Comments on Agenda Items for the 54th meeting of the Medicines Classification Committee on Tuesday 24 November 2015

Public Consultation

Medsafe
October 2015

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Excellence in Women's Health

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18 September 2015

Dr Stewart Jessamine
Chair, Medicines Classification Committee
Medsafe
Ministry of Health
Po Box 5013
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Dear Dr Jessamine

I write on behalf of the New Zealand Committee of RANZCOG to provide feedback to the discussion about widening access to selected oral contraceptives. We know that this is once again on your agenda and will be discussed at the next Medicines Classification Committee meeting.

We supported the submissions considered in March 2014 to reclassify four listed oral contraceptives and we wrote again in support in April 2015.

The NZ Committee of RANZCOG remains in support of any responsible development designed to improve access to quality contraceptive advice and service. Members are acutely aware that currently there are a number of barriers to access encountered by significant numbers of women. "Growing up in New Zealand" data shows that 55% of pregnancies to women living in the most deprived areas are unplanned.

To widen access in a responsible manner, NZ Committee members still believe that it would be effective to allow appropriately trained and accredited pharmacists working in suitable premises (ie with an appropriate, private space available for discussion and clinical checks) to write ***repeat*** prescriptions for the oral contraceptives.

The screening tools and information sheets provided recently to us by Green Cross Health provide further assurance to our members about the safety checks and balances.

We therefore continue to support the proposed reclassification of those four medicines from prescription to restricted.

Please contact me if you require further discussion or information.

Yours sincerely

Dr Ian Page
Chair, New Zealand Committee of RANZCOG

NZMA
New Zealand Medical Association

28 September 2015

Advisor Science (Secretariat for MAAC & MCC)
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Agenda for the 54th meeting of the Medicines Classification Committee

Dear Sir/Madam

The New Zealand Medical Association (NZMA) wishes to provide comment to the Medicines Classification Committee (MCC) regarding the agenda for the 54th meeting scheduled for 24 November 2015. The NZMA is New Zealand's largest medical organisation, with more than 5,500 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of New Zealanders.

Our feedback is limited to item 5.1.1 regarding objections to the Committee's recommendation that selected oral contraceptives should not be reclassified from prescription medicine to restricted medicine when supplied by a pharmacist. We note that the objectors feel the Committee was working outside of its guidelines and are of the view that the application for reclassification met the criteria for a medicine to be suitable for non-prescription sale. We note that the Committee's recommendation is to be reconsidered during the upcoming meeting on these procedural grounds.

We believe that the original concerns behind our strong opposition to the proposed reclassification of selected oral contraceptives from prescription medicine to restricted medicine remain of utmost relevance.[1] We note that the guidance document on how to change the legal classification of a medicine in New Zealand is focused primarily on a risk-benefit analysis of a proposed reclassification.[2] It is our view that our concerns about the risks associated with the use

[1] Paragraphs 6–10 in NZMA Submission to the MCC, 1 April 2015. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0011/40322/sub-agenda-for-53rd-meeting-of-the-Medicines-Classification-Committee.pdf
[2] Medsafe. How to change the legal classification of a medicine in New Zealand. Guidance Document. June 2014. Available from http://www.medsafe.govt.nz/downloads/How_to_change_medicine_classification.pdf

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of oral contraceptives do in fact fall clearly within the Committee's guidelines. We refer specifically to the following paragraph from our previous submission to the MCC:

> *9. The use of oral contraceptives is also not without risks that must be carefully considered before they are used and during their use. For example, combined oral contraceptives increase the risk of stroke in women who suffer from migraines with aura. They should not be started by women of any age who suffer from migraine with aura. Combined oral contraceptives also increase the risks of venous thromboembolism (VTE) and are contraindicated for women with a current or past history of VTE and best avoided for those at high risk. Various drugs interact with oral contraceptives to potentially decrease their efficacy, and it is important that patients are fully aware of these. Before prescribing oral contraceptives, therefore, it is necessary to obtain a thorough medical history, including cardiovascular risk factors, concurrent medications, allergies, and health problems (past and current). In many instances, a physical examination may be indicated (eg, when there is a suspected STI). We are not convinced that the tick box checklists that pharmacists are supposed to use before supplying oral contraceptives as part of this proposal will necessarily capture the requisite information to ensure the safe use of these medicines.*

