PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

2 April 2015 O1 02 01 03

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

Dear Sir/Madam

MEDICINES CLASSIFICATION COMMITTEE
SUBMISSIONS TO THE 53rd MEETING AGENDA 5 May 2015

Thank you for the opportunity to submit comments on the Agenda for the 53rd 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

5.2 Azelastine for nasal use

The Society **supports** the submission made by Medsafe to amend the classification wording of azelastine to:

- Prescription; except when specified elsewhere in the Schedule
- Pharmacy-only; **for nasal use in preparations containing 0.15% azelastine hydrochloride or less**; in topical eye preparations containing 0.05% or less

We are not aware of any evidence documenting specific risk of adverse effects with the slightly higher strength of the nasal spray; furthermore it would be sensible to harmonise the classification status with that of Australia which already lists the 0.15% strength as a pharmacy-only medicine.

5.3 Ketoprofen for topical use

The Society is concerned at the issues raised by the EMA documenting risk of photosensitivity reactions and co-sensitisation of ketoprofen. The concept of photosensitivity reactions is complex and something pharmacists have experience in counselling patients very carefully on, particularly when dispensing tetracyclines (especially for acne treatment) and methotrexate, where pharmacists utilise the Pharmaceutical Society's Cautionary Advisory Labelling (CAL) system.

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The Society's CAL system advocates the use of a specific bright label warning for all medicines that carry a risk of photosensitivity-type reactions, along with accompanying verbal advice that advises patients to:

- Avoid sunburn and prolonged exposure in the sun (including sunbeds) while they are on sun-sensitising medicines (especially if other sun-sensitising medicines are being used concurrently);
- Be sensible in the sun by using sunblock and protective clothing and sunglasses
- Avoiding methotrexate specifically for at least four days after acute sunburn due to the known "solar burn reactivation" reaction.

This advice requires careful explanation and the expectation on pharmacists is that this is not simply a matter of label advice, but requires additional verbal counselling to ensure the patient fully understands the risk of the photosensitivity reactions, particularly considering the unique UV environment in New Zealand. Despite these warnings and reminders, patients do not always follow this advice and suffer the consequences of sometimes quite severe reactions. They have commented to pharmacists that they wish they had taken the warnings more seriously. Patients do not fully appreciate the seriousness of such reactions therefore written warnings alone are not adequate.

From the experience and advice pharmacists have in counselling patients on such reactions, and in considering the EMA report, the Society **supports** upscheduling topical ketoprofen to a pharmacy-only classification.

6 SUBMISSIONS FOR RECLASSIFICATION

6.1 Nitrofurantoin – proposed reclassification from prescription medicine to restricted medicine

The Society **supports** the proposal to reclassify nitrofurantoin to permit supply by pharmacists who have successfully completed the New Zealand College of Pharmacists training in the treatment of urinary tract infections.

The reclassification of trimethoprim to permit the supply by pharmacists without a prescription has proven to be extremely successful in terms of offering women the opportunity to receive the empirical antimicrobial treatment for an uncomplicated urinary tract infection. Pharmacists have completed the training developed specifically for this original reclassification and have consistently followed the approved assessment and management pathway process to accurately assess the patient and supply trimethoprim safely and appropriately.

The benefits of adding nitrofurantoin to the options available for pharmacists to treat uncomplicated UTIs are that an alternative and well-tolerated first-line treatment will be available for women who have contraindications to trimethoprim, and/or are unsuitable for trimethoprim supply, such as having received antibiotics in the preceding 6 months. Dosing of nitrofurantoin is considerably less convenient compared to trimethoprim at one 50mg tablet four times daily for five days, therefore the decision to supply nitrofurantoin would not be made lightly, and only after careful consideration by the pharmacist. Additional education advice and treatment algorithm around the use and choice of trimethoprim and nitrofurantoin would be made available to all pharmacists who have already successfully completed the College of Pharmacists Urinary Tract Infection training specified for trimethoprim; and for pharmacists newly completing this certification. Such education and tools will guide pharmacists through the assessment and decision-making pathway and the opportunity to supply trimethoprim or nitrofurantoin or refer is made clear.

6.2 Oral contraceptives – proposed reclassification from prescription medicine to restricted medicine

In our submission to the 51st Meeting of MCC, the Society indicated our support of the proposal to reclassify the listed oral contraceptives to Restricted Medicines. The Society continues to **support** the proposal and endorses the evidence and arguments for reclassification as outlined in the submission by Pharmacybrands and Pharma Projects. We reiterate our submission to the 51st meeting and repeat this below:

The function of a prescription generally serves two purposes, to permit the supply of a prescription medicine, and/or to attract a government subsidy through the Pharmaceutical Schedule (as applicable).

Women who visit a prescriber for a prescription of the oral contraceptive are generally not sick. They present predominantly to access funding of an effective contraceptive option they have personal control over (compared to condoms, for example), and as with all medicines supplied by a health professional, clinical risks and benefits will be assessed, and the medicine prescribed accordingly.

