Public consultation paper

- Registration standard: Endorsement for scheduled medicines
- Guidelines: Endorsement for scheduled medicines

14 October 2016

You are invited to provide feedback on this public consultation

To provide feedback, please provide written submissions by email, marked 'Consultation – Endorsement for scheduled medicines' to podiatryconsultation@ahpra.gov.au by close of business on Friday 9 December 2016.

Please provide submissions in Word format (or equivalent)[1].

Public consultation

The Podiatry Board of Australia (the Board) is releasing this consultation paper on the review of the *Registration standard: Endorsement for scheduled medicines* (ESM registration standard) and the related *Guidelines: Endorsement for scheduled medicines* (ESM guidelines).

You are invited to provide your comments on the consultation paper, including the questions in the paper, by Friday 9 December 2016.

A template document for your response has been provided for your convenience.

How your submission will be treated

Submissions will generally be published unless you request otherwise. The National Boards publish submissions on their websites to encourage discussion and inform the community and stakeholders. However, the Boards retain the right not to publish submissions at their discretion, and will not place on their website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the consultation.

Before publication, the Board will remove personally-identifying information from submissions, including contact details. The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the Board.

[1] You are welcome to supply a PDF file of your feedback in addition to the Word (or equivalent) file, however we request that you do supply a text or Word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as Word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

The Board also accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act* 1982 (Cwlth), which has provisions designed to protect personal information and information given in confidence.

Please let the Board know if you do not want your submission published, or want all or part of it treated as confidential.

Contents

General overview of consultation

Purpose of the proposal

The Podiatry Board of Australia (the Board) has approval from the Australian Health Workforce Ministerial Council (Ministerial Council) to endorse the registration of a podiatrist or podiatric surgeon as being qualified to administer, obtain, possess, prescribe, sell, supply or use Schedule 2, 3, 4 or 8 medicines for the treatment of podiatric conditions, from the list of scheduled medicines approved by the Board (the *National Podiatry Scheduled Medicines List*).

The Board is reviewing *its Endorsement for scheduled medicines registration standard* (ESM registration standard). The ESM registration standard, which was approved by Ministerial Council and took effect on 1 July 2010, sets out the requirements for a podiatrist of podiatric surgeon to have their registration endorsed for scheduled medicines.

The Board is also reviewing its *Guidelines for endorsement for scheduled medicines* (ESM guidelines). The ESM guidelines, which took effect on 15 March 2011, provide guidance on the requirements of the registration standard.

The Board is inviting general comments from the public on updated drafts of the proposed revised ESM registration standard, the *National Podiatry Scheduled Medicines List* (which is attached to the registration standard), and the ESM guidelines.

There is an overview before each draft document that explains the proposed changes. There are also specific questions about the ESM registration standard, the *National Podiatry Scheduled Medicines List* and the ESM guidelines which you may wish to address in your response.

Please provide feedback in a Word document[2] by email to podiatryconsultation@ahpra.gov.au by close of business on Friday 9 December 2016. A response sheet has been provided with this consultation paper.

Next steps

The Board will consider the consultation feedback on the draft revised ESM registration standard, *National Podiatry Scheduled Medicines List* and related ESM guidelines before finalising these documents for approval by the Ministerial Council.

[2] You are welcome to supply a PDF file of your feedback in addition to the Word (or equivalent) file, however we request that you do supply a text or Word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as Word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx

Overview of review of the Registration standard: endorsement for scheduled medicines (ESM registration standard)

Background

The Board's current ESM registration standard sets out the requirements for endorsement for scheduled medicines for podiatrists and podiatric surgeons. The Board's ESM guidelines provide guidance to podiatrists and podiatric surgeons about the requirements of the ESM registration standard. The Board's *Endorsement for scheduled medicines: Clinical Practice Guidelines* are at Appendix A to the current guidelines and the *National Podiatry Scheduled Medicines List*, which sets out the scheduled medicines that endorsed podiatrists and podiatric surgeons are qualified to use and prescribe, is at Appendix B to the current guidelines.

The ESM registration standard has been in force since 1 July 2010 and the Board is undertaking a review of the standard in keeping with good regulatory practice. The associated ESM guidelines are also being reviewed. The review of the guidelines is discussed later in this consultation paper.

The current ESM registration standard was developed out of the practice and procedure relating to endorsement for scheduled medicines that was in place in Victoria prior to the commencement of the National Registration and Accreditation Scheme (National Scheme) on 1 July 2010. The ESM registration standard adapted the Victorian model to reflect that endorsement for scheduled medicines was now available nationally. The Board has had feedback that the existing ESM registration standard and associated guidelines are not clear and can be difficult to understand.

As part of the review, the Board has considered its experience with the ESM registration standard in the last five years as well as considering recent government initiatives relating to prescribing by health professionals including:

- the NPS Medicinewise *Prescribing Competencies Framework*[3] which describes the competencies that health professionals require to prescribe medicines judiciously, appropriately, safely and effectively in the Australian healthcare system, and
- the Health Professionals Prescribing Pathway (HPPP), a project of the former Health Workforce Australia (HWA) that seeks to deliver a national approach to prescribing by health professionals, other than doctors, that covers important concepts such as prescribing models, competency attainment, registration and endorsement, and safety, quality and practice issues.

Current ESM registration standard

The current ESM registration standard offers two pathways towards endorsement (Pathway 1 and Pathway 2).

Pathway 1

Pathway 1 was a necessary pathway for the transition to the National Scheme. In summary, it includes a requirement for seven years full-time, post-qualification clinical experience in an appropriate setting where active prescribing is occurring, supported by two references confirming the applicant's exposure to patient care involving scheduled medicines.

[3] *NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice*. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

Since the ESM registration standard commenced, the Board has had very few applications under this pathway and has identified issues in relation to the pathway. These issues include that it is difficult for the Board to be satisfied that applicants for endorsement for scheduled medicines using this pathway have had adequate exposure to prescribing the range of scheduled medicines on the Board's *National Podiatry Scheduled Medicines List* to ensure they have the required competencies to safely use and prescribe those medicines for the treatment of podiatric conditions.

The Board is proposing to remove this old transitional pathway from the revised ESM registration standard and replace it with a new contemporary pathway. The new pathway is discussed later in this paper.

Pathway 2

Pathway 2 is the pathway used by the majority of applicants for endorsement for scheduled medicines. It includes a 12-month period of supervised practice and the submission of 40 log sheets as evidence of undertaking the supervised practice and to demonstrate exposure to and knowledge of the safe use of the range of scheduled medicines on the Board's *National Podiatry Scheduled Medicines List* for the treatment of podiatric conditions.

Proposed key changes to the current ESM registration standard and National Podiatry Scheduled Medicines List

Registration standard

New Pathway 1

The Board is proposing to replace the current transitional Pathway 1 with a new contemporary Pathway 1.

The proposed new Pathway 1 will enable graduates from an accredited and approved program of study to be qualified for endorsement for scheduled medicines. The approved program of study would be aligned to the national prescribing competencies framework and include education and training in podiatric therapeutics, as well as clinically supervised practice, to ensure that graduates have the required competencies for endorsement for scheduled medicines.

The pathway would encompass entry level podiatry programs as well as post graduate programs for registered podiatrists and podiatric surgeons.

Updated Pathway 2

The Board is proposing to maintain Pathway 2 in the draft revised ESM registration standard with some modifications. Key changes include:

- making explicit reference to the competencies required for endorsement for scheduled medicines
- expanding of the type of evidence that may be submitted as part of a portfolio to demonstrate that the applicant has met the Board's supervised practice requirements and achieved the required prescribing competencies to have their registration endorsed for scheduled medicines.
- replacing the term 'supervisor' with 'mentor' to better reflect the nature of the role
- adding a definitions section to define the key terms in the standard, and
- introducing a requirement that during the period of supervised practice, a practitioner must submit a specified number of case studies for initial assessment by the Board.

The associated ESM guidelines have also been updated. The review of the guidelines is discussed later in this consultation paper.

National Podiatry Scheduled Medicines List

The *National Podiatry Scheduled Medicines List*, which specifies the scheduled medicines that a podiatrist or podiatric surgeon whose registration has been endorsed for scheduled medicines is qualified to administer, obtain, possess, prescribe, sell, supply or use for the treatment of podiatric conditions, is attached to the proposed revised ESM registration standard.

The list has been updated as a result of feedback the Board received about the list being out of date, highlighting the inherent difficulties with the current list structure and the difficulties in maintaining a contemporary list in terms of schedules, clinical indications and TGA indications/approvals, etc. The intention is to address the identified issues with the current list, without changing the substantive content of the list or the restrictions specified in the current list unless necessary. Proposed changes to the list include:

- collation of the list into therapeutic classes of medicines and further sub-division into sub-classes, in line with the Australian Medicines Handbook
- removal of references to scheduling and inclusion of definitions for the different schedules in the introductory section of the list
- adding a list of resources in the introduction section of the list, which is collated into 'essential' and 'additional useful resources'
- a statement in the introductory section of the list indicating that TGA-approved routes, doses or indications should be used
- specifying routes only where necessary. For example, the route is included where clear guidance is needed or a specific route is appropriate for podiatry practice. Practitioners are expected to follow best practice guidelines.
- Removal of some of the notes that were included against specific medicines and replacement with an overarching statement in the introduction to the list. For example, the reference to communicating with the general practitioner as to treatment and outcome, which was in the notes section against some medicines, has been replaced with an overarching statement in the introductory section of the list about communicating with the patient's nominated medical practitioner(s)
- the introduction to the anti-infectives section of the list (which includes antibacterials and antifungals) has a statement about anti-microbial stewardship
- removal of some medicines from the list (for example: felypressin, procaine, mepivacaine and temazepam) because they are not available in the form specified in the current list or the product specified in the current list is not registered for podiatric use
- change of combination products to a single product if this is the only form available
- removal of aspirin from 'anti-inflammatory agents' because the dose required to achieve an anti-inflammatory effect is high and more likely, therefore, to precipitate gastric irritation
- an update to the specified dose for oxycodone to reflect current recommended dosage
- the addition of naloxone to the list, as the Board considers that it would assist in circumstances where a person has an acute response to the opioid oxycodone. Naloxone is restricted to podiatric surgeons, and
- removal of the restriction limiting ciprofloxacin to podiatric surgeons, as the Board recognises that podiatrists with an endorsement are qualified to use this medicine where it is clinically indicated for the management of complex foot infections.

Strengths of preparations are not included as the Board considers that endorsed podiatrists and podiatric surgeons are qualified to use the medicines for treatment of podiatric conditions and will use appropriate resources to determine dosage where needed.

The Board has received feedback that the Board should move from a specified list of scheduled medicines to broad classes of medicines for the treatment of podiatric conditions or prescribing within scope of practice.

The Ministerial Council approval under the section 14 of the National Law for endorsement for scheduled medicines for the podiatry profession is for the endorsement to be linked to a specific list of scheduled medicines rather than broader classes of scheduled medicines. For the Board to move to an alternative to the *National Podiatry Scheduled Medicines List*, such as broader classes of scheduled medicines or prescribing within scope of practice, the Board would need to submit a proposal to Ministerial Council for an amendment to the existing approval. This would need to be supported by evidence that endorsed practitioners are competent for this expanded scope.

The Board will work towards gathering sufficient evidence to support a proposal to Ministerial Council for an amendment to the existing approval for endorsement for scheduled medicines in the next two to three years. Depending on the evidence obtained, the request would be to expand the scope of the approval from a specified list of scheduled medicines to broad classes of medicines for the treatment of podiatric conditions or prescribing within scope of podiatry practice.

Options statement – Registration standard: Endorsement for scheduled medicines

The Board has considered the following options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing registration standard. The Board has identified a range of issues with the current standard, including those outlined above as well as the need to clarify the language and structure to make it easier to understand.

Option 2 – Proposed revised ESM registration standard

Option 2 would involve the Board submitting a revised ESM registration standard to the Ministerial Council for approval. The registration standard would continue to establish the Board's requirements for endorsement for scheduled medicines, with some changes such as:

- clearer wording and structure, including a section with key definitions to make it easier to understand
- including specific reference to the required competencies for endorsement for scheduled medicines to reflect the NPS Medicinewise: *Prescribing Competencies Framework*[4]
- replacing the current *Pathway 1* with a new *Pathway 1*, where graduates from an accredited and approved program of study that includes an appropriate period of clinically supervised practice, are qualified for endorsement for scheduled medicines.
- maintaining an additional pathway (*Pathway 2*) which includes a post-registration period of supervised practice
- for *Pathway 2*:

[4] NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

- expanding the types of evidence that an applicant can submit to the Board to demonstrate that they have met the Board's supervised practice requirements and achieved the required prescribing competencies to have their registration endorsed for scheduled medicines.

