

**Pharmacy Council submission to the
57th meeting of the Medicines Classification Committee
1 November 2016**

**Pharmacy Council Medicines
Reclassification Management Process**

Purpose

To inform the Medicines Classification Committee (MCC) of the intended Pharmacy Council (Council) process around future reclassifications from Prescription Medicine to Pharmacist Only/Restricted medicine. Future proposals would be considered against a joint Council and Pharmaceutical Society of New Zealand (Society) competence framework and a report, endorsed by both parties forwarded to the MCC to be considered during their deliberations. This process has been developed at the request of MCC in order to provide information around pharmacist competence and practice standards. On a case-by-case basis, the framework will enable a recommendation to MCC around the level of upskilling/training required, if any, and the appropriate screening tool, if any to be used to ensure safe supply of the reclassified medicine. The outcome of the Council process is to balance competence assurance and risk management with increased patient access to timely medical care through pharmacist engagement.

Background

The reclassification of Prescription Medicines as Pharmacist Only Medicines/Restricted Medicines improves timely patient access to medicines supplied by a qualified health professional who is also a medicines manager. The level of pharmacological and pharmacotherapeutic education in the undergraduate programme ensures pharmacists are being trained with the level of knowledge required to safely manage the supply of many medicines. Pharmacists who undertook the undergraduate program or trained under older Diploma or apprenticeship programmes may not have the same level of fundamental education. Such pharmacists may instead have more developed soft skills, patient communication skills and decision making expertise.

In order to assist the MCC during its deliberation process Council was tasked with establishing a process to provide a recommendation regarding whether any additional upskilling or knowledge acquisition is necessary. It is vital to manage the risks of down-scheduling a Prescription Medicine to a Pharmacist Only Medicine to ensure safe supply and effective patient consultation occurs consistently.

The provision of many medicines will be within the competence of any community pharmacist, whereas some may require additional upskilling, more specialist knowledge or expertise and/or the provision of specification supportive patient information. The use of training programmes, credentialing or accreditation can provide assurance regarding pharmacist competence, however it should not be assumed that they must always be necessary before the medicine can be supplied. Unduly onerous, expensive or unnecessary training programmes can result in more cumbersome reclassification proposals, reductions in numbers of reclassifications and barriers to patients accessing medicines.

Framework to assess reclassification proposals

Where additional training or upskilling is required it is important that this is provided consistently in a quality manner. It is intended that the Council framework, established in collaboration with the Society will set out any programme requirements and mandatory patient consultation outcomes to provide quality assurance. This is of particular concern where there is potential for programmes to be provided by more than one organisation.

The framework is being designed to align closely with the criteria of the Medsafe Guidance document “How to change the legal classification of a medicine in New Zealand” and the Value-tree benefit-risk assessment for non-prescription drugs¹. The framework will also include the Pharmacy Council Competence Standards for the Profession 2015, Pharmacy Practice Standards 2014 and the Code of Ethics 2011.

Often the reclassification proposal includes recommendations for screening tools and algorithms to ensure consistency of supply. Screening tools contain details to identify patients for referral on to another health professional or assist with identifying those for whom the treatment is unwarranted or has potential for harm. Algorithms are purely summaries of important areas and are designed to act as reminders for pharmacists during patient consultations. The framework is intended to provide comment from the regulatory authority and professional body regarding content of screening tools and algorithms if necessary, as support for pharmacist competence and knowledge.

Collaborative communication to pharmacy profession

In order to ensure that tools are kept updated with current pharmacy practice, models of patient care, and accepted best practice or clinical management are maintained, a joint sector group has been formed to ensure review of currency of tools and consistency of practice. This process will primarily be led by the Society, the professional body, with support from Council, the Guild and Green Cross. Messaging and communication to the profession around best practice will be managed collaboratively by the organisations to ensure consistency of practice and synchronised organisational messaging around information provision. Pharmacists, through this communication strategy will be kept updated about the minimum levels of patient information associated with the safe and clinically appropriate supply of each reclassified medicine.

Infrastructure to support pharmacist competence

Ethical and professional obligations require all pharmacists to maintain competence through CPD, which may include refreshers for accredited trainings for example Trimethoprim (TMP) supply by pharmacists and supply of the Emergency Contraceptive Pill (ECP). The Society offers these courses as online training modules to improve access to all pharmacists around the country.

