



**PHARMACEUTICAL SOCIETY**  
of New Zealand Incorporated

21 April 2023

Medicines Classification Committee Secretary  
Medsafe  
PO Box 5013  
Wellington 6145  
via email: [committees@moh.govt.nz](mailto:committees@moh.govt.nz)

Dear Jessica,

### **MEDICINES CLASSIFICATION COMMITTEE (MCC) COMMENTS TO THE 70<sup>th</sup> MEETING AGENDA May 2023**

Thank you for the opportunity to submit comments on the agenda for the 70<sup>th</sup> meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 2,500 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Regarding the agenda items for the above meeting of the Medicines Classification Committee, the Pharmaceutical Society would like to note the following comments for consideration:

#### **6.1a Ibuprofen 400mg – proposed down scheduling change to classification.**

The Society supports the harmonisation of medicines between Australia and New Zealand, where it is appropriate. As mentioned in our submission to the 65<sup>th</sup> MCC meeting, the literature does indicate that 400mg dosing of ibuprofen may be clinically appropriate for certain conditions.<sup>1</sup> However, ibuprofen 200mg is already available as a single agent for self-selection in packaging of up to 100 dose units and patients can choose to take one or two tablets depending on their requirements. The difficulty for patients swallowing tablets is not necessarily dependant on the number of tablets. The study provided by the applicant to explain the challenges patients face with swallowing medicines relates to altering the formulation rather than specifically the number of tablets being consumed.<sup>2</sup> Pharmacists can assist patients with challenges around swallowing and an alternative formulation may be more appropriate than the self-selection of ibuprofen 400mg tablet. Unfortunately, if the medicine becomes self-selection there is nothing to prevent the product being used long term, where clinical oversight and therapeutic intervention may be required, to reduce the risks of taking high dose ibuprofen.

The key design features mentioned by the applicant to potentially mitigate risk were requested by the TGA during their reclassification.<sup>3</sup> These alerts may be useful if this product becomes available in New Zealand.

The applicant mentioned that there no evidence of a change in the safety profile or any signals of a change in the risk-benefit profile of ibuprofen. However, we would recommend that committee ask the applicant to provide copies of the reference mentioned, as they are not in the public domain, and this would be useful to help the committee with their discussions around any potential risk.

### **6.1b Trimethoprim- proposed up-scheduling change to classification**

The Society does not support the proposed reclassification for trimethoprim from “prescription except when” to “prescription only”. The Society believes that it is important to have available a second- line option from an appropriately trained pharmacist. i.e. trimethoprim for empiric treatment of uncomplicated UTIs available for those individuals where nitrofurantoin is contraindicated.

All healthcare settings are currently experiencing workforce shortages and moving trimethoprim to prescription only will create additional barriers to accessible and equitable care, as it will require access to a prescriber.

Treatment of uncomplicated UTIs with timely empiric treatment avoids the risk of the infection spreading to the kidneys and causing more serious systemic infection. Timely empiric treatment is best practice.

Community pharmacists are an integral component of primary care in New Zealand. Community pharmacists are located all over the country throughout urban and rural areas and are currently one of the most accessible health professionals. They are medicine experts and those providing treatment for uncomplicated UTIs are trained specifically in the treatment of this condition.

The current training UTI training course is presented by Dr Juliet Elvey (Clinical Microbiologist Southern Community Laboratories) and includes:

- International best practice guidelines for the treatment of uncomplicated UTIs.
- Clearly defined patient treatment group - females aged from 16 to 65 years.
- Training to distinguish uncomplicated from complicated UTIs.
- Clinical symptoms of an uncomplicated UTI and how to distinguish this from other causes.
- Symptoms or factors that warrant referral to the GP for further investigation (Red flags).
- The place of empiric antibiotic provision.
- Self-care strategies for patients to adopt during infection and to prevent recurrence of infection.
- A Pharmacist supply algorithm and checklist for nitrofurantoin and for trimethoprim that has been peer reviewed by Juliet and Sharon Gardiner, antimicrobial stewardship specialist pharmacist and co-founder and co-chair of the New Zealand Antimicrobial Stewardship and Infection Pharmacist Expert Group ([NAMSIPeG](#)).

