pharmacycouncil
Te Pou Whakamana Kaimatū o Aotearoa

26 April 2023

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145

By email only: committees@moh.govt.nz

Pharmacy Council submission on item 6.1d. Glecaprevir and Pibrentasvir
70th meeting of the Medicines Classification Committee 25 May 2023

Council View

Te Pou Whakamana Kaimatū o Aotearoa / Pharmacy Council (Council) supports initiatives that leverage the complementary competencies of health professionals to improve access to care and, ultimately, health outcomes for New Zealanders provided there are robust mechanisms in place to safeguard the public. Preparation for this submission has included meetings with stakeholders including Te Kaunihera Tapuhi o Aotearoa / Nursing Council of New Zealand.

This reclassification proposes an innovative interdisciplinary model to access medicines where two parties use their specific resources, differing from recent reclassification applications for which we have provided submissions[1] to Medicines Classification Committee (MCC). These typically have proposed reclassification from prescription medicine to alternative classification that that permits a pharmacist (pending certain criteria) to supply the medicine autonomously.

We consider pharmacists possess the competencies to appropriately supply the glecaprevir and pibrentasvir combination (Maviret) as per the proposal in the application. However, we recommend that pharmacists be required to complete a formal training programme that provides more in-depth and specific knowledge on:

- the medicines subject to proposal (glecaprevir and pibrentasvir),
- the condition being treated (chronic hepatitis C),
- how to respectfully engage populations most affected by chronic hepatitis C,
- the responsibilities and accountabilities of respective practitioners under the collaborative process, and
- infection control measures.

In addition, the training should minimise the potential for fragmentation of care and the training should ideally include a country-wide process to support the collaboration. This ensures that each practitioner understands their responsibilities and accountabilities, and that mechanisms for communication and documentation facilitate a safe, cohesive and unambiguous process. We recommend that the respective responsibilities and accountabilities are included as part of training.

Background

We are a Responsible Authority established by the Health Practitioners Competence Assurance Act (HPCA Act) 2003. Our purpose is to protect the public by ensuring that pharmacists are competent and fit to practise. Some of our core functions are summarised below, though a more comprehensive list is mandated within section 118 of the HPCA Act.

[1] As per Appendix 2 of Medsafe guidelines.

- Specifying scopes of practice
- Setting professional competence and ethical standards
- Prescribing and accrediting qualifications required to register in a scope of practice
- Setting requirements and processing applications for registration and recertification
- Maintaining a public register
- Investigating complaints or notifications where a pharmacist may be practising at a level below the expected standard

While it is our role to promote education and training (HPCAA s118 (k)), we are not legislated to provide education or practice support to practitioners. Instead, education provision is undertaken by providers able to provide training that meets the required criteria. This submission is therefore framed within the basis of this mandate. We believe that we are well placed to offer the Medicines Classification Committee (MCC) an independent opinion of pharmacists' competence, necessary for MCC to make an informed recommendation in the public interest.

Application to MCC for reclassifications of glecaprevir and pibrentasvir

Our view is based on our responsibilities under the HPCA Act, pharmacists' involvement in the AbbVie Care Pharmacy Programme and the Hepatitis C Pharmacy Test and Treat programme, stakeholder meetings facilitated by Te Whatu Ora, and application of the joint Medicine Reclassification framework developed by the Pharmaceutical Society of New Zealand (the Society) and Council.[2] We also note the existing MAVIRET® Quality Use of Medicines training programme that pharmacists are required to complete prior to dispensing the glecaprevir and pibrentasvir combination.

The Medicines Reclassification Framework is recognised and utilised by the MCC.[3] It provides a structure that facilities a robust analysis that informs Council's opinion of whether pharmacists may be competent to supply a medicine without prior assessment by a prescriber. If it is determined that pharmacists do possess required competencies, the framework will help determine whether a formal training programme, self-directed up-skilling, or no up-skilling is required. The framework and this submission are not intended to provide specific details of a potential training programme or practical implementation of the proposal.

The Society and Council applied the framework independently but collaborated to ensure that cohesive submissions and advice are produced for MCC. The framework breaks the analysis down into four broad elements. These are: the consultation, the medicine, documentation, and professionalism. For the purposes of this application, which proposes an innovative model to access medicines, we have also included a section on additional competencies and considerations.

We are satisfied that pharmacists possess competencies appropriate under each category to the required level, but we note that some knowledge training is likely required. Our final opinion to MCC is informed by a holistic review against the Competence Standards for the Pharmacy Profession 2015 in their full form; however, a short commentary of each category follows with particularly pertinent competence standards highlighted.[4]

[2] Pharmacy Council of New Zealand / Pharmaceutical Society of New Zealand. Pharmacy Council and Pharmaceutical Society Medicine Reclassification Framework. 2019. https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf.
[3] Medsafe. How to change the legal classification of a medicine in New Zealand. 2019. https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf.
[4] Pharmacy Council of New Zealand. Competence Standards for the Pharmacy Profession. 2015. https://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf.