- introducing a requirement that during the period of supervised practice, a practitioner must submit a specified number of case studies for initial assessment by the Board

- updating and reformatting the *National Podiatry Scheduled Medicine List* attached to the draft revised ESM registration standard to address currency issues with the existing list and to make it clearer and easier to understand.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised ESM registration standard:

- continues to protect the public by ensuring that only suitably qualified and competent practitioners can have their registration endorsed for scheduled medicines

- includes an explicit reference to the national prescribing competencies as described in the NPS Medicinewise *Prescribing competencies framework* so that the required prescribing competencies for an endorsement for scheduled medicines are clear

- provides two pathways for podiatrists and podiatric surgeons to achieve the prescribing competencies required for endorsement for scheduled medicines

- introduces a new contemporary pathway (*Pathway 1*) where graduates from an accredited and approved program of study that includes an appropriate period of clinically supervised practice, are qualified for endorsement for scheduled medicines

- for *Pathway 2*, provides greater flexibility for practitioners with regard to the evidence they can submit to the Board to demonstrate their competence to prescribe, and

- is clearer and easier to understand.

The costs of the preferred option are:

- practitioners, mentors,other stakeholders and AHPRA will need to become familiar with the new standard

- there will need to be a period of transition to the proposed revised standard, if approved.

- the introduction of the new *Pathway1* is dependent on the current ESM accreditation standards being reviewed to ensure they are robust enough to ensure graduates of accredited and approved programs of study for endorsement for scheduled medicines have the prescribing competencies required for endorsement for scheduled medicines. The accreditation authority for the profession is currently undertaking this review, and

- the availability of this option (new *Pathway 1*) will depend on education providers seeking and achieving accreditation for their podiatry program against the revised ESM accreditation standards. By introducing this new pathway, the Board is putting the enabling infrastructure in place for this to occur.

Estimated impacts of the draft revised ESM registration standard

The introduction of a new pathway (*Pathway 1*) as proposed in the draft revised ESM registration standard provides an additional pathway where future graduates of an accredited and approved program of study that includes an appropriate period of clinically supervised practice, are qualified for endorsement for scheduled medicines. The pathway would encompass entry-level programs as well as post graduate programs for registered podiatrists and podiatric surgeons.

The Board understands that the majority of education providers in Australia are not yet ready to offer podiatry courses that would meet *Pathway 1*. The Board also understands that in order for a course to be accredited and approved for this pathway, a change may be required to the way the podiatry course is taught to ensure that therapeutics is embedded into all aspects of the course, including clinical placements.

Some education providers may wish to make this change to their podiatry program over time and seek accreditation for *Pathway 1*. However, others may wish to maintain their current program, which includes education and training in podiatric therapeutics but does not include the clinically supervised practice that is required for endorsement for scheduled medicines. Graduates of these programs have the opportunity to work towards endorsement for scheduled medicines under the proposed *Pathway 2*, undertaking the required period of supervised practice as a registered practitioner.

The proposed *Pathway 2* for endorsement for scheduled medicines is very similar to *Pathway 2* in the current ESM registration standard, which is the pathway that has been used by most applicants for endorsement for scheduled medicines to date. The changes to the evidence requirements provide more flexibility for practitioners with regard to the evidence they can provide to demonstrate that they have met the Board's requirements for supervised practice and have the required prescribing competencies for endorsement for scheduled medicines. Practitioners and their mentors will need to become familiar with the different requirements for evidence.

Relevant sections of the National Law

Sections 38, 40 and 94

Questions for consideration

The Board is inviting feedback on the following questions:

1. ESM registration standard

1.1 Is the content and structure of the draft proposed revised ESM registration standard helpful, clear, relevant and more workable than the ESM registration standard that was released for preliminary consultation in May 2015?

1.2 Is the proposed new *Pathway 1* clear and easy to understand?

1.3 Are the definitions clear and easy to understand?

1.4 Is there any content that needs to be changed or deleted in the draft proposed revised ESM registration standard?

1.5 Is there anything missing that needs to be added to the draft proposed revised ESM registration standard?

1.6 Do you have any other comments on the draft proposed revised ESM registration standard?

2. National Podiatry Scheduled Medicines List

2.1	Is the draft updated and reformatted *National Podiatry Scheduled Medicines List* clearer and easier to understand now that it has been collated into therapeutic classes of medicines and further sub-divided into sub-classes in line with the *Australian Medicines Handbook*?
2.2	Is the list clear with respect to the scheduled medicines that endorsed practitioners are qualified to use and prescribe, including appropriate route, doses and indications?
2.3	Do you have any other comments or feedback on the draft updated and reformatted *National Podiatry Scheduled Medicines List*?

Attachments

The proposed revised *Registration standard: Endorsement for scheduled medicines* follows at page 12 of this consultation paper. The draft reformatted *National Podiatry Scheduled Medicines List* is at Attachment A to the registration standard.

The Board's *Statement of assessment against AHPRA's Procedures for development of registration standards and COAG principles for best practice regulation* is at Attachment 1 to this consultation paper (page 56).

Registration standard: Endorsement for scheduled medicines **(DRAFT)**

Effective from: <<date>>

This registration describes the Podiatry Board of Australia's (the Board) minimum requirements for a podiatrist or podiatric surgeon to have their registration endorsed for scheduled medicines under section 94 of the **National Law**[5], the scope of the endorsement, and what the Board expects of practitioners with this type of endorsement.

Does this standard apply to me?

This registration standard applies to all podiatrists and podiatric surgeons:

- applying to have their registration endorsed for scheduled medicines under section 94 of the **National Law**, or
- whose registration is endorsed for scheduled medicines.

Scope of endorsement

A podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines under section 94 of the **National Law** is qualified to administer, obtain, possess, prescribe, sell, supply or use Schedule 2, 3, 4 or 8 medicines for the treatment of podiatric conditions, included in the *National podiatry scheduled medicines list*.[6]

What must I do?

To demonstrate that you are eligible to apply for endorsement for scheduled medicines you must provide evidence that you meet the requirements of one of the following pathways:

1. Pathway 1 Approved qualification pathway

To meet the requirements for this pathway you must provide evidence that you hold one of the following qualifications:

a. an **approved qualification for endorsement for scheduled medicines**, or

b. another qualification that the Board considers to be substantially equivalent to, or based on similar competencies to, an approved qualification for endorsement for scheduled medicines.

The qualification must be current (not more than seven years old) at the time of applying for endorsement for scheduled medicines.

2. Pathway 2 Supervised practice pathway for registered practitioners

To meet the requirements of this pathway you must provide evidence that you have successfully completed four (4) key components:

[5] Bolded terms are defined in the *Definitions* section of this registration standard
[6] The *National podiatry scheduled medicines list* is attached to this registration standard - see Attachment A.

- qualification
- online case studies
- supervised practice, and
- portfolio of evidence.

The requirements of these key components are described in 2.1 to 2.4 below.

There are progress steps you must complete before commencing your period of supervised practice (see 2.3.2 below) and during your period of supervised practice (see 2.5 below).

2.1 Qualification

You must provide evidence that you hold one of the following qualifications:

a. an **approved qualification in podiatric therapeutics**, or

b. another qualification that the Board considers to be substantially equivalent to, or based on similar competencies to, an approved qualification in podiatric therapeutics.

The qualification must be current (not more than seven years old) at the time of applying to the Board to commence supervised practice (see 2.3.2 below).

2.2 Online case studies

You must provide evidence that you have successfully completed 15 **Board approved online case studies**.

The online case studies must be completed after you have obtained your approved qualification in podiatric therapeutics (or equivalent), and not more than three years prior to first applying for endorsement for scheduled medicines.

2.3 Supervised practice

2.3.1 You must complete a period of **supervised practice** in Australia that:

a. involves learning through observation, experience, discussion and reflection in a range of prescribing environments as described Board's *Guidelines: Endorsement for scheduled medicines* (ESM guidelines)

b. is undertaken over a minimum of 150 hours within a 12-month period

c. is under the guidance of a mentor who meets the Board's requirements for a mentor as described in the ESM guidelines and with whom you have a signed mentor agreement in place before you commence your period of supervised practice, and

d. includes preparing a portfolio of evidence (as described in 2.4 below) and submitting the items of evidence from the portfolio as required by this registration standard and the ESM Guidelines.

2.3.2 Before you commence your period of supervised practice you must:

a. be registered as a podiatrist or podiatric surgeon in Australia, and

b. apply to the Board to commence supervised practice in accordance with the procedure described in the ESM Guidelines. This includes submitting the documents described in the ESM Guidelines to demonstrate you have the prerequisites to undertake supervised practice.

2.3.3 You must not commence your period of supervised practice until you have been advised in writing that the Board is satisfied you have met the prerequisites for supervised practice.

2.3.4 The period of supervised practice must be completed within 12 months of the date that you are advised in writing that you have met the prerequisites for supervised practice.

Further information about the requirements for supervised practice is in the ESM Guidelines.

2.4 Portfolio of evidence

You must submit within the timeframe and in the manner required by this registration standard and the ESM Guidelines a portfolio of evidence for assessment by the Board.

The portfolio of evidence must meet the requirements for a portfolio of evidence as set out in the ESM Guidelines and demonstrate to the Board's satisfaction that you have:

a. the required **prescribing competencies** to have your registration endorsed for scheduled medicines, and

b. met the Board's supervised practice requirements.

2.5 Initial assessment of clinical studies

During your period of supervised practice you must, among other things, prepare clinical studies as part of your portfolio of evidence. The clinical studies relate to patient cases you have observed during your period of supervised practice.

When you have completed a minimum of 25 hours of supervised practice you must submit to the Board for assessment three clinical studies. You can continue with your period of supervised practice while these case studies are being assessed.

The Board will advise you whether the clinical studies you have submitted are satisfactory. You must have three clinical studies assessed as satisfactory by the Board by the time you complete your period of supervised practice.

Further information about the requirements for clinical studies and the initial assessment by the Board, including what happens if the clinical studies are assessed as not satisfactory can be found in the ESM Guidelines.

2.6 When can I submit application for endorsement under Pathway 2?

You may submit your application to the Board to have your registration endorsed for scheduled medicines under Pathway 2, together with your portfolio of evidence when:

a. you have completed your period of supervised practice, and

b. three clinical studies have been assessed as satisfactory by the Board.

Your application must be submitted within 12 months of completing your period of supervised practice.

If you have not provided sufficient evidence in your portfolio to demonstrate you have the required prescribing competencies to have your registration endorsed for scheduled medicines the Board may:

- require you to undertake a further period of supervised practice
- require you to complete further education
- require you to provide further information, and/or
- refuse your application for endorsement.

Guidelines

This registration standard must be read in conjunction with the following guidelines. You are expected to apply these guidelines together with this registration standard.

Guidelines: Endorsement for scheduled medicines (ESM Guidelines)

These guidelines provide more information and guidance about how to meet the requirements of this registration standard, including:

- the required prescribing competencies to have your registration endorsed for scheduled medicines
- approved qualifications for endorsement for scheduled medicines
- information about Board-approved online case studies
- the requirements for supervised practice
- the evidence to be included in the portfolio
- information about initial assessment of clinical studies, and
- useful references and resources.

The ESM guidelines can be found on the Endorsement for scheduled medicines page of the Board's website.

Clinical practice guidelines: Endorsement for scheduled medicines

These guidelines outline the ongoing clinical practice requirements for podiatrists and podiatric surgeons with an endorsement for scheduled medicines. They include guidance about:

- appropriate clinical practice relating to the safe and effective use of scheduled medicines, including communication with the patient and members of the patient's healthcare team
- quality use of medicines (QUM)
- adverse event reporting; prescriptions
- supply of scheduled medicines, and
- antimicrobial stewardship.

The clinical practice guidelines can be found at Appendix 3 to the ESM Guidelines.

