PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

29 September 2015

Medicines Classification Committee Secretary
Medsafe, Wellington
via email: committees@moh.govt.nz

Dear Sir/Madam

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 54TH MEETING AGENDA 24 November 2015

Thank you for the opportunity to submit comments on the Agenda for the 54th meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 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:

5 MATTERS ARISING
5.1.1 Objection to recommendation made at the 53rd Meeting: Oral contraceptives – proposed reclassification from prescription medicine to restricted medicine

The Pharmaceutical Society would like to note our previous objection to the original decision against reclassification of oral contraceptives made at the 51st meeting. Our objection dated 5 June 2014 stated:

> "…the Committee believed that the only way this proposal would work is if general practitioners and other members of the health professional community supported it. The Committee considered that future applications to down schedule medicines should include references to consultation with the medical fraternity as a whole."
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> The submissions in support of the proposal (including from appropriate medical specialists) met all of the criteria "for a shift from prescription to non-prescription status" as defined in the Classification Committee's 'Classification Categories and Criteria' outlined on the Medsafe website at the following address: http://www.medsafe.govt.nz/profs/class/classificationCategoriesAndCriteria.asp
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> Indeed, the minutes reflect that these criteria were met, but the Committee appears to have created a new requirement that reclassifications should include references to consultation with the medical fraternity and a "degree of coproduction and collaboration" or "integration".

> Our objection is that such criteria have never been grounds for reclassification from prescription to non-prescription status historically, that such criteria are unacceptable and never been consulted on. The Society is also extremely concerned at the precedent that such requirements might set, particularly when all other reclassification criteria previously defined by MCC have been met in this proposal."

The Society fully supports and is committed to an integrated and collaborative approach to the provision of healthcare, as is demonstrated by the vision areas identified in the 'Vision 2020 Partnership for Care' statement jointly issued by The Society and the NZMA. The National Framework for Pharmacist Services also describes a number of health services delivered by pharmacists that describe collaboration and integration, and indeed some mandate this.

While The Society is committed to integrated and collaborative care, we also recognise that pharmacists are autonomous health professionals, regulated by the profession's own Codes and Standards of Practice. As the Committee will also be aware, pharmacists have a legislated authority granted by provisions within the Medicines Act 1981 and Medicines Regulations 1984, to treat patients from the unique list of 'restricted medicines' where they must be personally involved in the assessment and supply. Such medicines are classified on their own risks vs benefits as appropriate for pharmacists to supply, although professional practice guidance can further assist pharmacists in ensuring that the assessment and decision to treat with those medicines is safe and appropriate. In some cases, mandatory training can be used to ensure pharmacists have a minimum standard of skills and knowledge.

The Society considers that decisions by the MCC to classify a medicine as a 'restricted medicine' should be made on the merits of the submitted proposal for reclassification - when the benefits of doing so outweigh the risks. There should not be a requirement by the Committee for mandatory consultation or collaboration with prescribers for a medicine to be classified as restricted (or supplied by pharmacists without a prescription), and such requirements are not described in the Committee's Terms of Reference. If collaboration with prescribers is required in order for a medicine to be supplied safely or appropriately, then this suggests that the risks outweigh benefits of pharmacist supply, and other methods for increasing the accessibility or utility of a medicine using pharmacists should be considered - such as delegated prescribing or standing orders.

If the Committee considers, as the minutes of the 51st meeting note, that "the risk:benefit profile of oral contraceptives is similar to other restricted medicines", then women should be permitted to access their oral contraceptive as a 'restricted medicine' from their pharmacist *should they wish to do so*.

6 SUBMISSIONS FOR RECLASSIFICATION

6.1 Influenza vaccine – extension of influenza vaccination by pharmacists

The Society **fully supports** the proposal to reduce the minimum age for administration of the influenza vaccine by pharmacist vaccinators to 13 years of age. The Society requested comments from our members who are accredited pharmacist vaccinators on this proposal, and our comments below are guided by this feedback.

The vast majority of pharmacist vaccinators responding to our request for comments report receiving multiple requests for administering the flu vaccine to teenagers and do support the vaccine being able to be administered from the age of 13 years. In many circumstances, requests for teenagers came from families presenting to the pharmacy together for their vaccine, only to find that those under 18 must then arrange separate appointments to see their GP. These families have expressed frustration that two separate trips must be arranged for the whole family to be vaccinated – the moment is lost to vaccinate the family together at once. Further requests from under 18s have come when there is a wait to get the vaccine at their general practice, or available appointment times at the general practice are during school hours, also from international students without a GP, teenagers in the workforce where

employers have organised a group vaccination, and even pharmacy staff members under 18 who cannot receive the vaccine at work. Removing this age barrier will improve the accessibility of the flu vaccine and overall vaccine coverage.

All pharmacist vaccinators responding agreed that they considered themselves willing and competent to administer the flu vaccine to persons aged 13 and over. The Ministry-approved training for vaccinators is equivalent for all health professionals, and as a pharmacist vaccinator their training does not place age limits on whom they may administer a vaccination to - just as any other authorised vaccinator may vaccinate persons of any age. However, the classification of vaccines available to pharmacist vaccinators without a prescription does place some minimum age restrictions.

Consent and 'Children'

All pharmacist vaccinators are required to obtain written consent when administering vaccines. In considering the requirements for informed consent and administration of vaccines to teenagers aged between 13 and 18 years of age, The Society refers to guidance described in the Immunisation Handbook 2014 which states:

> **2.2.6 Consent and children**
> Under the Code of Rights, every consumer, including a child, has the right to the information they need to make an informed choice or to give informed consent. The law relating to the ability of children to consent to medical treatment is complex. There is no one particular age at which all children can consent to all health and disability services. The presumption that parental consent is necessary in order to give health care to those aged under 16 years is inconsistent with common law developments and the Code of Rights.
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> The Code of Rights makes a presumption of competence (to give consent) in relation to children, although New Zealand is unusual in this respect (ie, the obligations regarding consent of minors are greater in New Zealand than in many other jurisdictions).
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> A child aged under 16 years has the right to give consent for minor treatment, including immunisation, providing he or she understands fully the benefits and risks involved. In 2001 the Health and Disability Commissioner provided an opinion of a child's consent to a vaccine, whereby the Commissioner was satisfied that a 14-year-old was competent to give informed consent for an immunisation event due to an injury where a tetanus toxoid vaccine would be commonly given.

In considering the advice above, The Pharmaceutical Society intends advising pharmacists that parental consent for administration of the influenza vaccine in a 'child' aged under 16 years is *strongly recommended*. We will also issue specific guidance emphasising the importance of ensuring informed consent and if the competence or understanding of information by any recipient of a vaccine is questionable, then the vaccine should not be given.

Such advice related to obtaining informed consent and not mandating parental consent is consistent with current professional practice when pharmacists provide the Emergency Contraceptive Pill to 'children' under 16 years of age.

Thank you for consideration of this submission.

Yours sincerely,

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Chief Pharmacist Advisor