We accept that some of our other concerns relating to a proposed reclassification (eg, inability to provide continuity of care; fragmentation of care; missed opportunity to address other sexual health issues) are not strictly captured by the current guidelines. However, it is our firm belief that the guidelines for the MCC must be broadened so that the Committee can take into account contextual factors such as those identified above in its decision making. A focus solely on the direct effects of a medicine when considering reclassification reflects an erroneous assumption that prescribing is a discrete activity. Prescribing is inextricably linked with diagnosis, evaluation of general health and wellbeing, and represents an opportunistic point for screening/intervention. In addition, the information arising from this interaction should contribute towards improving the quality of information in an integrated health record.

We note that applications for all new substances automatically fall into a high risk category, and such substances would be a prescription medicine if approved. When the MCC is considering an application for the reclassification of a medicine from prescription to non-prescription status, it is essential to take into account **all** relevant factors, including the impact of the reclassification on the wider health and well being of the population. This is of particular importance as there is no other agency or process that is able to consider these factors.

We urge the MCC to stand by its original recommendation with respect to oral contraceptives, and to widen its decision criteria to ensure that it is able to take into account contextual factors when making recommendations on reclassification of medicines. We look forward to learning the outcomes from this meeting.

Yours sincerely

Dr Stephen Child
NZMA Chair

Dame Margaret June Sparrow DNZM MBE
BSc MBChB DipVen FAChSHM HonDSc FRANZCOG(Hon)

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29 September 2015

The Secretary
Medicines Classification Committee
Ministry of Health
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Dear Andrea Kerridge

Re: Agenda 54th Meeting Medicines Classification Committee
5.1.1 Oral Contraceptives – proposed reclassification from prescription medicine to restricted medicine

I write to support the application of Green Cross Health and the Pharmacy Guild of New Zealand for the reclassification of selected oral contraceptives (ethinylestradiol with norethisterone, ethinylestradiol with levonorgestrel, norethisterone, levonorgestrel and desogestrel) from prescription medicine to restricted medicine when supplied for oral contraception by a registered pharmacist who has successfully completed a training course in accordance with an approved protocol.

I am a retired sexual health physician and this is a personal submission. I remain an active member of RANZCOG (Honorary Fellowship), RACP (Australasian Chapter of Sexual Health Medicine), New Zealand Family Planning (Honorary Vice President and Life Member) and ALRANZ (Past President).

My experience includes 12 years as a Student Health doctor, 34 years as a Family Planning doctor and 17 years as an abortion operating doctor when I took a particular interest in the reasons for contraceptive failure. In 2002 I was involved in the training of pharmacists in Wellington and Palmerston North for the supply of emergency contraception. I have attended a number of conferences where the benefits and risks of over the counter supply of contraceptives have been discussed, most recently in Edinburgh in October 2012 when the results of the London (Southwark and Lambeth) programme were presented. (Reference: Parsons J. et al. Evaluation of a community pharmacy delivered oral contraception service. *Journal of Family Planning & Reproductive Health Care* 2013; 39: 97-101.)

My considered opinion is that the benefits outweigh the risks.

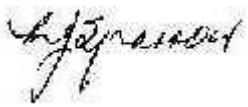
To address some of the concerns raised at the previous meeting:

(1) The high number of unintended pregnancies indicates a need for improved access to all methods of contraception, including oral contraception.
(2) The amount of pharmacist time can be managed, as demonstrated by the successful introduction of emergency contraception in 2002.
(3) The fact that not all pharmacies would be resourced to provide such a service is not a reason to stop those who can.
(4) Fragmentation of records, while not to be disregarded, is less important than the risks associated with unintended pregnancies.
(5) The fact that poor and young women may not have a general practitioner is no reason to deny them access to a very safe medicine at a critical time in their lives.
(6) Prescribing by nurses is an excellent idea but some women will prefer to obtain supplies from a pharmacy.
(7) Collaboration between doctors and pharmacists, with the consent of the patient, is to be encouraged. This should include pharmacists initiating a prescription for first time users, according to agreed protocols, as well as providing repeat prescriptions. Attending a pharmacy for emergency contraception may well be an opportune time to initiate oral contraception.
(8) In my opinion greater consideration must be given to the views of women, their unmet needs and their preferences. These are just as important as the views of primary healthcare practitioners.
(9) The support from RANZCOG, a major medical representative body, is significant although in my opinion prescription need not be confined to repeat prescriptions. I believe it would be safe to recommend a 3-month prescription for initial supply and a 6-month prescription for repeats.

The prevention of unintended pregnancies is an important goal with economic and public health benefits. This moderate proposal from the applicants is not the only answer to the problem of unintended pregnancies but it is a step in the right direction.

I attach separately the MCC Public Consultation Cover Sheet.

Yours sincerely



Dame Margaret Sparrow DNZM MBE

ALRANZ

Abortion Law Reform Association New Zealand Inc.

29 September 2015

Andrea Kerridge
Secretary
Medicines Classification Committee
Ministry of Health
committees@moh.govt.nz

by email

Dear Ms Kerridge

ALRANZ supports reclassification of oral contraceptives

ALRANZ supports Pharmacybrands Ltd and Pharma Projects Ltd's application to reclassify oral contraceptives as a restricted medicine.

Purpose
The main purpose of oral contraceptives is to prevent unwanted pregnancy. Unwanted pregnancy creates stress and expense for patients and drains funds from the health care system. Oral contraceptives have proven their safety and efficacy over 50 years. ALRANZ believes the public health benefits of safe, reliable oral contraception can be enhanced by making oral contraception available over the counter.

In ALRANZ's previous submission we noted those patients most likely to benefit from reclassification are younger, poorer, and more vulnerable to the barriers the high cost of contraception creates. Statistics from the Abortion Supervisory Committee bear this out: 55% of patients who presented for abortion services in 2013 were not using any form of birth control, and a further 25% used only condoms. This means 80% of patients presenting for abortion services in New Zealand could potentially benefit from the increased availability of oral contraception.

The minutes of the Committee's meeting 5 May 2015 read:

> *The Committee considered the application in the context of the requirements of younger women and those from lower socio-economic groups who may not have a general practitioner.*
>
> *In these scenarios, the Committee considered that reclassification could increase the risk of fragmentation of patient care.*

The Committee's concern seems misplaced. The choices here are fragmented care or no care at all. No care at all can result in unwanted pregnancy. Contraceptive care from a trained pharmacist is preferable to no care at all.

If the Committee refuses to reclassify oral contraception it would be acting against the interests of patients and the health system. It would unnecessarily prolong the risk of unwanted pregnancy and abortion for the most vulnerable patients, and force the public health system to shoulder those costs.

Safety
Oral contraception has been proven safe and effective over 50 years' use by millions of people across the globe. The safety of currently recommended medications is so widely accepted as to require no footnote.

In addition to the medicine itself, the model of pharmacists providing medicine without a prescription has also been tested and proven safe and effective. The provision of emergency contraception by pharmacists in New Zealand without a prescription has been a success.

Other jurisdictions, including California and the Netherlands, have made oral contraception available over the counter, with no ill effects on patients' safety or quality of care. Does the Committee consider New Zealand women to be especially unfit to manage their own contraceptive choices as compared to women in other jurisdictions?

All women deserve to manage their own fertility free of paternalism by the medical establishment.

The Committee's Decision
The Ministry of Health sets out its principles and rules for the regulation of medicines in its *Guidelines on the Regulation of Therapeutic Products in New Zealand, Part 2A: Over the Counter Medicines: Pre-market application and evaluation process* (Edition 1.0), April 2013 ("Guidelines"). The guiding principle of this document is the evaluation of risk.

Other sections of the Guidelines apply that principle, establishing criteria that include safety, quality, efficacy, and risks/benefits to consumers.