The course specifically informs learners about the antibiotic resistance situation and covers first line treatment and second (or third line treatment). Juliet also presented the UTI training course previously at a time when trimethoprim was considered appropriate for first line treatment of uncomplicated UTIs. She acknowledges the change in practice and fully covers the reasons for this in the current course.

Pharmacists understand the resistance issues with trimethoprim and do not supply it as a first line option for uncomplicated UTIs. They can be trusted as antimicrobial stewards to ensure their practice is aligned with international best practice guidelines and to use trimethoprim appropriately and sparingly where indicated. Trimethoprim has not been deregistered as an approved medicine in New Zealand and elsewhere. It still has a place in practice as an alternative antibiotic when other options are contraindicated. This applies regardless of its classification as prescription medicine or supplied by pharmacist under the conditions of the current classification.

If the Committee is considering reclassifying, we would suggest an amended classification statement to help position the medicine as a second line option. We would like the committee to consider, either at their current or at a future meeting, if the Terms of Reference do not allow this to occur, the following changes to the classification statement:

**Prescription except when** in medicines for oral use containing 300 milligrams or less per dose unit when sold in a pack of 3 solid dosage units to a woman aged 16-65 years for the **second-line empiric treatment** of an uncomplicated urinary tract infection by a registered pharmacist who has successfully completed the Pharmaceutical Society of New Zealand training in the treatment of urinary tract infections.

#### **6.1c Flurbiprofen – proposed down scheduling change to classification**

The Society does not support the proposed reclassification for Flurbiprofen from pharmacy only to general sale medicine, based on the information provided. Topical oral products such as flurbiprofen are indicated for relief of pain, swelling and inflammation associated with severe sore throat. When a person has severe, sore throat, it is important that they have access to a health professional to assess whether it could be a more serious condition such as glandular fever or streptococcal infection. The latter is a significant issue for certain population groups in New Zealand.

Although pharmacists and their support teams are not able to diagnose these conditions, they are well placed to provide an effective triage and refer at-risk patients to the GP for diagnosis and appropriate treatment. This approach also aligns with the Heart Foundation and Te Whatu Ora guidance for the management of sore throats.<sup>4,5</sup>

The applicant has mentioned New Zealand specific consumer research has demonstrated some positive outcomes when balancing sore throat and diagnosis of Strep A. However, this study has not been published and is referenced as confidential data on file. We would like to suggest that the Committee have access to this information to help support their discussions, especially around any potential reclassification.

#### **6.1d Glecaprevir and Pibrentasvir – proposed change to prescription classification statement**

The Society supports this application and the potential opportunity through the reclassification to increased access to Maviret for those New Zealanders requiring diagnostic services and treatment for hepatitis C.

The applicant's suggested collaborative approach is a novel and the intended outcomes to improve the health of New Zealanders are clear.

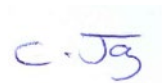
We are of the opinion that some additional thinking may be required around the governance requirements for the potential cohort of nurses delivering the proposed service and how they will collaborate with the pharmacists providing the required treatment.

### **6.1e Naproxen- proposed up-scheduling change to classification**

The Society supports Medsafe's requests for the committee to apply a consistent approach to the current variety of clinical indications and the classification of naproxen, under the pharmacy medicine category.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,



Chris Jay  
**Manager Practice and Policy**

### **References**

- 1) Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes. 2015. url: <https://www.nice.org.uk/guidance/ng5> [cited 4/4/23]
- 2) Lau ETL, Steadman KJ, Mak M, Cichero JAY, Nissen LM. Prevalence of swallowing difficulties and medication modification in customers of community pharmacists. Journal of Pharmacy Practice and Research. 2015;45(1):18-23.
- 3) TGA, Department of Health. Notice of interim decisions to amend (or not amend) the current Poisons Standard, 9 Sept 2020. url: <https://www.tga.gov.au/sites/default/files/notice-interim-decisions-proposed-amendments-poisons-standard-acms-and-joint-acms-accs-meetings-june-2020.pdf> [cited 4/4/23].
- 4) Heart Foundation. Rheumatic fever and heart disease. url: <https://www.heartfoundation.org.nz/your-heart/heart-conditions/rheumatic-heart-disease/> [cited 21/4/23]
- 5) Te Whatu Ora. Rheumatic fever. url: <https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/rheumatic-fever> [cited 21/4/23]