We note the considerable weight of expert opinion internationally expressing that the benefits of over-the-counter access to oral contraceptives outweighs the low risk. These expressions of opinion do not just come from individuals, but include *pre-eminent* professional colleges such as the Committee on Gynecologic Practice of the American College of Obstetricians and Gynecologists(ACOG)[1] and the Royal College of Obstetricians and Gynaecologists(RCOG)[2]. In considering over-the-counter supply of the oral contraceptive, we agree with the sentiment of the RCOG when they state:

> *"robust precautionary procedures and standards need to be in place to ensure patient safety"*

and that

> *"If dispensed by the pharmacist without prescription, information provided to women taking oral contraception needs to include contraindications, side effects and administration."*[2]

We also agree where they highlight issues regarding privacy and access to and the recording of personal data, and would assert that pharmacists manage their obligations under the Privacy Act 1993 and Health Information Privacy Code 1994 as part of their daily practice, and we do not see any difference in this should the oral contraceptive be made available as a pharmacist-only medicine. Proposed training and education of pharmacists will ensure all precautions and standards are met, and the Pharmaceutical Society has the support of the National Medical Advisor of Family Planning New Zealand to develop and deliver this (discussed below).

Safety

As the statement from the ACOG acknowledges, no drug or intervention is completely without risk of harm, and safety concerns about oral contraceptives frequently focus on the increased risk of venous thromboembolism. However,

> *"it is important to understand that the rate of venous thromboembolism for OC users is extremely low […] and to put this risk in context by recognizing the much greater risk of venous thromboembolism during pregnancy […] or in the postpartum period. Overall, the consensus is that OC use is safe."*[1]

The ACOG statement goes on to describe existing evidence demonstrating that women can self-screen for contraindications, however the present submission for reclassification is not asking for this and keeps the requirement for an educated health professional, the pharmacist, being involved in the screening for appropriate supply.

Accessibility

The burden on general practice to meet the health needs of the community is widely noted in both lay and professional media. The "New Zealand Health Survey: Annual update of key findings 2012/13" published by the Ministry of Health noted that

> *Twenty-seven percent of adults had experienced unmet need for primary care in the past 12 months. This includes unmet need for GP or after-hours services due to cost, transport or appointment availability. Women were more likely to have had an unmet need for primary care (32%) than men (22%)*[3]

Acknowledging that the Health Survey did not detail the clinical 'need' being sought, with this in mind, the Pharmaceutical Society considers that healthy women without the relevant risk factors should not need to visit their GP for the supply of their oral contraceptive, if they choose not to. This is an acceptable way of reducing unnecessary appointments, allowing GPs to focus on addressing those patients with health needs requiring medical assessment and management.

Furthermore, legislation currently permits a 6 month quantity of supply for the oral contraceptive. It is then extremely common that a considerable proportion of women do not then physically see their GP for repeat prescriptions, but will have these generated by request over the phone or by speaking with the practice nurse. This is a sentiment expressed by many women both to pharmacists, but also anecdotally by many of our female pharmacist colleagues. Significant periods of time will pass where a prescriber will not see a woman, fitting with our earlier stated recognition that these women are not ill. They do not need to see their GP for the sole purpose of prescribing of their oral contraceptive. With the described safeguards in place, women who choose to visit their pharmacist for supplies of their oral contraceptive will be continually screened for changes in risk and any women not meeting the strict criteria will be referred to their prescriber.

STIs and Women's Health Promotion

Pharmacists have been providing women with over-the-counter access to the emergency hormonal contraceptive pill (ECP) since 2002. A key function of this service, which is specifically expressed in the training and accreditation provided by the Pharmaceutical Society, is the risk of sexually transmitted infections from unprotected sexual intercourse. Pharmacists discuss this with women during an ECP consultation and have information available to provide and recommend further investigation as appropriate. Likewise, condoms have been available from pharmacies for a considerable time, so discussions around STIs, risk factors and signs and symptoms requiring medical investigation are not new for the pharmacy profession. Furthermore it would be an ideal service to offer supply of an oral contraceptive at the time of an ECP consultation where appropriate.

The Society would not see any difference in sexual health promotion by pharmacists should they be able to provide the oral contraceptive over the counter, in fact this is likely to be enhanced. As would encouragement to participate in regular cervical screening by their GP – the more accessible and visible pharmacist would have a key role in further promoting this important public health issue.