State or territory authority

The endorsement of your registration for scheduled medicines indicates that you are qualified to administer, obtain, possess, prescribe, sell, supply or use Schedule 2, 3, 4 or 8 medicines specified in the endorsement but does not authorise you to do so.

The authorisation for you to administer, obtain, possess, prescribe, sell, supply or use scheduled medicines in a state or territory will be provided by or under legislation and regulations of the state or territory in which you are practising.

You must administer, obtain, possess, prescribe, sell, supply or use scheduled medicines within the scope of the state or territory authority at all times.

What does this mean for me?

When you apply for endorsement for scheduled medicines

When you apply to have your registration endorsed for scheduled medicines you must meet the requirements of this registration standard.

At renewal of registration

When you apply to renew your registration, you are also applying to renew your endorsement for scheduled medicines.

You must have recent practice relating to your endorsement for scheduled medicines in accordance with the Board's *Registration standard: Recency of practice* and must have completed continuing professional development (CPD) relevant to your endorsement in accordance with the Board's *Registration standard: Continuing professional development*.

When you apply to renew your registration you must declare whether you have met the Board's recency of practice, continuing professional development and professional indemnity insurance arrangements registration standards.

During the registration period

You must:

- administer, obtain, possess, prescribe, sell, supply or use only the scheduled medicines listed in the Board's *National podiatry scheduled medicines* list at Attachment A in accordance with your endorsement and the restrictions specified in that list, and only to the extent that you are authorised by the relevant legislation and regulations in the state or territory in which you are practising
- be aware of, understand and comply with relevant state or territory drugs and poisons legislation and regulations including provisions relating to the secure storage of medicines in your possession
- comply with the relevant state, territory or commonwealth legislation and regulations relating to the reporting of adverse events related to medication incidents and the advertising of therapeutic goods, including scheduled medicines
- ensure that you **prescribe** within your scope of practice
- work collaboratively with your patient and their healthcare team
- practise in accordance with the Board's *Clinical practice guidelines: Endorsement for scheduled medicines*
- have recent experience in this scope of practice that meets the Board's *Registration standard: Recency of practice*
- maintain and enhance your competence to prescribe scheduled medicines including completing the required amount of CPD relevant to your scheduled medicines endorsement as set out in the Board's *Registration standard: Continuing professional development*.

What happens if I don't meet this standard?

The **National Law** establishes possible consequences if you don't meet this standard, including that:

- the Board can refuse your application for endorsement or renewal of registration, or impose conditions on your endorsement (sections 102, 103 and 112 of the **National Law**), and
- registration standards, codes or guidelines may be used in disciplinary proceedings against health practitioners as evidence of what constitutes appropriate practice or conduct for the health profession (section 41 of the **National Law**).

Authority

The Board has approval from the **Ministerial Council** under section 14 of the **National Law** to endorse the registration of a podiatrist or podiatric surgeon to the extent described in this registration standard.

This registration standard was approved by the **Ministerial Council** on <<date>>.

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

Definitions

The following terms are defined for the purpose of this registration standard:

Approved qualification for endorsement for scheduled medicines means a qualification obtained by completing a podiatry program of study that has been accredited by the accreditation authority for the podiatry profession and subsequently approved by the Board as providing a qualification for the purpose of endorsement for scheduled medicines for the podiatry profession. The program of study is aligned to the NPS MedicineWise *Prescribing Competencies Framework* and includes education and training in podiatric therapeutics as well as clinically-supervised practice to ensure that graduates have the required competencies for endorsement for scheduled medicines.

Approved qualification in podiatric therapeutics means a qualification that includes education and training in podiatric therapeutics. It does not include the clinically supervised practice that is required for endorsement for scheduled medicines.

Board approved online case studies are case studies relevant to endorsement for scheduled medicines delivered online by a university or other approved education provider and approved by the Board. These case studies include an assessable component. Information about Board-approved online case studies is in the ESM Guidelines, published on the Endorsement for scheduled medicines page of the Board's website.

Ministerial Council means the Australian Health Workforce Ministerial Council.

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

Supervised practice for the purpose of Pathway 2 means the observational clinical placements undertaken under by a registered podiatrist or podiatric surgeon in a range of prescribing environments, encompassing reflective practice and sessions with their mentor culminating in a portfolio of evidence that meet the requirements of this registration standard and the ESM guidelines.

Prescribe, when the term is used on its own in this registration standard means the iterative process involving the steps of information gathering, clinical decision making, communication and evaluation which results in the initiation, continuation or cessation of a medicine.[7]

Prescribing competencies means the prescribing competencies described in the NPS MedicineWise *Prescribing Competencies Framework*[8] as it may be updated from time to time - or such other national prescribing competencies that the Board may adopt by notice published on the Board's website.

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[7] Adapted from the definition of 'prescribing' in the *Health Professionals Prescribing Pathway,* which includes the following statement about the definition - *The definition of prescribing used in the HPPP may be different to the definition of prescribing provided in the legislation governing the use of medicines in each jurisdiction. Health professionals are advised to review the legislation in effect in the State or Territory in which they practice to ensure they understand their legal authorisation to prescribe medicines.*

[8] *NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice*. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

Review

This registration standard will be reviewed from time to time as required. This will generally be at least every three years.

Last reviewed: <insert date>

This standard replaces the previously published registration standard dated 1 July 2010.

Attachment A to *Registration standard: Endorsement for scheduled medicines*

Introduction

The **National Podiatry Scheduled Medicines List** specifies the Schedule 2, 3, 4 and 8 medicines that podiatrists and podiatric surgeons whose registration has been endorsed for scheduled medicines by the Podiatry Board of Australia are **qualified** to administer, obtain, possess, prescribe, sell, supply or use for the treatment of podiatric conditions.

Endorsed practitioners may only administer, obtain, possess, prescribe, sell, supply or use the scheduled medicines in the *National Podiatry Scheduled Medicines List* to the extent that they are **authorised** by the relevant drugs and poisons legislation and regulations in the state or territory in which they are practising. This includes ensuring they comply with relevant state or territory drugs and poisons legislation relating to the secure storage, labelling, record-keeping, disposal, loss or theft of medicines in their possession

The list is collated into Therapeutic classes of medicines and further sub-divided into sub-classes. Certain medicines (or routes of administration) are restricted to podiatric surgeons who have a demonstrated clinical need to use those medicines.

Therapeutic Goods Administration (TGA) approved routes, doses or indications should be used.

In line with the principles of Quality Use of Medicines (QUM) and specifically shared care, if a podiatrist or podiatric surgeon with endorsement for scheduled medicines is initiating a medicine, communication with the patient's nominated medical practitioner(s) is essential regarding the treatment and expected outcome.

When incorporating scheduled medicines into a patient care plan, podiatrists and podiatric surgeons should utilise resources which inform evidence based practice and support contemporary and appropriate use of scheduled medicines.

Practitioners should be aware of the Australian Register of Therapeutic Goods (ARTG) https://www.tga.gov.au/australian-register-therapeutic-goods and the requirements for any exemptions under the Special Access Scheme (SAS) and the Authorised Prescriber Scheme (AP) for medicines that are not included on the ARTG.

Various resources are utilised by podiatrists and podiatric surgeons to underpin and support the best possible use of medicines in podiatric practice.

References used should be the most current editions to ensure your knowledge is current.[9] Some of the following references are essential:

Essential references

- Australian Medicines Handbook
  https://shop.amh.net.au/products/electronic/down-2015
- Therapeutic Guidelines (eTG and latest hard copy versions) – relevant to your practice
  http://www.tg.org.au/
- NPS MedicineWise
  www.nps.org.au
- MIMS Australia
  http://www.mims.com.au/
- *MIMS online*
  http://www.mims.com.au/index.php/products/mims-online

[9] There may be a cost for accessing some of these resources

Additional useful references

- Quality Use of Medicines (QUM)
  http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm
- Antimicrobial stewardship
  http://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/antimicrobial-stewardship/
- TGA Medicines Safety Update
  https://www.tga.gov.au/publication/medicines-safety-update
- TGA[10]
  https://www.tga.gov.au/
- Medication safety - Australian Commission on Safety and Quality in Health Care
  https://www.safetyandquality.gov.au/our-work/medication-safety/
- Choosing Wisely Australia
  http://www.choosingwisely.org.au/home

Scheduling

Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison, required to protect public health and safety.

The Schedules are published in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) - referred to as the *Poisons Standard*.[11] The schedules relevant to the National Podiatry Scheduled Medicines List are:

Schedule 2	**Pharmacy Medicine** – Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.
Schedule 3	**Pharmacist Only Medicine** – Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription.
Schedule 4	**Prescription Only Medicine** OR Prescription Animal Remedy – Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription.
Schedule 8	**Controlled Drug** – Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence.

[10] The TGA website includes useful information for health professionals, including reporting adverse events; Product Information (PI); and Consumer Medicine Information (CMI) that can be printed off and provided to the patient when the medicine is prescribed https://www.tga.gov.au/publication/poisons-standard-susmp#susmp

[11] See https://www.tga.gov.au/publication/poisons-standard-susmp#susmp

The National Podiatry Scheduled Medicines List

The **National Podiatry Scheduled Medicines List** specifies the Schedule 2, 3, 4 and 8 medicines that podiatrists and podiatric surgeons whose registration has been endorsed for scheduled medicines by the Podiatry Board of Australia are **qualified** to administer, obtain, possess, prescribe, sell, supply or use for the treatment of podiatric conditions.

From April 2016, the TGA is updating some medicine ingredient names used in Australia to align with names used internationally. Information about the changes can be found on the TGA website.

This list has been updated to reflect the new names. The medicines on this list that are affected are marked with an asterix*. Some of the changes are minor spelling changes only.

Allergy and Anaphylaxis	
Sympathomimetics **Antihistamines** • **Sedating antihistamines** • **Less sedating antihistamines**	
Sympathomimetics	Restrictions/ additional notes
Adrenaline (epinephrine)*	For anaphylaxis IV route is restricted to podiatric surgeons only
Antihistamines	
Sedating antihistamines	Restrictions/ additional notes
Promethazine	Oral route only
Less sedating antihistamines	Restrictions/ additional notes
Desloratadine	
Fexofenadine	
Loratadine	

Anaesthetics	
General anaesthetics • **Inhaled anaesthetics** **Drugs for local anaesthesia** • **Local anaesthetics**	
General anaesthetics	
Inhaled anaesthetics	Restrictions/ additional notes
Methoxyflurane	Short-term analgesia and may be of use in acute trauma, pre-injection and wound dressing Should only be used where appropriate resuscitation facilities are available
Drugs for local anaesthesia	
Local anaesthetics	Restrictions/ additional notes
Tetracaine (amethocaine) hydrochloride*	Skin preparation only For use in hospital and podiatry practice setting only
Bupivacaine Plain or with adrenaline (epinephrine)*	
Levobupivacaine	
Lidocaine (lignocaine)* Plain or with adrenaline (epinephrine)*	
Prilocaine	
Ropivacaine	

Analgesics	
Drugs for pain relief • **Non-opioid analgesics** • **Opioid analgesics**	
Drugs for pain relief	
Non-opioid analgesics	Restrictions/ additional notes
Aspirin (analgesic)	
Paracetamol	
Opioid analgesics	Restrictions/ additional notes
Codeine phosphate *	For use as a combination product only
Oxycodone (in short-acting/immediate release form)	Restricted to podiatric surgeon only Route restricted to oral only Must only prescribe up to 10mg doses for a maximum of three days. Schedule 8: Controlled drug – see reference to storage of scheduled medicines in *Introduction* section

Antidotes and Antivenoms	
Antidotes	Restrictions/ additional notes
Naloxone	Restricted to podiatric surgeon only Route restricted to injection only

Anti-infectives
Antibacterials • **Cephalosporins** • **Lincosamides** • **Macrolides** • **Nitroimidazoles** • **Penicillins** • **Quinolones** • **Tetracyclines** **Antifungals** • **Other antifungals**
• Inappropriate and overuse of antimicrobials contributes to the emergence of resistant bacteria and causes patient harm. In line with the principles of anti-microbial stewardship, prolonged treatment (i.e. longer than the standard course of treatment) should only be considered with medical practitioner advice. If there is no improvement or a worsening of clinical signs during the course of the treatment, the choice and dose of agent must be reviewed with referral for further investigation. • IM and IV routes are restricted to use by podiatric surgeons only and must only be used in association with a hospital admission (including a registered day surgery facility) • When route of administration by podiatric surgeon is intramuscular (IM), use is restricted to one bolus injection to initiate therapy

