

31 March 2022

Medicines Classification Committee Secretary
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Pharmacy Council submission on the reclassification of nitrofurantoin 68th meeting on 26 April 2022

Council View

Te Pou Whakamana Kaimatū o Aotearoa / Pharmacy Council (Council) believes that pharmacists possess the competencies to appropriately supply nitrofurantoin as per the proposal in the application. However, we recommend that pharmacists be required to complete a formal training programme that focuses on assessment and triage of suspected urinary tract infection, supply of nitrofurantoin according to current practice and gazetted requirements, and provision of appropriate self-care and disease prevention measures.

Background

Council is 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 Council's core functions are summarised below, though a more comprehensive list is mandated within section 118 of the HPCA Act.

- 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

It is important to note that while it is Council's role to promote education and training (HPCAA s118 (k)), Council is 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. Though making this submission is not within Council's core functions, we believe that we are well placed to offer the Medicines Classification Committee (MCC) an independent opinion of pharmacists' competence. We believe that this opinion is necessary for MCC to make a decision in the public interest.

Application to MCC for reclassification of nitrofurantoin

Council's view is based on its responsibilities under the HPCA Act, observed practice of pharmacists when supplying non-prescription trimethoprim, and application of the joint Medicine Reclassification framework developed by the Pharmaceutical Society of New Zealand (the Society) and Council.¹

¹ <https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/Council-and-Society-Medicine-Reclassification-Framework.pdf>

The framework is recognised and utilised by the MCC. It provides a structure that facilitates 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 a cohesive submission is produced for MCC. The framework breaks the analysis down into four broad elements. These are: the consultation, the medicine, documentation, and professionalism.

Council is 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.²

Consultation Elements

The consultation includes pharmacist activities to gather relevant information from the patient; 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. 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
- O2.2 Health promotion

Council notes that the diagnosis of uncomplicated urinary tract infection remains the same regardless of treatment options (trimethoprim or nitrofurantoin). Information from a patient consultation may be supplemented by on-site pharmacy medication records and/or clinical information sharing services. The empirical evidence since trimethoprim's reclassification demonstrates pharmacists' competence to triage presentations of urinary tract infection effectively, and determine whether differential diagnosis, non-prescription treatment, or referral to another health professional is appropriate.

A training programme will need to ensure that a pharmacist is familiar with the pathophysiology and aetiology of urinary tract infection, can diagnose a urinary tract infection, and determine when non-prescription supply or referral to another health professional is appropriate.

Medicine Elements

To determine whether a medicine is a viable option, a health professional must possess the competencies to access appropriate medicine data, 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

² <https://pharmacycouncil.org.nz/wp-content/uploads/2021/03/CompStds2015Web-1.pdf>

Broadly speaking, the cautions and contra-indications for trimethoprim and nitrofurantoin are similar. Pharmacists' appropriate provision of trimethoprim since its reclassification again offers an additional level of assurance of competence to supply.

Training will focus on the cautions and contraindications, safe use, and expected treatment outcomes (including adverse effects) of nitrofurantoin treatment.

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.

A documentation process must be developed and integrated into the training.

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

Training should provide information on the populations that benefit most from improved access to treatment. It should also reinforce that conversations regarding genitourinary health may be uncomfortable for some patients and consultations must be carried out in a culturally safe manner.

Training

Although Council's view is that pharmacists possess the competencies to supply nitrofurantoin without prescription as per the proposal in the application, 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. Training should ensure that pharmacists can effectively assess and triage a suspected urinary tract infection; (if appropriate) supply the medicine according to current practice and legal requirements; provide appropriate medicine use, self-care and disease prevention advice, and overview a documentation process.



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