Training and Professional Standards
The Pharmaceutical Society has a longstanding history of delivering education and training for pharmacists through the Emergency Contraceptive Pill training, and also through continuing education sessions on contraception and women's health. In considering a training programme to meet the needs of this reclassification, we have indications of support from appropriate medical specialists to develop education and training for pharmacists to ensure pharmacists' supply of the oral contraceptive is appropriate and safe. This will include full understanding of the risks and benefits of using the oral contraceptive, assessment and screening criteria (including blood pressure measurement, which is already conducted in many pharmacies), reasons for medical referral for those women who do not meet criteria for supply and determining the appropriate choice between pharmacist-available contraception and other available methods of contraception available that an individual may wish to consider. We understand that clear assessment and decision-support tools have already been developed by Green Cross Health and PharmaProjects to facilitate this process. Should the proposal to reclassify be accepted, the Pharmaceutical Society will work with these specialists to develop and deliver this training and could supply a detailed training proposal to MCC if requested.

As with the provision of all medicines and services by pharmacists, professional standards and legal and ethical obligations are expected to be observed. Any pharmacist acting outside of these would be subject to a formal Pharmacy Council or Health and Disability Commissioner complaints process. As has been demonstrated through a number of reclassifications from prescription to pharmacist-only medicine over the years, the Pharmaceutical Society does not expect anything other than the utmost professional duty of care by pharmacists when providing medicines.

7 NEW MEDICINES FOR CLASSIFICATION

7.1 Bilastine – proposed classification as a pharmacy-only medicine

The Society **supports** the proposed classification of bilastine as a pharmacy-only medicine in tablets containing 20 mg or less, when sold in a pack containing not more than 30 tablets, for the treatment of the symptoms of allergic rhinoconjunctivitis (seasonal and perennial) and urticaria.

One major review published recently concluded that bilastine has been shown to have comparative efficacy and tolerability to other second-generation antihistamines used as active comparators in phase III trials. However bilastine may have an advantages over cetirizine in having a significantly lower incidence of somnolence.[4] The Society considers bilastine to be appropriate for supply as a pharmacy-only medicine.

7.2 Otilonium bromide – proposed classification as a restricted medicine

The Society **supports** the proposal to classify otilonium bromide as a restricted (pharmacist-only) medicine and endorses the evidence and argument for this presented in the submission made to the Committee. Pharmacists practicing in the community are frequently approached by patients seeking options for the management of symptoms associated with irritable bowel syndrome (IBS). The availability of otilonium introduces a new possibility for people with IBS to obtain relief of the debilitating symptoms of cramping and spasm.

We agree with the approach in the submission that pharmacists could assess the symptoms of IBS through taking a targeted history to determine the suitability for otilonium treatment. While patients would be referred to their medical practitioner where appropriate 'red flags' were signalled, and/or if an initial trial of otilonium did not adequately address their symptoms. Wide accessibility of pharmacists could provide the first presentation for a potential

assessment of IBS, with a possible trial of treatment either successfully managing their symptoms, or the patient is referred for a more detailed medical assessment.

Proposed ongoing support of the classification of otilonium as a pharmacist-only medicine includes the development of an Irritable Bowel Syndrome patient Self-Care card to be added to the Pharmaceutical Society of New Zealand's Self Care Programme (consumer orientated leaflet). As well as an update of the currently available Continuing Professional Development programmes on IBS, it's assessment, management and treatment, with an addendum to include the place in therapy of otilonium.

There is building evidence showing that in addition to dietary/lifestyle interventions, a wide range of pharmacologic therapies which act directly on intestinal smooth muscle contractility, such as otilonium bromide, are well tolerated and effective for IBS; particularly in the relief of abdominal pain, severity of abdominal bloating and protecting from symptom relapse.[5], [6]

The Society therefore **supports** this proposal to list otilonium bromide as a pharmacist-only medicine.

Thank you for consideration of this submission.

Yours sincerely,

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Chief Pharmacist Advisor

1. ACOG - Over-the-Counter Access to Oral Contraceptives [Internet]. [cited 2014 Mar 26]. Available from: http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Over-the-Counter_Access_to_Oral_Contraceptives

2. RCOG statement on the widening of access to the Pill | Royal College of Obstetricians and Gynaecologists [Internet]. [cited 2014 Mar 26]. Available from: http://www.rcog.org.uk/what-we-do/campaigning-and-opinions/statement/rcog-statement-widening-access-pill

3. New Zealand Health Survey: Annual update of key findings 2012/13 [Internet]. Ministry of Health NZ. [cited 2014 Mar 25]. Available from: http://www.health.govt.nz/publication/new-zealand-health-survey-annual-update-key-findings-2012-13

4. Carter N J. Bilastine In Allergic Rhinitis and Urticaria. Drugs. 2012 Jun;72(9):1257–69.

5. Boeckxstaens G, Corazziari ES, Mearin F, Tack J. IBS and the role of otilonium bromide. Int J Colorectal Dis. 2013 Mar;28(3):295–304.

6. Clavé P, Acalovschi M, Triantafillidis JK, Uspensky YP, Kalayci C, Shee V, et al. Randomised clinical trial: otilonium bromide improves frequency of abdominal pain, severity of distention and time to relapse in patients with irritable bowel syndrome. Aliment Pharmacol Ther. 2011 Aug;34(4):432–42.