted before the endorsement application can be granted.

Summary

These guidelines help you to understand:

- [list any information related that helps applicants understand application requirements e.g. supervised practice arrangements], and
- what you need to do to [administer, obtain, possess, prescribe, sell, supply and/or use] scheduled medicines safely and effectively.

Applying for endorsement for scheduled medicines

[This section may not be relevant for some professions if endorsement does not apply. When it does apply, it must be remembered that guidelines cannot set out primary eligibility requirements. This section may provide information on where an applicant may find information on approved programs of study etc.

A registration standard may need an applicant for endorsement to undertake a period of supervised practice; these guidelines may provide additional information on these arrangements or make cross reference to any other relevant supervised practice supportive material. It cannot require anything more of a practitioner than that described in a registration standard.]

Scope of endorsement

[The associated registration standard should describe the scope on an endorsement, including the class of practitioners, individual or class of medicines, and which activities apply (e.g. administer, supply, prescribe etc.).

A registration standard must either include or attach a list of the scheduled medicines covered by the endorsement, or include a clear description of the class(es) of scheduled medicines to which the endorsement applies.

If a scheduled medicines endorsement registration standard includes a description of the class(es) of scheduled medicines covered by the standard, the National Board may publish additional information for practitioners provided it is in the parameters of the registration standard including the scope of the class(es). For example, a National Board could:

- publish a factual list of the scheduled medicines currently within the class(es) in the registration standard, for ease of reference by practitioners and other stakeholders, and/or
- provide additional in this guideline about appropriate use of various medicines within the classes in the registration standard, as long as this guidance does not attempt to constrain the scope of the class(es).]

Maintaining competence

[The National Board's recency of practice and continuing professional development registration standards apply equally to endorsed practitioners. These standards may have specific requirements related to endorsed practitioners.

These guidelines can make a cross-reference to this material but cannot require any additional requirements of the endorsed practitioner].

[Appropriate use of scheduled medicines]

[A National Board could provide additional information in this guideline about appropriate use of various medicines within the classes in the registration standard, as long as this guidance does not attempt to constrain the scope of the class(es).

Some classes of medicines may be associated with particular risks or considerations (e.g. Schedule 8 medicines).

This section provides some common information that is likely to apply to all professions with endorsement regardless of the scope of the endorsement.]

Quality use of medicines [expected to be common across all regardless of scope of the endorsement]

[Name of profession] who prescribe scheduled medicines should observe the *Quality Use of Medicines* (QUM)[3] principles as they apply to the scope of the endorsement.

Quality use of medicine means:

a. Selecting management options wisely by:
   - considering the place of medicines in treating illness and maintaining health, and
   - recognising there may be better ways than medicine to manage many disorders.
b. Choosing suitable medicines (if a medicine is considered necessary) so that the best available option is selected by taking into account:
   - the individual
   - the clinical condition

3 This can be found at www.health.gov.au.

- risks and benefits
- dosage and length of treatment
- any coexisting conditions
- other therapies
- monitoring considerations, and
- costs for the individual, the community and the health system as a whole.

c. Using medicines safely and effectively to get the best possible results by:
- monitoring outcomes
- minimising misuse, over-use and under-use
- improving people's ability to solve problems related to medication, such as negative effects, and
- managing multiple medications.

Adverse event reporting [expected to be common across all regardless of scope of endorsement]

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products.

The TGA also collects reports of adverse events associated with medicines and medical devices. Monitoring of adverse events allows the TGA to investigate and take action on medicines safety issues.

[Name of profession] can help the TGA in safeguarding public health by reporting all suspected adverse events associated with medicines, particularly those associated with new products.

This information forms an important part of the TGA's monitoring activities and plays a key role in helping identify potential relationships between a therapeutic good and a series of adverse events. When a link can be established, the TGA takes action to ensure that medicines available in Australia continue to meet appropriate standards of safety, efficacy and quality.

Further information can be found on the TGA website.

Prescriptions [delete if not in scope of endorsement][4]

A prescription is a legal document. It is a precise written instruction from a prescriber to a pharmacist for preparing and dispensing a drug for a patient.