Antibacterials	
Cephalosporins	Restrictions/ additional notes
Cefalexin*	
Lincosamides	Restrictions/ additional notes
Clindamycin	
Macrolides	Restrictions/ additional notes
Erythromycin	Restricted to podiatric surgeon only Route restricted to oral only
Roxithromycin	
Nitroimidazoles	Restrictions/ additional notes
Metronidazole	IV route restricted to podiatric surgeon only

Anti-infectives	
Antibacterials • **Cephalosporins** • **Lincosamides** • **Macrolides** • **Nitroimidazoles** • **Penicillins** • **Quinolones** • **Tetracyclines** **Antifungals** • **Other antifungals**	
Penicillins	Restrictions/ additional notes
Amoxicillin*	IM and IV route restricted to podiatric surgeon only
Amoxicillin* with clavulanic acid	
Dicloxacillin	
Flucloxacillin sodium*	IM and IV route restricted to podiatric surgeon only
Phenoxymethylpenicillin	Restricted to podiatric surgeon only Route restricted to oral only
Quinolones	Restrictions/ additional notes
Ciprofloxacin	Route restricted to oral only
Tetracyclines	Restrictions/ additional notes
Doxycycline hyclate (hydrochloride)*	Restricted to podiatric surgeon only Route restricted to oral only
Other antifungals	Restrictions/ additional notes
Terbinafine	When oral therapy using antifungal agents is initiated by a podiatrist or podiatric surgeon with endorsement for scheduled medicines, the prescriber must inform, request and ensure agreement from a medical practitioner with regard to who takes responsibility for monitoring the systemic status of the patient in line with the principles of Quality Use of Medicines (QUM).
Griseofulvin	

Dermatological Drugs	
Drugs for eczema • **Corticosteroids (skin)** **Drugs for skin infections** • **Azoles (skin)** • **Other antifungals (skin)** • **Anti-bacterials (skin)** **Drugs for actinic keratoses**	
References to the word 'skin' against some medicines generally refers to the topical application of the medicine, rather the treatment of a skin condition	
Corticosteroids	Restrictions/ additional notes
Betamethasone (skin)	
Desonide (skin)	
Hydrocortisone (skin)	
Methylprednisolone (skin)	
Mometasone (skin)	
Triamcinolone (skin)	
Azoles	Restrictions/ additional notes
Bifonazole	
Clotrimazole (skin)	
Econazole	
Ketoconazole (skin)	
Miconazole (skin)	
Other antifungals (skin)	Restrictions/ additional notes
Amorolfine	
Nystatin (skin)	
Terbinafine (skin)	
Anti-bacterials (skin)	Restrictions/ additional notes
Mupirocin	
Silver sulfadiazine	
Drugs for actinic keratoses	Restrictions/ additional notes
Diclofenac (skin)	

Immunomodulators and antineoplastics	
Immunosuppressants • **Corticosteroids**	
Corticosteroids	Restrictions/ additional notes
Dexamethasone	Injection only Injection limited to injection in the foot for local effect
Betamethasone	Injection and topical only Injection limited to injection in the foot for local effect
Methylprednisolone	
Triamcinolone	

Neurological drugs	
Antiepileptics • **Benzodiazepines (neurology)**	
Benzodiazepines (neurology)	Restrictions/ additional notes
Diazepam	Restricted to podiatric surgeon only Route restricted to oral only Can be used for up to 10 days for treatment of muscle spasm

Psychotropic drugs	
Drugs for anxiety and sleep disorders • **Benzodiazepines**	
Benzodiazepines	Restrictions/ additional notes
Diazepam	Restricted to podiatric surgeon only Route restricted to oral only One dose orally for pre-procedural anxiety
Lorazepam	Route restricted to oral only One dose orally for pre-procedural anxiety

Rheumatological drugs
Drugs for gout **Drugs for other musculoskeletal conditions** • **NSAIDs**
• In the case of initial diagnosis and treatment for gout, a medical practitioner **must** be notified. The medical practitioner should be requested to undertake further confirmatory diagnostics (unless already arranged by the podiatrist or podiatric surgeon) and to undertake the long-term management of the condition. • NSAIDs (prescription and Over the Counter (OTC)) are associated with significantly increased risks of cardiovascular events (e.g. stroke, heart attack) and therefore should be used with caution especially in patients with predisposing cardiovascular risk factors.

Drugs for gout	Restrictions/ additional notes
Colchicine	Route restricted to oral only As a therapeutic dose over a 24 hour period as per the *Australian Medicines Handbook* dosage guidelines
Drugs for other musculoskeletal conditions	
NSAIDs	Restrictions/ additional notes
Celecoxib	
Diclofenac	
Ibuprofen	
Indometacin *	
Ketorolac	Restricted to podiatric surgeon only For peri-operative treatment only
Meloxicam	
Naproxen	
Sulindac	

Overview of the review of the Guidelines for endorsement of scheduled medicines

Background

Under section 39 of the National Law, a National Board may develop and approve of codes and guidelines to provide guidance to the health practitioners it registers, and about other matters relevant to the exercise of its functions.

The Board's current *Guidelines for Endorsement for Scheduled Medicines* (ESM guidelines) were developed under Section 39 of the National Law to provide further guidance to podiatrists and podiatric surgeons about the Board's ESM registration standard. The Board's *Endorsement for scheduled medicines: Clinical Practice Guidelines* are at Appendix A to the current guidelines and the *National Podiatry Scheduled Medicines List*, which sets out the scheduled medicines that endorsed podiatrists and podiatric surgeons are qualified to use and prescribe, is at Appendix B to the current guidelines

The ESM guidelines are being reviewed at the same time as the ESM registration standard.

Proposed key changes to the ESM guidelines

The key changes that the Board has made to the proposed revised ESM guidelines are:

- updating and restructuring to reflect the updated requirements of the revised ESM registration standard
- the types of evidence that an applicant can submit to the Board under Pathway 2 to demonstrate that they have met the Board's supervised practice requirements and achieved the required prescribing competencies to have their registration endorsed for scheduled medicines have been expanded, and
- definitions of key terms and a list of references and resources has been included.

Options statement

The Board has considered the following options in developing this proposal.

Option 1 – Status quo

Option 1 would continue with the existing ESM guidelines. The existing guidelines supplement the current ESM registration standard (which is part of this review), which established the Board's initial requirements for endorsement for scheduled medicines under the National Law. However, the Board is proposing changes to the draft revised ESM registration standard and the ESM guidelines need to reflect those changes. The Board has also identified a range of opportunities to improve the current guidelines, including the ability to clarify the language and structure to make the guidelines easier to understand.

Option 2 – Proposed revised guidelines

Option 2 would involve the Board publishing revised ESM guidelines. The proposed draft revised ESM guidelines reflect the requirements of the proposed revised ESM registration standard and would continue to supplement the ESM registration standard. The revised guidelines have clearer wording and structure to make them easier to understand, and provide additional information and guidance about:

- the prescribing competencies required for endorsement for scheduled medicines
- the Board's requirements and procedures for endorsement for scheduled medicines

- for the proposed *Pathway 2*:
  - the principles the Board will use when assessing an application for endorsement for scheduled medicines under this pathway
  - requirements for mentors
  - the evidence to be submitted to the Board to demonstrate competency for endorsement for scheduled medicines, and
- ongoing requirements for podiatrists and podiatric surgeons with endorsement for scheduled medicines, including information about clinical practice requirements, maintaining competence, and useful references and resources.

Clinical practice guidelines: Endorsement for scheduled medicines

The Board's proposed revised *Clinical practice guidelines: Endorsement for scheduled medicines* (ESM clinical practice guidelines) are included as an appendix to the proposed revised ESM guidelines. The ESM clinical practice guidelines have been updated and reformatted and as well as including information about communication with other members of the patient's treating team, they now also include information about:

- Quality Use of Medicines (QUM)
- adverse event reporting
- prescriptions
- supply of scheduled medicines, and
- antimicrobial stewardship.

Preferred option

The Board prefers Option 2.

Issues for discussion

Potential benefits and costs of the proposal

The benefits of the preferred option are that the draft revised ESM guidelines:

- reflect the requirements of the proposed revised ESM registration standard and provide further guidance on the requirements for endorsement, particularly for *Pathway 2*, including clear information about the evidence requirements and requirements for mentors
- provide clear information about the prescribing competencies required for endorsement for scheduled medicines, and
- are clearer and easier to understand than the existing guidelines.

The costs of the preferred option are:

- practitioners, other stakeholders and AHPRA will need to become familiar with the new guidelines, and
- there will need to be a period of transition to the proposed revised guidelines.

Estimated impacts of the draft revised guidelines

Because the changes proposed in the draft revised ESM guidelines reflect the changes in the proposed revised ESM registration standard, the Board does not expect any additional impact to those outlined in relation to the proposed revised ESM registration standard outlined at pages 9 and 10 of this consultation paper.

Relevant sections of the National Law

Section 39.

Questions for consideration

The Board is inviting feedback on the following questions regarding the draft proposed revised ESM guidelines:

1. Is the content of the draft proposed revised ESM guidelines helpful, clear, relevant and more workable than the current guidelines.
2. Is there any content that needs to be changed or deleted in the draft proposed revised ESM guidelines?
3. Is there anything missing that needs to be added to the draft proposed revised ESM guidelines?
4. Do you have any other comments on the draft proposed revised ESM guidelines?
5. Do you have any comments on the draft proposed revised *Clinical practice guidelines: Endorsement for scheduled medicines*?

The proposed revised ESM guidelines follow at page 32 of this consultation paper.

Guidelines: Endorsement for scheduled medicines **(DRAFT)**

Effective from :<< date>>

Introduction

These guidelines have been developed by the Podiatry Board of Australia (the Board) to provide guidance about how to meet the requirements of the Board's *Registration standard: Endorsement for scheduled medicines* (ESM registration standard) when you are applying for endorsement for scheduled medicines and when endorsed. You are expected to understand and apply these guidelines together with the ESM registration standard.

Do these guidelines apply to me?

These guidelines should be used by podiatrists and podiatric surgeons:

- seeking to have their registration endorsed for scheduled medicines, and/or
- whose registration is endorsed for scheduled medicines.

These guidelines must be read in conjunction with the ESM registration standard, published on the Endorsement for scheduled medicines page of the Board's website.

Summary

These guidelines are divided into the following parts:

1. **Prescribing competencies for endorsement for scheduled medicines** – information about the required prescribing competencies to have your registration endorsed for scheduled medicines and to ensure that you can safely and effectively administer, obtain, possess, prescribe, sell, supply or use the scheduled medicines listed in the *National podiatry scheduled medicines list*[12] for the treatment of podiatric conditions.
2. **Requirements for endorsement for scheduled medicines** – further information and guidance about the Board's requirements for endorsement for scheduled medicines, including information about the two pathways to endorsement; qualifications for each pathway; and for Pathway 2, information about online case studies, supervised practice, portfolio of evidence, and assessment, including information about the principles the Board will use when assessing an application for endorsement for scheduled medicines under Pathway 2.
3. **Ongoing requirements for podiatrists and podiatric surgeons with endorsement for scheduled medicines** – information about clinical practice requirements, and maintaining competence.
4. **References and resources** – a list of useful references for endorsed practitioners and practitioners working towards endorsement, and

[12] The *National podiatry scheduled medicines list* is at Attachment A to the Board's ESM registration standard.

5. **Appendices** – additional details and further information about some of the material covered in the body of these guidelines.

    - Appendix 1 contains detailed information about the requirements for a mentor under Pathway 2
    - Appendix 2 contains detailed information about the evidence to include in the portfolio that must be developed as part of Pathway 2, and
    - Appendix 3 contains the Board's *Clinical practice guidelines: Endorsement for scheduled medicines*.

The information contained in these guidelines is complementary to and must be read in conjunction with the Board's ESM Registration standard.

Bolded terms are defined in the *Definitions* section of these guidelines.

1. Prescribing competencies for endorsement for scheduled medicines

As required by the Board's ESM registration standard, if you are applying for an endorsement for scheduled medicines you must be able to demonstrate that you have the required prescribing competencies to have your registration endorsed for scheduled medicines.