Consultation Elements

The consultation includes pharmacist activities to gather relevant information from the person; form an appropriate treatment plan via shared decision-making; and convey information regarding safe use of the medicine, and recovery from and prevention of disease. In this case shared decision-making includes the person (and as appropriate whānau or other support), a pharmacist, and a nurse (and any other relevant party). These activities are described by the following competencies within the Competence Standards.

- M2.1: Communicate effectively
- M1.6: Make effective decisions
- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3: Review and manage patient's medicine therapy
- O2.1: Contribute to community health
- O2.2: Health promotion
- O3.5: Provide patient counselling

Under the proposed pharmacist-led model, pharmacists will be responsible for providing an initial antibody screening test via capillary blood (finger prick) sampling. They will not be responsible for the diagnosis of hepatitis C. Pharmacists must understand the theory, mechanics, and limitations of the screening test.

Based on the profiles of populations most affected by hepatitis C, people seeking treatment may have complex comorbidities that may or may not be diagnosed and / or treated. A complete medical and medicine record may also not be available. Training should ensure that pharmacists are aware of these challenges and can provide guidance on how to appropriately manage them. In addition, pharmacists require knowledge of the risks and benefits of hepatitis C treatment and non-treatment to assist the person in making an informed decision on whether to engage with treatment or seek alternatives.

The collaborative nurse-pharmacist team should also ensure that the person is familiar with lifestyle factors / public health measures regarding "infective behaviours" to reduce risk of transmission and reinfection. To ensure a cohesive experience for the person, process or communication between practitioners should, as much as practicable, preclude unnecessary duplication of information provision.

Medicine Elements

To determine whether a medicine is a viable option, a health professional must possess the competencies to access appropriate medicine information, and patient-specific medical and medicine history. They must also be able to integrate the information via a rational and evidence-based decision-making process. The competence standards that relate to these activities are below.

- O1.1: Consult with the patient
- O1.2: Provide healthcare
- O1.3: Review and manage patient's medicine therapy
- O1.5: Access, evaluate and provide medicines information
- O3.4: Administer medicines

Pharmacists may not have existing, in-depth knowledge of glecaprevir and pibrentasvir, but all pharmacists have base competencies to assess and apply medicines information appropriately. We note and accept expert opinion that the medicines are extremely effective while possessing a generally favourable risk profile. Despite this, pharmacists must be aware of mechanisms of action, cautions and contraindications, dosing regimes, drug-drug

and drug-condition interactions, and both common and serious adverse drug reactions and their management.

Pharmacists may be asked to facilitate administration or self-administration of the glecaprevir and pibrentasvir combination. In our view, no additional training, above and beyond what has already been recommended in this submission, is required.

Given that efficacy of treatment is contingent on completion of course at the appropriate dose and that the costs of the medicines and failed treatment are substantial, we would encourage a prescribed process should non-adherence be suspected. Pharmacists have broad obligations to ensure optimal use of medicines and benefits to the person.

Documentation Elements

Competence standard O1.4: Deliver quality and safe services, includes behaviours which describe professional requirements to maintain effective documentation for the purposes of continuous quality improvement, continuity of care, and pharmacovigilance.

With multiple independent (yet collaborative) parties involved, ineffective communication and lack of clarity regarding professional responsibilities and accountabilities increase opportunities for avoidable risk. A detailed process where, at each step, the responsibilities of each party are unambiguous will contribute to both efficiency and safety of the process. We support standardised communications that are embedded within the broader process and are included as part of training. Standardised communications (both in form and content) will reduce risk of misinterpretation between nurse and pharmacist and allow any trained practitioner to participate in the process without prerequisite tacit knowledge of *ad hoc* process.

Timely and accurate update of the patient record is essential for maintaining safe and continuous person-centred care. Ideally all clinical decisions and events would be recorded within a centralised cloud-based clinical information sharing service accessible to all relevant care providers. We acknowledge that national health information technology infrastructure may not be mature enough to facilitate this. Fundamentally, it is imperative that mechanisms are in place that enable pharmacists to meet their professional obligations to facilitate continuity of care across relevant care providers.

Documentation is also required for review of practice and continuous quality improvement purposes. These general principles are already embedded within current expectations, and no additional specific training is required.

Professionalism Elements

Across all medicines, safe supply must meet legal, professional, and ethical requirements, while also seeking to deliver services that contribute to optimum clinical, cultural safety, access, and equity goals. These aspects of practice and the application were considered with reference to the competence standards below:

- M1.2: Comply with ethical and legal requirements
- M1.4: Practise pharmacy within New Zealand's culturally diverse environment
- M1.5: Understand Hauora Māori
- M1.6: Make effective decisions
- M2.2: Establish and maintain collaborative working relationships
- O1.5: Access, evaluate and provide medicines information

As an innovative and collaborative model, it is important that pharmacists are clear on the permissions and limitations of the finally gazetted reclassification. A new model also means that new awareness and relationships may need to be forged. Opportunities for nurses,

pharmacists, and other stakeholders who may be collaborating to engage in whakawhānaungatanga (establishing relationship) may be facilitated by relevant organisations.