The endorsed [name of profession] has a duty of care to provide a prescription that is legible; this reduces the potential for errors in treatment. Computer generated prescriptions are generally more legible than those that are handwritten.

Regardless of the format of the prescriptions, endorsed [name of profession] need to constantly check the details of the prescription.

The essential information needed for a legal prescription may vary between states and territories. Endorsed [name of profession] need to be aware of these variances if practising in different jurisdictions. The requirements generally include:

- prescribers name, address, telephone number and qualifications
- patient's full name, address and date of birth
- date the prescription is written
- drug name in full
- drug strength
- drug form (e.g. tablet, capsule, or mixture)
- quantity of drug to be supplied
- drug dose, route of administration, frequency, and duration of treatment (if necessary)
- clear instructions for the patient (in English) – it is not appropriate to write 'take as directed'
- any further instructions necessary for the pharmacist, and
- the handwritten signature of the prescriber.

4 Oral and Dental Expert Group. *Therapeutic Guidelines: Oral and dental*. Version 2. Melbourne: Therapeutic Guidelines Limited 2012.

Self prescribing

The National Board advises against endorsed [name of profession] self-diagnosing and then self-prescribing schedule [4 and/or 8] medicines.

Supply of scheduled medicines [delete if supply is not included in scope of endorsement]

The National Board supports the view that the division of responsibility between an endorsed [Name of profession] who prescribes a scheduled medicine and a pharmacist who dispenses the scheduled medicine to the patient, provides an important check designed to safeguard patients.

The expertise of the pharmacist in counselling patients is important in the follow-up care of the patient. This includes checking adherence to the prescriber's instructions, confirming administration times and techniques, screening for adverse reactions and referring back to the prescriber for further investigations or advice when required.

[Name of profession] who choose to supply a scheduled medicine directly to a patient need to meet the labelling and record-keeping requirements of the jurisdiction in which they are practising, provide counselling about the use of the medicine, its side effects and potential interactions and if available provide a *Consumer Medicines information leaflet*[5].

Antimicrobial resistance [delete if not in the scope of the endorsement]

Antimicrobial resistance (AMR) is the ability of a microorganism (like bacteria, viruses and parasites) to stop an antimicrobial (such as antibiotics, antivirals and antimalarials) from working against it. As a result, standard medical treatments become ineffective and infections persist and may spread to others. Healthcare professionals are left with limited or in some instances, no available treatment options.

Endorsed [name of profession] using antimicrobial preparations should understand all issues relating to the emergence of resistance by pathogenic organisms and mechanisms for limiting this. Selection of an antimicrobial should always involve consideration of the risk that microbial resistance could develop.

NPS Medicinewise provide a range of information for prescribers to help them understand the risks of AMR and what they can do to help contain this.

Working with other practitioners

[There are inherent risks associated with an increasing number of health practitioners involved in the use of scheduled medicines. How these risks are managed need to be considered by National Boards under the AHMAC guidance.

The *Code of Conduct* or similar profession specific codes, make reference to what National Boards expect of practitioners in communicating to other practitioners, including referral.

A National Board may decide to include particular guidance or further information on such requirements as shared care arrangements].

Authority

The [name of National Board] has developed these guidelines under section 39 of the National Law.

Guidelines approved by the National Board may be used as evidence of what constitutes appropriate professional conduct or practice for [name of profession] in proceedings against a health practitioner under the National Law, or a law of a co-regulatory jurisdiction.

Definitions

Terms used in these guidelines should be defined here.

Terms likely to need definition are:

- Class of practitioners, noting that section 14 of the National Law needs ministerial approval to state what class of practitioners the approval relates to.

Review

The Board will monitor this guideline for effectiveness and review it at least every [x] years. This guideline replaces any previously published National Board guidelines on use of scheduled medicines. [delete if not applicable]

Date of issue: [insert date]

Date of review: [insert date]

5 Consumer Medicines information sheets are available at www.medicines.org.au.