The required **prescribing competencies** are defined in the ESM registration standard as the prescribing competencies described in the NPS MedicineWise *Prescribing Competencies Framework*[13] as it may be updated from time to time – or such other national prescribing competencies that the Board may adopt by notice published on the Board's website.

The NPS MedicineWise *Prescribing Competencies Framework* describes the competencies that health professionals require to prescribe medicines judiciously, appropriately, safely and effectively in the Australian healthcare system. In summary, the prescribing competencies (as set out in the framework) relate to seven main areas. Five competencies are specific to prescribing and two are more general professional competencies that are also critical to safe prescribing.

The areas are as follows:

1. **Assessment**: Understands the patient and their clinical needs.
2. **Treatment options**: Understands the treatment options and how they support the patient's clinical needs.
3. **Shared decision making**: Works in partnership with the person to develop and implement a treatment plan.
4. **Coordination**: Communicates the treatment plan clearly to other health professionals.
5. **Monitors and reviews**: Monitors and reviews the patient's response to treatment.
6. **Professional**: Practises professionally.
7. **Communicates**: Communicates and collaborates effectively with the person and other health professionals.

2. Requirements for endorsement for scheduled medicines (ESM)

The Board's ESM registration standard sets out the requirements for a podiatrist or podiatric surgeon to have their registration endorsed for scheduled medicines under section 94 of the National Law.

[13] NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

The requirements are designed to ensure that a podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines has the required prescribing competencies to safely administer, obtain, possess, prescribe, sell, supply or use scheduled medicines for the treatment of podiatric conditions.

There are two pathways for endorsement for scheduled medicines:

1. Pathway 1 – approved qualification pathway.

2. Pathway 2 – supervised practice pathway for registered practitioners.

2.1 Pathway 1 Approved qualification pathway

Evidence that you hold an **approved qualification for endorsement for scheduled medicines** (or equivalent) is required by the Board for this pathway.

The definition of an approved qualification for endorsement for scheduled medicines is in the Board's ESM registration standard and these guidelines. The qualification is obtained by completing a Board-approved program of study for endorsement for scheduled medicines.

The qualification must be current. This means that it must not be more than seven years old at the time you apply for endorsement for scheduled medicines. The date the qualification was conferred is that date that is used to determine its currency.

The Board's approved programs of study for endorsement for scheduled medicines are published on the accreditation page of the Board's website. Information about the process for assessing whether a qualification is substantially equivalent to, or based on similar competencies to, an approved qualification is published on the Endorsement for scheduled medicines page of the Board's website.

2.2 Pathway 2 Supervised practice pathway for registered practitioners

2.2.1 Overview of Pathway 2

Pathway 2 provides a pathway for registered podiatrists and podiatric surgeons to meet the requirements for endorsement for scheduled medicines through a combination of:

- an approved qualification in podiatric therapeutics
- successful completion of approved online case studies relevant to the endorsement
- a period of supervised practice, and
- development of a portfolio of evidence.

There are also steps you must complete before commencing your period of supervised practice and to progress during your period of supervised practice.

Further guidance about each of these requirements can be found below.

A simple flowchart which provides an overview of the requirements for Pathway 2 is published on the Endorsement for scheduled medicines page of the Board's website.

2.2.2 Approved qualification in podiatric therapeutics

The definition of an **approved qualification in podiatric therapeutics** is in the ESM registration standard and these guidelines.

The qualification is obtained by completing a Board-approved program of study in podiatric therapeutics. The qualification must be current. This means that it must not be more than seven years old at the time you apply to the Board to commence supervised practice under this pathway. The date the qualification was conferred is that date that is used to determine its currency.

If you think your qualification will be more than seven years old by the time you apply to commence supervised practice, you will need to complete another approved program of study in podiatric therapeutics before commencing the other requirements under this pathway.

The Board's approved programs of study in podiatric therapeutics are published on the accreditation page of the Board's website. Information about the process for assessing whether a qualification is substantially equivalent to, or based on similar competencies to, an approved qualification is published on the Endorsement for scheduled medicines page of the Board's website.

You must submit evidence of your approved qualification with your application to the Board to commence supervised practice. If your qualification has been assessed as substantially equivalent to, or based on similar competencies to, an approved qualification you must submit evidence of that assessment.

2.2.3 Board approved online case studies

Online case studies are a well-accepted method for integrating knowledge, skills and key aspects of clinical decision making.

Board approved online case studies are defined in the ESM registration standard and these guidelines. The online case studies must be completed after you have obtained your approved qualification in podiatric therapeutics (or equivalent).

You must submit evidence of having successfully completed 15 Board approved online case studies when you apply to the Board to commence supervised practice. The evidence required will usually be in the form of a certificate from the education provider certifying that you have successfully completed the online case studies.

A list of education providers who deliver approved online case studies is published on the Endorsement for scheduled medicines page of the Board's website.

2.2.4 Supervised practice

Overview

The definition of **supervised practice** for the purpose of Pathway 2 is in the ESM registration standard and these guidelines.

The period of supervised practice must meet the requirements of the ESM registration standard and these guidelines. You must be registered as a podiatrist or podiatric surgeon in Australia before you can commence supervised practice under this pathway. The purpose of undertaking a period of supervised practice is to further develop your capacity to undertake best practice in prescribing which will build on the profession specific knowledge that you have gained through attaining a qualification in podiatric therapeutics.

You must have a signed mentor agreement in place with a mentor who meets the requirements set out in **Appendix 1**. A mentor agreement template is on the Endorsement for scheduled medicines page of the Board's website.

Apply to commence supervised practice

Before you commence your period of supervised practice you must apply to the Board to commence supervised practice and submit the following to the Board for approval:

- evidence that you hold an approved qualification in podiatric therapeutics, or equivalent
- evidence of having successfully completed Board-approved online case studies, and
- a signed mentor agreement.

The *Application to commence supervised practice* form can be found on the Endorsement for scheduled medicines page of the Board's website.

You must not commence your period of supervised practice until the Board is satisfied that you have met these prerequisites and has advised you in writing that you have met the prerequisites.

Supervised practice – clinical experience

As required by the ESM registration standard, you must complete a minimum period of 150 hours of supervised practice within a 12-month period under the guidance of a mentor. Your mentor has a key role in ensuring you understand the requirements for safe and effective prescribing of scheduled medicines for the treatment of podiatric conditions.

Information about the role and responsibilities of the mentor are set out in **Appendix 1**. You and your mentor must be familiar with the information in this appendix.

It is essential that you are exposed to a variety of settings to ensure a mix of clinical experiences. You should have an opportunity to observe and review clinical encounters with patients across the continuum of care.

The supervised practice must involve podiatric pathology and be sufficient to allow substantial exposure to podiatric conditions, interventions and their management through the use of scheduled medicines. It will involve learning through observing prescribing clinicians in patient consultations or other clinical encounters and discussion and reflection in a range of prescribing environments under the guidance of your mentor.

It must be completed within 12 months of the date that you are advised in writing that the Board is satisfied you have met the prerequisites for supervised practice.

If you are unable to complete the minimum of 150 hours of supervised practice within a 12-month period, the Board may grant an extension of time to complete the supervised practice in exceptional circumstances. A Board policy on when an extension may be granted is published on the Endorsement for scheduled medicines page of the Board's website.

Attending prescribing clinician for patient consultations

The attending prescribing clinician for the clinical encounters you are observing will be an experienced health practitioner who can prescribe scheduled medicines. This may be your mentor or another health practitioner.

The use of more than one prescribing clinician is encouraged as this may assist you in getting exposure to a mix of clinical experiences. It will also enable you to benefit from different perspectives on prescribing, according to different contexts. Examples of prescribing clinicians include: a podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines; a GP; specialist nurse practitioner; hospital medical officer; pharmacist; or dermatologist.

The Board expects that rather than just being a passive observer you will take an active role in the clinical decision making for the particular patient in discussion with the attending prescribing clinician and that this will be reflected in the evidence that you submit with your portfolio.

The attending prescribing clinician is required to sign and date your log of supervised practice activities for each clinical attendance. See **Appendix 2** for information about the log of supervised practice activities, which forms part of your reflective journal.

2.2.5 Portfolio of evidence

As required by the ESM registration standard, during your period of supervised practice you will progressively develop a portfolio of evidence that will demonstrate to the Board that you have the required **prescribing competencies** to have your registration endorsed for scheduled medicines and that you have met the Board's requirements for supervised practice.

The portfolio allows you to describe and provide evidence of your learning through your clinical experience, related education, interaction with your mentor and self-reflection.

There is no formal prescribed format for the portfolio, however the evidence contained in your portfolio must:

- demonstrate clearly and in detail that you have dealt with a diverse range of patient cases and clinical settings involving the use of scheduled medicines in the management of podiatric conditions

- be sufficient to satisfy your mentor and the Board that you have the required **prescribing competencies** to be able to safely administer, obtain, possess, prescribe, sell, supply or use the scheduled medicines in the *National podiatry scheduled medicines list* for the treatment of podiatric conditions, and

- demonstrate how you have reflected on your performance during the period of supervised practice.

Remember: you need to be able to demonstrate that you meet each of the competencies described in the NPS MedicineWise *Prescribing Competencies Framework* and that you have the related podiatric-specific knowledge, skills and behaviours for each competency

It is essential that you are familiar with and understand the NPS MedicineWise *Prescribing competencies framework* and can clearly demonstrate through the evidence in your portfolio that you meet each of the **prescribing competencies** described in the framework or such other national prescribing competencies that the Board may adopt by notice published on the Board's website.

Examples of evidence

The evidence in your portfolio must include de-identified clinical studies and a reflective diary/journal. It can also include de-identified case notes, journal reviews and additional formal education.

More detailed information on the evidence to be included in your portfolio, including examples of evidence is set out in **Appendix 2**.

The documents included in your portfolio as evidence must be signed by you and your mentor. Verification by your mentor of the content of the evidence in your portfolio will help ensure that your portfolio accurately reflects that you have completed the Board's requirements for supervised practice and have met the required **prescribing competencies**.

The evidence in your portfolio should be clearly presented and labelled and accompanied by an evidence matrix to show which piece of evidence demonstrates what competency. A template evidence matrix is published on the Endorsement for scheduled medicines page of the Board's website.

2.2.6 Principles for assessment of application for ESM under Pathway 2

The Board will apply the following principles when assessing your application for endorsement for scheduled medicines under Pathway 2:

- evidence submitted must be a valid, reliable and accurate record of your learning and must be signed by you and your mentor, and

- the evidence you submit will be assessed against the competencies described in the NPS MedicineWise *Prescribing Competencies Framework*. It is therefore essential that you are familiar with this framework and associated knowledge, skills and behaviours related to each competency outlined in the framework.

2.2.7 Assessment

Initial assessment of clinical studies

As set out in **Appendix 2** to these guidelines, you must include a **minimum of 15 clinical studies** in your portfolio.

As required by the ESM registration standard, when you have completed a minimum of 25 hours of supervised practice, you must submit to the Board for assessment three clinical studies that have been completed in accordance with the requirements set out in **Appendix 2** and reviewed and signed

off by your mentor. All three clinical studies must include a completed prescription (see Appendix 2). The clinical studies must be accompanied by a brief report from you which outlines which of the prescribing competencies are demonstrated in each clinical study.

This provides an opportunity for the Board to provide feedback to you in the early part of your period of supervised practice and provide you with an opportunity to reflect on the feedback, discuss it with your mentor and address any concerns before you complete your period of supervised practice.

Clinical studies that have been assessed as satisfactory by the Board will be returned to you and you must resubmit them in your portfolio to the Board when you apply to have your registration endorsed for scheduled medicines at the end of the period of supervised practice. These clinical studies are counted towards the minimum of 15 that you are required to submit in the portfolio.

Any clinical studies that are assessed during this initial assessment as unsatisfactory will be returned to you with a clear statement about why the particular clinical study was unsatisfactory. This provides you with an opportunity to reflect on the feedback you have received and then apply that learning to another clinical study.

You will be given an opportunity to submit one further clinical study to replace each unsatisfactory clinical study. In other words, you can present up to three new clinical studies for initial assessment.

You will not be allowed to re-submit any clinical study you have previously submitted.