Under the proposed pharmacist-led model, pharmacists will receive initial enquires from people who may have been referred from another service provider (e.g., an outlet participating in the New Zealand Needle Exchange Programme) or who have been informed by hepatitis C public health messaging. Training should prepare pharmacists to understand and, as far as reasonable, accommodate the circumstances and needs of particular populations via adapted or different approaches. This applies to both how the practitioner interacts with people and the environment in which interactions occur (e.g., privacy and nature of premises). This aligns with principles of person-centred care and culturally safe practice.

The application notes that "Māori are likely to be disproportionately affected by hepatitis C", as such, training should address relevant aspects of te ao Māori and hauora Māori to enable "effective and respectful interaction with Māori".[5] More broadly, populations disproportionately affected by hepatitis C may have reservations about engaging with the health and disability system, they may suffer from shame or stigma due to history of illegal activity (e.g., illicit drug use), or as mentioned above they may be affected by complex comorbidities. Person-centred care should be non-judgemental and agnostic to current or historical circumstances not relevant to care.

Other relevant competencies and considerations

The Medicines Reclassification Framework was formulated primarily to assess proposals for a prescription medicine to reclassified to permit supply by a pharmacist pursuant to pharmacist assessment. This application proposes a different model. Because of this, we have identified some additional competencies and considerations.

O3.1 Assess prescriptions

Although this competence standard is framed with the context of the supply of a medicine pursuant to a prescription as defined by Medicines Act 1981; pharmacists have an obligation to only provide products or services, "…when satisfied that it is appropriate, and the person understands how to use it correctly and safely".[6] The competencies and behaviours within O3.1: Assess prescriptions are relevant. In particular, a pharmacist must undertake a clinical assessment and if the pharmacist has concerns that the medicines may not be appropriate, they are obligated to raise concerns and work to address issues via shared decision-making processes.[7,8] In these circumstances, the pharmacist would likely consult with the patient/carer and/or the nurse in the first instance.

The clinical assessment should review the use of glecaprevir and pibrentasvir against concomitant pharmacological treatments and any other known health conditions. This includes, but is not limited to, rongoā Māori, traditional medicines, natural health products, and other pharmacological agents (including recreational drugs). Pharmacists will require access to relevant and accurate records to meet their professional obligations.

[5] Health Practitioners Competence Assurance Act 2003, section 118 (1)(i)
[6] Pharmacy Council of New Zealand. Code of Ethics, Principle 1, Clause H. 2018. https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf.
[7] Competence Standard Behaviour O3.1.3: Applies knowledge in undertaking a clinical assessment of the prescription to ensure pharmaceutical and therapeutic appropriateness of the treatment and to determine whether any changes in prescribed medicines are warranted
[8] Competence Standard Behaviour O3.1.4: Initiates action, in consultation with patient/carer and/or prescriber to address identified issues

Ultimately, in their professional opinions, both the nurse and pharmacist must be satisfied that the glecaprevir and pibrentasvir combination treatment is appropriate for the person. Each practitioner will use their profession-specific expertise to assess particular aspects of treatment appropriateness. The process must be clear on which aspects each practitioner is responsible for assessing.

O4.4 Provide safe working environment

Pharmacists have competencies with respect to the handling of biologics. Capillary blood (finger prick) sampling is a procedure familiar to pharmacists. However, this proposal would involve handling of samples from individuals suspected to carry hepatitis C infection. Training should reinforce practices to prevent risk of infection and the processes to follow should inadvertent exposure occur.

Training

Although our view is that pharmacists possess the competencies to participate in the proposed collaborative models for supply of the glecaprevir and pibrentasvir combination, we believe that additional knowledge training is required. The level of additional knowledge required is beyond what could be expected via self-directed upskilling, and so Council is recommending that a formal training programme be required. Broad areas where we believe additional knowledge would be beneficial are listed below.

- Relevant information of glecaprevir and pibrentasvir including, but not limited to,
  - pharmacokinetic and pharmacodynamic considerations,
  - contraindications and precautions,
  - drug-drug and drug-condition interactions, and
  - adverse drug reactions and their management.
- Overview of hepatitis C:
  - aetiology, pathophysiology, and
  - public health campaigns and measures.
- Information on the populations most affected by chronic hepatitis C and how to practise in a culturally safe manner.
- Detailed review of the process including, but not limited to,
  - theory, mechanics, and limitations of the screening test,
  - responsibilities and accountabilities of each practitioner at each step, and
  - standardised communications and documentation processes.
- Safe handling of biologics and infection control.

Nā māua noa, nā

Owain George
Manager Strategy, Policy and Practice

Michael A Pead
Chief Executive