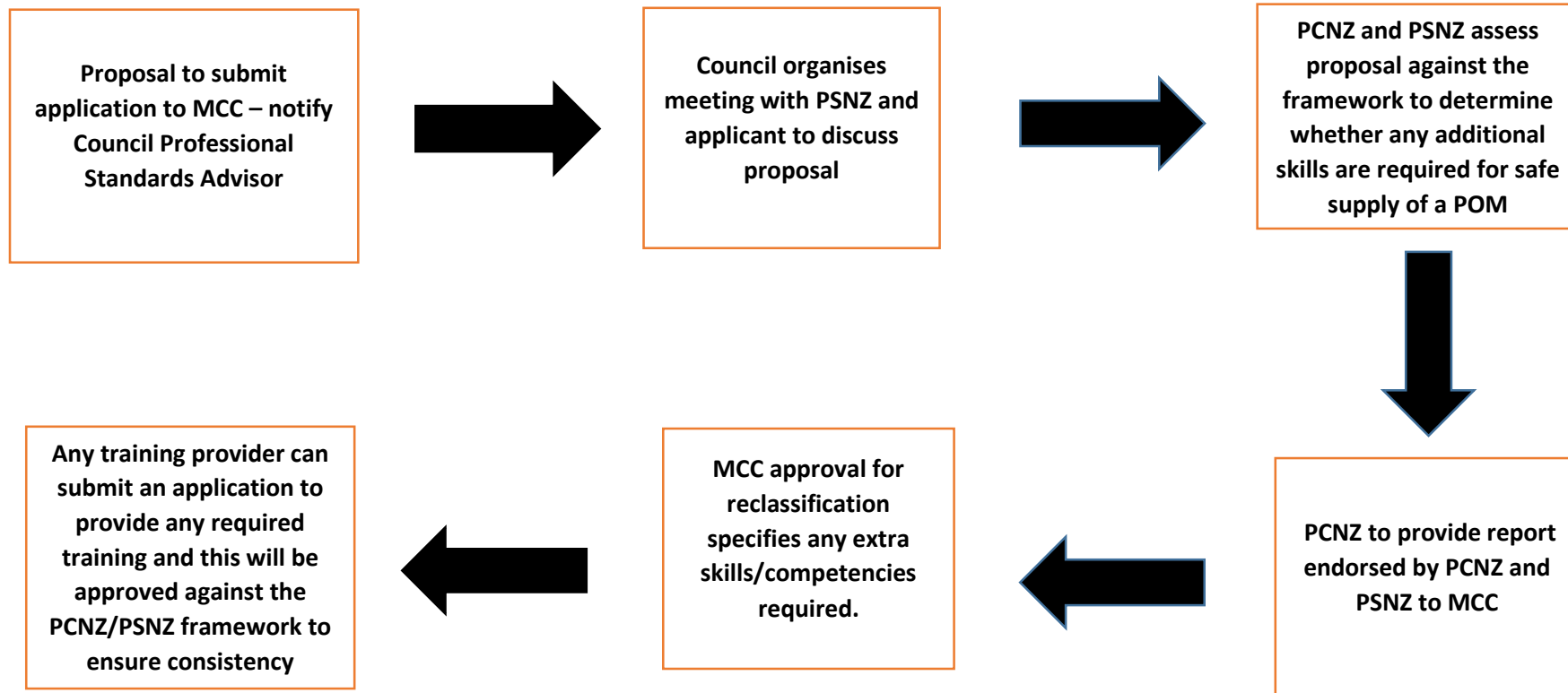
Since there may be potential for erosion of use of screening tools, provision of supportive patient information or algorithms over time, the joint sector group will also be tasked with ensuring pharmacists are reminded of their professional obligations, and alerted to the clinical importance of following guidelines consistently. There may be circumstances during patient consultations that are not covered by screening tools or algorithms, when pharmacists will have to consider the information available and make an educated decision regarding whether it is safe to supply the reclassified medicine or whether to refer the patient.

Summary of submission

Summary of submission – to provide MCC with an explanation of the Council reclassification process and the joint Council/Society framework to consider and provide recommendations to MCC regarding competence assurance and risk management for future medicine reclassifications. The attached flow diagram serves to illustrate the Council reclassification management process. Council staff are prepared to attend the 57th MCC meeting to present and discuss the submission with the Committee and answer any queries regarding the Council medicines reclassification process. The framework is currently being developed as a collaborative process between Council and the Society.

¹ Value-tree framework of benefits and risks for non-prescription drugs (Brass EP, Lofstedt R and Renn O. 2011. Improving the Decision-Making Process for Non-prescription Drugs: A Framework for Benefit-Risk Assessment. *Clinical Pharmacology & Therapeutics* 90(6): 791-803.)

Process for medicines reclassification



Note: it is anticipated that reclassifications will be within the pharmacist scope and either some additional reading or refreshing of knowledge may be recommended/required as identified by the Pharmacy Council of NZ (PCNZ)/Pharmaceutical Society of NZ (PSNZ) reclassification framework.

The PCNZ/PSNZ framework will determine whether screening tools/algorithms/education or extra training is required by pharmacists. Pharmacists must be competent to supply Pharmacist Only Medicines (POM) – and if operating outside best practice, must be able to clinically justify their actions. (for example where a discussion with the patient’s GP facilitates patient focussed supply of a POM).