Three clinical studies must be assessed as satisfactory by the Board before you finish your period of supervised practice.

If a total of six clinical studies are assessed as unsatisfactory during the initial assessment, the Board may decide that you are required to undertake further education before continuing with any further supervised practice.

Final assessment for Pathway 2

The ESM registration standard sets out when you can submit your application to the Board to have your registration endorsed for scheduled medicines under Pathway 2.

The *Application for endorsement of registration for scheduled medicines* form can be found on the Endorsement for scheduled medicines page of the Board's website.

Your application and portfolio of evidence will be assessed in line with the principles for assessment outlined above at 2.2.6. In accordance with section 100 of the National Law, the Board may seek further information before deciding your application for endorsement.

If you have not provided sufficient evidence in your portfolio to demonstrate you have the required prescribing competencies to have your registration endorsed for scheduled medicines, the Board may take one or more of the following actions:

- require you to provide further information
- require you to undertake a further period of supervised practice
- require you to complete further education, and/or
- refuse your application for endorsement.

3. Ongoing requirements for practitioners with an endorsement for scheduled medicines

ESM clinical practice guidelines

The Board's *Clinical practice guidelines: Endorsement for scheduled medicines* at **Appendix 3** provide guidance about appropriate clinical practice relating to the safe and effective use of scheduled medicines, including communication with the patient and members of their healthcare team; quality use of medicines (QUM); adverse event reporting; prescriptions; supply of scheduled medicines; and antimicrobial stewardship.

You are expected to understand and apply the clinical practice guidelines in your practice.

Maintaining competence

If your registration is endorsed for scheduled medicines you must maintain your competence to **prescribe** scheduled medicines for the treatment of podiatric conditions, including through:

- completing the required amount of CPD relevant to your scheduled medicines endorsement as set out in the Board's *Registration standard: Continuing professional development* and *Guidelines: Continuing professional development*, and
- maintaining recent experience in this scope of practice that meets the Board's *Registration standard: Recency of practice*.

4. References and resources

You should utilise resources which inform evidence based practice in prescribing medicines in Australia. This applies when:

- undertaking your period of supervised practice
- preparing your portfolio, and
- practising once your registration has been endorsed for scheduled medicines.

References used must be the most current editions to ensure your knowledge is up to date.[14]

Essential references

- Australian Medicines Handbook (AMH)
  https://shop.amh.net.au/products/electronic/down-2015
- Therapeutic guidelines (eTG and latest hard copy versions) – relevant to your practice
  http://www.tg.com.au
- NPS MedicineWise
  http://www.nps.org.au/
- MIMS Australia
  http://www.mims.com.au/
- MIMS online
  http://www.mims.com.au/index.php/products/mims-online

Additional useful references

- Quality Use of Medicines (QUM)
  www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm
- Antimicrobial stewardship
  http://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/antimicrobial-stewardship/
- TGA Medicines Safety Update
  https://www.tga.gov.au/publication/medicines-safety-update
- TGA[15]
  https://www.tga.gov.au/

[14] There may be a cost for accessing some of these resources.

- Medication safety - Australian Commission on Safety and Quality in Healthcare http://www.safetyandquality.gov.au/our-work/medication-safety/
- Choosing Wisely Australia http://www.choosingwisely.org.au/home
- Recent textbook on Clinical Pharmacology
- Journals – e.g. Medical Journal of Australia

The Board may publish additional useful references on its website from time to time.

Authority

The Podiatry Board of Australia has developed these guidelines under section 39 of the **National Law**.

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

Definitions

The following terms are defined for the purpose of the ESM registration standard and these guidelines:

Approved qualification for endorsement for scheduled medicines means a qualification obtained by completing a podiatry program of study that has been accredited by the accreditation authority for the podiatry profession and subsequently approved by the Board as providing a qualification for the purpose of endorsement for scheduled medicines for the podiatry profession. The program of study is aligned to the NPS MedicineWise *Prescribing Competencies Framework*[16] and includes education and training in podiatric therapeutics as well as clinically supervised practice to ensure that graduates have the required competencies for endorsement for scheduled medicines.

Approved qualification in podiatric therapeutics means a qualification that includes education and training in podiatric therapeutics. It does not include the clinically supervised practice that is required for endorsement for scheduled medicines.

Board approved online case studies are case studies relevant to endorsement for scheduled medicines delivered online by a university or other approved education provider and approved by the Board. These case studies include an assessable component. Information about Board-approved online case studies is included in the ESM registration standard and these guidelines.

Ministerial Council means the Australian Health Workforce Ministerial Council.

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

Supervised practice for the purpose of Pathway 2 means the observational clinical placements undertaken by a registered podiatrist or podiatric surgeon in a range of prescribing environments, encompassing reflective practice and sessions with their mentor culminating in a portfolio of evidence that meet the requirements of the ESM registration standard and these guidelines.

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[15] The TGA website includes useful information for health professionals, including reporting adverse events; Product Information (PI); and Consumer Medicine Information (CMI) that can be printed off and provided to the patient when the medicine is prescribed.

[16] NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

Prescribe, when the term is used on its own in the ESM registration standard and these guidelines (including the appendices), means the iterative process involving the steps of information gathering, clinical decision making, communication and evaluation which results in the initiation, continuation or cessation of a medicine.[17]

Prescribing competencies means the prescribing competencies described in the NPS MedicineWise *Prescribing competencies framework*[18] as it may be updated from time to time – or such other national prescribing competencies that the Board may adopt by notice published on the Board's website.

Review

These guidelines will be reviewed from time to time as required. This will generally be at least every three years.

These guidelines replace the previously published guidelines dated 15 March 2011.

Last reviewed: <insert date>

[17] Adapted from the definition of 'prescribing' in the *Health Professionals Prescribing Pathway,* which includes the following statement about the definition - *The definition of prescribing used in the HPPP may be different to the definition of prescribing provided in the legislation governing the use of medicines in each jurisdiction. Health professionals are advised to review the legislation in effect in the State or Territory in which they practice to ensure they understand their legal authorisation to prescribe medicines.*

[18] NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

Appendix 1

Pathway 2: Information about mentors

Who can be your mentor?

Your mentor **must** be experienced and knowledgeable in relation to the use of scheduled medicines for the treatment of podiatric conditions, with a minimum of **two (2) years** clinical experience in the use and prescribing of scheduled medicines.

As required by the ESM registration standard your mentor can be either:

- a podiatrist or podiatric surgeon whose registration has been endorsed for scheduled medicines for at least two years, or
- a registered medical practitioner.

Who cannot be your mentor?

A registered medical practitioner or podiatrist or podiatric surgeon cannot be a mentor if their registration or endorsement is subject to a restriction (such as condition(s) or an undertaking) which restricts their prescribing scope of practice and they don't have access to the full range of medicines in the *National podiatry scheduled medicines list*.[19]

If a mentor has restrictions of this nature placed on his or her registration during the supervision period a new mentor must be engaged.

Professional relationship

The relationship between you and your mentor must be professional. Whilst your mentor is not a supervisor in the strict sense, the same principles that would apply with regard to a supervisor apply to your relationship with your mentor. As stated in the Board's Code of conduct, good practice involves avoiding any potential for conflict of interest in the supervisory relationship. For example, this means avoiding mentoring someone who is a close relative or friend, or where there is another potential conflict of interest that could impede objectivity and/or interfere with your achievement of learning outcomes or relevant experience.

Meetings with your mentor

It is critical that your mentor has adequate time for this role and allows for regular, protected time with you to:

- discuss every clinical consultation or encounter with a view to determining what understanding you have of the issues dealt with and the lessons to be learnt
- review the evidence that you wish to include in your portfolio and provide constructive feedback on any identified prescribing errors or other errors
- assist you to determine what additional evidence you may need to include in your portfolio
- discuss any problems or issues relating to your supervised practice, in a supportive environment
- facilitate and/or guide you in finding placements which will enhance the objectives of your supervised practice, and

[19] The *National podiatry scheduled medicines list* can be found at Attachment A to the Board's *Registration standard: Endorsement for scheduled medicines*

- ensure that you understand what resources are available to facilitate the successful attainment of endorsement for scheduled medicines under Pathway 2.

It is preferable that your meetings with your mentor are face-to-face. However if this is not possible, due to unavailability of a suitable mentor in your area, these meetings can be conducted by teleconference or other means of communication such as web conferencing.

In assessing whether they have adequate time to take on the role of mentoring you, potential mentors are encouraged to consider the responsibilities they will need to fulfil as described in these guidelines, as well as the associated time commitments.

Mentor agreement

Before you commence your period of supervised practice you must have a signed mentor agreement in place with your mentor. The mentor agreement must be submitted with your application to the Board to commence supervised practice.

A mentor agreement template is published on the Endorsement for scheduled medicines page of the Board's website.

Change of mentor

It is expected that you will have only one mentor during your period of supervised practice. However, if you do need to change mentors (for example, if your mentor is no longer available or suitable to mentor you) you must have a signed mentor agreement in place with a new mentor.

The new mentor agreement must be submitted to the Board as soon as possible after it is signed by the mentor.

Role and responsibilities of your mentor

Your mentor has a key role in ensuring you understand the requirements for safe and effective prescribing of scheduled medicines for the treatment of podiatric conditions. The supervised practice you undertake will involve learning through observation, experience, discussion and reflection in a range of prescribing environments under the guidance of your mentor.

Your mentor oversees the supervised practice period and ensures that you have exposure to a range of consultations/clinical experiences that include the management of podiatric conditions through the use of scheduled medicines.

Your mentor may not always be directly involved in your clinical experiences but will provide guidance to you during subsequent discussion of and reflection on those clinical experiences.[20]

Through their knowledge and experience, your mentor provides support for the development of your skills to **prescribe** scheduled medicines across a range of prescribing environments.

Your mentor must be familiar with and understand these guidelines, as well as:

- the NPS MedicineWise *Prescribing Competencies Framework*
- Quality Use of Medicines (QUM)[21]
- the Podiatry Board of Australia's *Registration standard: Endorsement for scheduled medicines*

[20] You will be observing and/or participating in patient consultations where the attending prescribing clinician may be the mentor or another experienced health practitioner. Involvement of more than one type of prescribing clinician is suggested to facilitate exposure to a mix of clinical experiences and different perspectives on prescribing.

[21] Quality Use of Medicines (QUM) http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm

Appendix 1 – Information about mentors

- the *National podiatry scheduled medicines list* (Attachment A to the Board's *Registration standard: Endorsement for scheduled medicines*)
- the Podiatry Board of Australia's *Clinical practice guidelines: Endorsement for scheduled medicines* (see Appendix 3)
- the relevant code of conduct for their profession – that is, either the Podiatry Board of Australia's *Code of conduct*[22] or the Medical Board of Australia's *Good medical practice*.[23]

Review of evidence by mentor

A critical component of the supervised practice period is the requirement for you to develop a portfolio of evidence to demonstrate that you have met the prescribing competencies described in the NPS MedicineWise *Prescribing Competencies Framework*. Your mentor is responsible for reviewing, assessing, and providing constructive feedback on the evidence you have developed.

As soon as practicable after completing each piece of evidence for your portfolio, you must discuss the content with your mentor and discuss the prescribing competency or competencies that it is intended to demonstrate. A learning outcome may be written post observation to highlight new learning upon reflection.

You and your mentor should together ensure that you:

- are exposed to a range of therapeutic uses of the scheduled medicines on the *National podiatry scheduled medicines list* for the treatment of podiatric conditions
- observe the pharmacological reasoning, decision-making and management of podiatric conditions through the use of scheduled medicines
- observe and reflect on the Quality Use of Medicines[24]
- demonstrate the communication between the patient and the health professionals who contribute to the patient's health management
- are exposed to and involved with prescription writing
- consider your ethical and legal obligations in relation to the prescribing of scheduled medicines
- understand the importance of explaining the cost implications for the patient of the medicines that you prescribe, and
- can clearly demonstrate, through the evidence in your portfolio, that you meet each of the prescribing competencies described in the NPS MedicineWise *Prescribing Competencies Framework*.

Once you and your mentor are satisfied with the content of the evidence document, you must both sign and date the document.

Certificate of completion of supervised practice

When you have completed your period of supervised practice, your mentor is required to review your portfolio of evidence and complete the *Certification of completion of supervised practice* form. The form is available on the Endorsement for scheduled medicines page of the Board's website.

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[22] The Podiatry Board of Australia's *Code of conduct* can be found on the Board's website under Policies, Codes and Guidelines

[23] the Medical Board of Australia's *Good medical practice* can be found on the Medical Board's website under Codes, Guidelines, Policies

[24] Quality Use of Medicines (QUM) http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm

Appendix 1 – Information about mentors

You and your mentor should ensure that the portfolio of evidence reflects that you have completed at least 150 hours of supervised practice in Australia.

It should also reflect that your mentor has noted:

- a diversity of patients and medical conditions
- a diversity of clinical settings
- a diversity of prescribing of scheduled medicines for the treatment of podiatric conditions from each of the classes of drugs in the *National podiatry scheduled medicines list*[25]
- observance of Quality Use of Medicines[26]
- that you have understood your ethical and legal obligations in relation to the prescribing of scheduled medicines and that you understand the importance of explaining the cost implications for the patient of the medicines that you prescribe, and
- that you have the required prescribing competencies to have your registration endorsed for scheduled medicines.

[25] The *National podiatry scheduled medicines list* is at Attachment A to the Board's *Registration standard: Endorsement for scheduled medicines*

[26] Quality Use of Medicines (QUM) http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm

Appendix 2

Pathway 2: Evidence for inclusion in your portfolio

As required by the ESM registration standard, during your period of supervised practice you will progressively develop a portfolio of evidence that will demonstrate to the Board that you have met the Board's supervised practice requirements and you have the required prescribing competencies to have your registration endorsed for scheduled medicines.

The required **prescribing competencies** are the prescribing competencies described in the NPS MedicineWise *Prescribing competencies framework.*[27] You may include various types of evidence in your portfolio to demonstrate that you have met each of the **prescribing competencies**.

Some pieces of evidence may be used to demonstrate that you have met a number of the prescribing competencies. You may use multiple pieces of evidence to address any of the competencies.

Each piece of evidence in your portfolio must:

- be your own work
- be reviewed by and discussed with your mentor as soon as practicable after you have completed it. This will enable the mentor to be confident that your clinical experience relates, or is relevant to podiatric interventions and contributes to the diverse scenarios required for the Board to consider your application for endorsement for scheduled medicines
- be signed and dated by you and your mentor, and
- must be referenced to one or more of the required **prescribing competencies**.

If the Board considers that the evidence submitted in your portfolio does not provide sufficient information to demonstrate you have the required **prescribing competencies** to have your registration endorsed for scheduled medicines, depending on the information you have submitted, it may:

- require you to provide further information, or
- require you to undertake a further period of supervised practice, or
- refuse your application for endorsement, or
- impose conditions on your endorsement.

The examples of evidence outlined below are key types of evidence that will assist you in demonstrating that you have met the required **prescribing competencies**.

You don't have to use all of the examples of evidence set out below but you must include clinical studies and a reflective journal as part of your evidence. These must meet the requirements set out below.

The list is not exhaustive and you may wish to include additional types of evidence to support your application. You are encouraged to use a variety of evidence to demonstrate that you have met all of the NPS prescribing competencies.

[27] NPS: Better choices, Better health. Competencies required to prescribe medicines: putting quality use of medicines into practice. Sydney:National Prescribing Service Limited, 2012. Available at http://www.nps.org.au/health-professionals/cpd/prescribing-competencies-framework

Appendix 2 – Evidence for inclusion in your portfolio

You need to be able to demonstrate that you meet each of the competencies described in the NPS MedicineWise *Prescribing Competencies Framework* and that you have the related podiatric-specific knowledge, skills and behaviours for each competency

1. Essential evidence

As noted above, clinical studies and a reflective journal must be submitted as part of your portfolio of evidence.

1.1 Clinical studies

Your portfolio must include records of individual de-identified cases and consultations[28] in the form of clinical studies. Clinical studies are an important means of demonstrating your knowledge and skills and your clinical reasoning in relation to the particular case.

You must include **a minimum of 15 clinical studies** which must:

- reflect a variety of placements during the period of supervised practice, such as (but not restricted to) high-risk foot clinics, teaching clinics, emergency departments, the operating room, rheumatology clinics, endocrinology clinics, general medical practice and aged care facilities
- involve podiatric pathology in at least 12 of the clinical studies and be related to a podiatric condition, intervention or management. Clinical studies that don't involve podiatric pathology must deal with conditions that would allow the knowledge and skills to transfer to podiatry
- include at least five high-risk cases, for example, diabetes-related cases
- include cases where patients have a range of co-morbidities and are at risk of adverse outcomes related to polypharmacy
- demonstrate complexity in patient cases – you must include at least five cases which involve more than one class of medicines. These cases must include at least one medicine from the *National podiatry scheduled medicines list* and may also include the medicines that the patient is already taking, and
- clearly show your patient assessment and clinical decision making processes, and demonstrate your knowledge and critical thinking in relation to the use of scheduled medicines in your clinical practice.

As required by the Board's ESM Registration standard and explained in the body of these guidelines, three of the clinical studies must be submitted to the Board for assessment after you have completed at least 25 hours of supervised practice. See the body of these guidelines under *Initial assessment of clinical studies* for further information.

Each individual clinical study

Each clinical study you include in your portfolio must be comprehensive, and include a medicines assessment and evaluation. A clinical study may be used as evidence of a number of the required prescribing competencies. It must be prepared as though you were the prescribing practitioner.

A comprehensive clinical study also includes the following:

- relevant medical history
- medication history and current medications (including prescription and over-the-counter medicines or complementary medicines)

[28] De-identified means removing any individual's name and any information from which an individual's identity could be revealed.

Appendix 2 – Evidence for inclusion in your portfolio

- the presenting complaint
- assessment
- relevant clinical findings and investigations
- diagnosis/differential diagnosis
- recommended treatment plans and alternatives
- scheduled medicines assessment and evaluation, including:
  - medicines prescribed and mode of administration
  - indication/purpose for medicines prescribed
  - evidence for use and effectiveness
  - rationale for prescribing a particular agent
  - pharmacodynamics and pharmacokinetics
  - dosing and administration issues
  - adverse effects
  - interactions
  - contraindications and patient precautions
  - appropriateness for the patient
  - patient education and information provided to patient about the medicine(s) prescribed
  - consideration of your ethical and legal obligations in relation to the prescribing of scheduled medicines
  - explanation of the cost implications for the patient of the medicines prescribed, and any alternatives
  - outline of collaboration and/or communication with other health providers
  - shared care protocols, and
  - a ‘reflective component’ to indicate how your knowledge has developed and grown, and
- a plan for monitoring and review.

Each clinical study should demonstrate that:

- you have been directly involved, as one of the attending practitioners
- you have discussed with the attending prescribing clinician the management of a podiatric condition and the prescription or administration of a scheduled medicine
- you have considered options other than a pharmacological intervention
- there are sound reasons for prescribing a scheduled medicine and, in particular, the scheduled medicine(s) prescribed

- the choice of scheduled medicine has been made in consideration of various schedules which contain the same medicines in differing presentations and the cost considerations in respect to pharmacy dispensing fees, and
- you have met one or more of the prescribing competencies.

Completed prescription

All clinical studies you submit must be accompanied by a sample completed prescription that you have prepared for that individual patient. The sample prescription must demonstrate your ability to clearly and unambiguously prescribe the scheduled medicines in the *National podiatry scheduled medicines List*.[29]

An example of a prescription is available on the Endorsement for scheduled medicines page of the Board's website.

Additional requirements for some clinical studies

Some of your clinical studies must also include the following:

- *Sample of communication with members of the patient's healthcare team*

  At least five clinical studies must include a de-identified sample letter or other form of communication to one or more members of the patient's healthcare team, such as their GP or other health professional. This may be used to demonstrate your competency in communication and collaboration with other health professionals to achieve optimal health outcomes for the patient.

  The communication must be clearly referenced to the particular clinical study and reflect the outcomes of the consultation with that patient.

  The five clinical studies that include the communication must reflect different clinical scenarios so that you can demonstrate your communication and collaboration in different situations.

- *Clinical outcome of medicine*

  In at least five clinical studies the actual outcome of the medicine(s) prescribed must be reported.

Template clinical study

The Board has developed a template for a clinical study, which is available on the Endorsement for scheduled medicines page of the Board's website.

1.2 Reflective journal

The purpose of a reflective journal is to enable you to demonstrate that:

a. you have undertaken a minimum of 150 hours of supervised practice within a 12-month period.

   Your reflective /journal must include a log of the activities you have undertaken during your supervised practice. The attending prescribing clinician at each clinical attendance must sign and date each attendance.[30]

[29] The *National podiatry scheduled medicines list* is at Attachment A to the *Board's Registration standard: Endorsement for scheduled medicines.*

[30] A sample log of activities can be found on the Board's website under *Registration and Endorsement*.

b. you have reflected on your prescribing practice

The reflective component may include, for example:

- your reflection on one or more of your case studies that involved a broad issue regarding prescribing/use of scheduled medicines
- your reflection on medico-legal aspects of the use and prescribing of scheduled medicines
- a reflective piece (no more than one page) that demonstrates your discussion with a patient from one of your case studies around an element of prescribing unique to the case
- a clinical narrative, which is a written account of an interaction with a patient from one of your case studies that highlights a particular issue relating to the use of scheduled medicines. For example it may include:
  - a situation where things did not go as well as planned, such as a breakdown in communication or failure of patient to comply, and how you managed the situation and learnt from it, and/or
  - a clinical scenario that was particularly complex or demanding
- a theoretical or simulation case scenario that involves the use of the emergency drugs in the *National podiatry scheduled medicines list*
- an outline of policies and protocols that you would introduce to your practice to support and reinforce the Quality Use of Medicines[31]
- your reflection on maintaining your prescribing competencies. This could include an outline of how you plan to:
  - audit the outcomes of your prescribing activity
  - regularly review and reflect on your prescribing practices and identify your learning needs, and/or
  - maintain your prescribing knowledge and skills, including the continuing the professional development activities you consider would be appropriate to address your learning needs, and
- a reflection that demonstrates a higher understanding of issues around prescribing in Australia. Topics are open but examples could include:
  - antibiotic stewardship
  - access to NSAID without prescription
  - cost of agents on PBS versus non PBS
  - reporting mechanisms to the TGA for adverse drug reactions and why this is important
  - legislative requirements about safe storage of medicines
  - protocols for off label use of medicines in podiatry practice, and
  - communication strategies with other health care practitioners.

2. Additional types of evidence

The following are examples of additional types of evidence that you may wish to include in your portfolio to demonstrate that you have met the required **prescribing competencies**.

The list is not exhaustive and you may wish to include further types of evidence.

2.1 Mentor/clinician feedback

A written account from your mentor or attending prescribing clinician from one or more of your clinical studies is a useful way to demonstrate one or more of the **prescribing competencies**.

For example:

- a written account by your mentor or attending prescribing clinician relating to one or more of your clinical studies (de-identified) which focuses specifically on their observation of your professionalism and communication skills and how you have demonstrated competency in

[31] See Quality Use of Medicines (QUM) www.health.gov.au/internet/main/publishing.nsf/Content/nmp-quality.htm

relation to the following horizontal competencies described in the NPS MedicineWise *Prescribing Competencies Framework:*

- *H1: Practices professionally,* and
- *H2 Communicates and collaborates effectively with the person and other health professionals,* and/or

- a statement from your mentor which focuses on your progress. That is, how your learning has developed during the period of supervised practice. It should include examples and context relating to specific **prescribing competencies**.

2.2 Review of journal articles or relevant textbooks

It is also possible to use a review of relevant journal articles or textbooks to provide evidence of meeting specific **prescribing competencies**.

For example, you may review a journal article and outline how you may change your prescribing practice based on what you have learnt from that article (that is, what changes you would make and why). The review should include a brief analysis of the article and you should also attach the article to your review.

2.3 Additional education

You may wish to submit evidence of additional formal education relating to prescribing scheduled medicines.

For example:

- NPS MedicineWise e-learning modules.
- Therapeutics update course.
- TGA online learning modules – e.g. safety through reporting modules.

2.4 Pharmacy rotation

A rotation in a retail or hospital pharmacy provides an opportunity to observe communication strategies between a number of parties in the prescription/dispensing process.

For example, you may observe the interaction between pharmacist and patient/carer, or interaction between pharmacist and prescriber, where clarification is sought in relation to a prescription. A reflection on learning from a rotation in a pharmacy may assist you to demonstrate one or more of the NPS prescribing competencies.

2.5 Simulation

Simulation-based education includes the development and application of clinical knowledge and, of clinical skills such as assessing and examining patients, communicating with patients, performing procedural skills and clinical reasoning. The mode of simulation-based education within the clinical environment can be achieved with mannequins, part-task trainer models, simulated patients (patient actors), online simulations or hybrid simulators.

You may wish to submit evidence of simulation based education that you have undertaken relating to the safe use of scheduled medicines.

Appendix 3

Clinical Practice Guidelines: Endorsement for scheduled medicines

Clinical guidelines and protocols for podiatrists and podiatric surgeons with endorsement for scheduled medicines

These guidelines outline the ongoing clinical practice requirements for podiatrists and podiatric surgeons with an endorsement for scheduled medicines. They include guidance about appropriate clinical practice relating to the safe and effective use of scheduled medicines, including:

1. Communication with other members of the patient's treating team
2. Quality Use of Medicines (QUM)
3. Adverse event reporting
4. Prescriptions
5. Supply of scheduled medicines, and
6. Antimicrobial stewardship.

1. Communication with other members of the patient's treating team

A number of health practitioners are often involved in providing care to patients. This may be referred to as *shared care*. Within a shared care arrangement it is recognised that patient care is provided by two or more practitioners, each practising within his or her sphere of expertise. Shared care aims to co-ordinate patient care to provide high-quality, integrated care that is readily accessible and convenient to the patient and cost-effective for all parties involved. Communication and clear demarcation of roles and responsibilities are essential for effective shared care.

1.1 Ethical and legal obligations associated with shared patient care

Podiatrists and podiatric surgeons participating in shared care must be competent to collect clinical information according to set protocols and must ensure they have the equipment, expertise and skills required to perform their role safely and effectively. An appropriate level of professional indemnity insurance is required.[32] Podiatrists and podiatric surgeons must act in the best interest of the patient at all times. The needs and requirements of the patient must determine the decision of where and/or when to refer the patient. The patient should be informed of alternative management, providers and facilities. In a shared care arrangement, the practitioner who actually writes and signs the prescription carries the accountability for prescribing the scheduled medicines.

1.2 Informed financial consent

Patients must be informed that the scheduled medicines prescribed by a podiatrist or podiatric surgeon with endorsement for scheduled medicines are not eligible for the Pharmaceutical Benefits Scheme (PBS) rebate and therefore may cost more to the patient than if prescribed by a medical practitioner.

1.3 Communication in shared patient care

Communication is the lynchpin of effective shared care. Open discussion, communication and documentation are paramount. Participating practitioners and their patients must understand clearly which practitioner is responsible for providing each of the various aspects of care.

[32] See the Board's *Registration standard*: *Professional indemnity insurance arrangements*

To avoid repetition and confusion, each treating party must have a clear understanding of:

- the other's diagnoses, treatment(s) and ongoing recommendations to the patient
- the information to forward to others involved in the patient's care
- timeframes in which this information should be forwarded
- the preferred format for this information
- who is responsible for ongoing patient care and the follow-up of patients who miss scheduled appointments, and
- the roles and responsibilities of each person participating in the shared care.

The use of standardised protocols and forms are recommended to clarify responsibilities and facilitate the transfer of information and communication between practitioners involved in shared care. Such systems may involve standardised forms used by all parties participating in the shared care arrangement, or may be a less regimented arrangement which places emphasis on contemporary communicated documentation. As a minimum requirement, practitioners sharing patient care should have a clear understanding of which tests should be completed during review appointments.

Ongoing discussion between the podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines and the involved medical practitioner should review these protocols and make any changes necessary over time to ensure optimal patient care. All practitioners involved in shared care of patients should receive a copy of the results of any review appointments the patient attends.

1.4 Required communications

Formal consultation and communication with others in the patient's treating team aims to affect safe and effective care.

Due to the potential for systemic effect and/or the requirement for a definitive diagnosis or more extensive treatment, the Board requires podiatrists and podiatric surgeons with endorsement for scheduled medicines to establish processes for clear communication and consultation with a medical practitioner for certain drug classes in Schedule 4, for example in the management of gout and mycosis where ongoing health monitoring is required. The podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines is required to prescribe in accordance with these guidelines.

1.5 Patient involvement in shared care

In a shared care arrangement, patients must be clearly informed of who maintains responsibility for their primary care and when they are required to attend reviews with each practitioner. Patients must be provided the opportunity to choose whether or not they wish their care to be shared between the general practitioner and their podiatrist or podiatric surgeon. Similarly, the patient reserves the right to seek a second opinion if they so choose. Written information for patients regarding shared care may prove a useful adjunct to verbal discussions with their podiatrist or podiatric surgeon whose registration is endorsed for scheduled medicines.

2. Quality Use of Medicines (QUM)

When incorporating scheduled medicines into a patient care plan, podiatrists and podiatric surgeons should be familiar with and utilise contemporary resources to support the best possible use of medicines in podiatric practice. Podiatrists and podiatric surgeons who **prescribe** scheduled medicines should observe the Quality Use of Medicines (QUM) 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
- 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.

The National Strategy for Quality Use of Medicines (QUM) can be found at:
http://www.health.gov.au/internet/main/publishing.nsf/content/nmp-quality.htm

3. Adverse event reporting

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.

Podiatrists and podiatric surgeons can assist 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.

4. Prescriptions

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 podiatrist or podiatric surgeon must 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 podiatrist and podiatric surgeons need to constantly check the details of the prescription.

The essential information required for a legal prescription may vary between states and territories. Endorsed podiatrists and podiatric surgeons 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.

4.1 Self-prescribing

The Board advises against endorsed podiatrists and podiatric surgeons self-diagnosing and then self-prescribing schedule <4 and/or 8 medicines.

5. Supply of scheduled medicines

The Board supports the view that the division of responsibility between an endorsed podiatrist or podiatric surgeon 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.

Podiatrists and podiatric surgeons 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.[33]

6. Antimicrobial stewardship

When considering the use of antibiotics for the treatment of podiatric pathology, podiatrists and podiatric surgeons should be familiar with and utilise contemporary resources to support the safe and appropriate use of antimicrobials.

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 podiatrists and podiatric surgeons 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.

Antimicrobial stewardship resource materials can be found at: http://www.safetyandquality.gov.au/our-work/healthcare-associated-infection/antimicrobial-stewardship/.

[33] Consumer Medicines information leaflets are available at www.medicines.org.au.

Appendix 3 – Clinical practice guidelines: Endorsement for scheduled medicines

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.

Attachment 1

Statement of assessment

Board's statement of assessment against AHPRA's *Procedures for development of registration standards* and *COAG principles for best practice regulation*

- *Registration standard: Endorsement for scheduled medicines*
- *Guidelines: Endorsement for scheduled medicines*

The Australian Health Practitioner Regulation Agency (AHPRA) has *Procedures for the development of registration standards*, which are available at: www.ahpra.gov.au

These procedures have been developed by AHPRA in accordance with section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) which requires AHPRA to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

Below is the Board's assessment of its proposal for proposed revised *Registration standard: endorsement for scheduled medicines* and related *Guidelines: Endorsement for scheduled medicines* against the following elements outlined in the AHPRA procedures:

- the objectives and guiding principles in the National Law
- the consultation requirements in the National Law, and
- the COAG principles for best practice regulation.

1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law

Board assessment

The Board considers that the proposed revised draft *Registration standard: Endorsement for scheduled medicines* (ESM registration standard) and related revised *Guidelines: Endorsement for scheduled medicines* (ESM guidelines) meet the objectives and guiding principles of the National Law.

The revised draft ESM registration standard, if approved, will continue to provide for the protection of the public by ensuring that podiatrists and podiatric surgeons seeking to have their registration endorsed for scheduled medicines are suitably qualified and competent to practise safely in this scope of practice.

The revised draft ESM registration standard and ESM guidelines also support the National Scheme to operate in a transparent, accountable, efficient, effective and fair way.

2. The consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on proposed registration standards and guidelines. The National Law also requires the Board to consult other boards on matters of shared interest.

The Board will ensure that there is public exposure of its proposals for a draft revised ESM registration standard and related ESM guidelines and there is opportunity for public comment by undertaking an eight-week public consultation process. The process includes the publication of the consultation paper (and attachments) on its website.

Attachment 1

The Board has drawn this consultation paper to the attention of key stakeholders.

The Board will take into account the feedback it receives when finalising its proposals for submission to the Ministerial Council for approval.

3. The proposal takes into account the COAG Principles for Best Practice Regulation

Board assessment

In developing the revised draft ESM registration standard and related ESM guidelines for consultation, the Board has taken into account the Council of Australian Governments (COAG) *Principles for Best Practice Regulation*.

As an overall statement, the Board has taken care not to propose unnecessary regulatory burdens that would create unjustified costs for the profession or the community.

The Board makes the following assessment specific to each of the COAG principles expressed in the AHPRA procedures.

COAG Principles

A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

Board assessment

The Board considers that the proposal is the best option for ensuring protection of the public. The proposal for a revised draft ESM registration standard maintains the pathway to endorsement for scheduled medicines that has been used by the majority of applicants to date (*Pathway 2*), with some changes to improve the pathway to make it clearer and easier to understand and provide more flexibility for practitioners with regard to the evidence they can submit to demonstrate their competence to safely use and prescribe scheduled medicines for the treatment of podiatric conditions.

The Board has introduced a new pathway (*Pathway 1*) where graduates from an accredited and approved program of study are qualified to apply for endorsement for scheduled medicines. The program of study would be aligned to the national prescribing competencies framework and include education and training in podiatric therapeutics as well as clinically supervised practice to ensure that graduates have the required competencies for endorsement for scheduled medicines. The introduction of this new pathway provides flexibility and expands the options for practitioners who wish to have their registration endorsed for scheduled medicines.

The Board considers that the revised draft ESM registration standard and related ESM guidelines would have a low impact on the profession. Any impacts of the proposed revised ESM registration standard and guidelines are significantly outweighed by the benefits of protecting the public and providing clear and robust pathways for endorsement for scheduled medicines for the podiatry profession.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

Board assessment

The Board considered whether its draft revised ESM registration standard and related ESM guidelines could result in an unnecessary restriction of competition among health practitioners. The proposed revised ESM registration standard and ESM guidelines are not expected to affect the current levels of competition among health practitioners, given the nature of the revisions. The revised ESM registration standard will facilitate competition by enabling more podiatrists to achieve scheduled medicines endorsement where they can show the necessary competencies to safely use and prescribe medicines in their podiatric practice.

C. Whether the proposal results in an unnecessary restriction of consumer choice

Board assessment

The Board considers that the proposed revised ESM registration standard and related ESM guidelines will support consumer choice, by establishing clear and robust requirements for endorsement for scheduled medicines for the podiatry profession, including ongoing professional requirements for practitioners whose registration is endorsed for scheduled medicines.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

Board assessment

The Boards considered the overall costs of the revised draft ESM registration standard and related ESM guidelines to members of the public, registrants and governments and concluded that the likely costs are reasonable when offset against the benefits that the proposed revised registration standard and guidelines contribute to the National Scheme.

Subject to stakeholder feedback on the proposed revisions and if the ESM registration standard is approved by the Ministerial Council, the revised draft standard and guidelines should have only a minor impact on the costs to practitioners who wish to have their registration endorsed for scheduled medicines, compared to the current requirements.

E. Whether the requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants

Board assessment

The Board considers that the draft revised registration standard and related guidelines have been written in plain English that will help practitioners to understand the requirements of the standard and guidelines. The Board has changed the structure of the standard and related guidelines and reviewed the wording to make the standards easier to understand. As a result, the Board expects that the registration standard and guidelines will be easier to understand and comply with.

F. Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time

Board assessment

If approved, the Board will review the draft revised ESM registration standard and ESM guidelines as required. This will generally be at least every three years, however, the Board may choose to review the standard and/or guidelines earlier, if it is necessary to ensure the standards' continued relevance and workability.

Any review would include wide ranging consultation and an assessment against the objectives and guiding principles in the National Law and the COAG principles for best practice regulation.