The Guidelines do not discuss the presence or absence of support from major medical representative bodies as a criterion for the evaluation of medicines for reclassification.

The minutes of the Committee's meeting 5 May 2015 say the Committee resolved that in the absence of support from major medical representative bodies it could not support reclassification. The Committee appears to have placed greater weight on this criterion than on the criteria of safety and efficacy. If so, it calls into question the legitimacy of the Committee's decision by demonstrating it gave undue consideration to an irrelevant factor and did not give sufficient consideration to relevant factors.

The Committee also appears to have given insufficient consideration to the personal benefits patients would receive from avoiding unwanted pregnancy, and the financial benefits the health care system would receive from reducing unwanted pregnancy.

To whatever extent the members of the Committee belong to the major medical representative bodies that do not support reclassification, the Committee's decision may also suffer from the appearance of bias.

Conclusion
New Zealand patients deserve the highest quality health care. That includes access to oral contraceptives without unnecessary medical gatekeeping.

Yours sincerely

Terry Bellamak
President, ALRANZ

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."
>
> 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
>
> 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.
>
> 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).
>
> 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,

Bob Buckham BPharm, PGCertPharm, PGDipClinPharm, MPS, ANZCP, RegPharmNZ
Chief Pharmacist Advisor

FACULTY OF MEDICAL AND HEALTH SCIENCES
Department of Obstetrics and Gynaecology

Professor Cindy Farquhar

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12 October 2015

Medicine Classification Committee

MEDSAFE

Ministry of Health

Dear Medicines Classification Committee

I am the Postgraduate Professor of Obstetrics and Gynaecology at the University of Auckland and work as a consultant gynaecologist for the Auckland District Health Board and Auckland Gynaecology Group. I am a Fellow of the Royal Australian and New Zealand College of Obstetrics and Gynaecology and a Fellow of the Royal College of Obstetrics and Gynaecology (NZ). In these various roles, I teach medical gynaecology to medical, nursing and midwifery students and graduates, primary care doctors and specialist trainees in Obstetrics and Gynaecology. I am also the Coordinating editor of the Cochrane Gynaecology and Fertility Group. However, the commentary and recommendations in this letter are my own and I do not speak on behalf of any of the institutions or organisations that I am involved with.

Natalie Gauld who is working with Green Gross Health has asked me to provide my opinion on the proposal to have the availability of selected oral contraceptives widened in order to improve the access to women seeking oral hormonal contraception.

Declarations of interest: I understand that Green Cross Health and Natalie Gauld will potentially benefit as Natalie Gauld works as a consultant for Green Cross Health and that Green Cross Health will receive increased business if this application is a successful. Therefore it must be stated that the research presented in the application cannot be considered truly independent.

I have no conflicts of interest with any commercial group and have not and will not be receiving any payment or gift from Green Cross Health.

I have read the application as provided to me by Natalie Gauld and I consider that there is some merit in the strategy offered. However, I understand that a previous application was unsuccessful in 2014 and again in 2015 as major medical bodies (NZMA and the RNZCGP) opposed it.

The application is well written and provides a thorough and comprehensive review of the literature. I had a number of concerns before I began reading the document but by the end of reading a number of these had been answered. For example, I was concerned about the safety issues but the use of the screening tool based on the WHO medical

eligibility criteria and developed with family planning experts allayed those concerns. Indeed, it would seem that the tool may be a more comprehensive screen than many gynaecologists currently use (although I have not audited this). Another concern I has was how to maintain privacy of a woman seeking contraception but I now understand that the majority of pharmacies have a private room/area available. A further concern related to the opportunity for primary care doctors and nurses to initiate STI and cervical screening at the time of prescribing for contraception but this is dealt with in the document and again I feel is not a reason not to increase access to oral contraception. See further comments below.

I was also interested to see the international literature on this strategy. A list of countries with more liberal policies than New Zealand is provided in the application. Some of them only allow pharmacy prescribing after an initial medical consultation and others are less proscriptive.

I note the benefits and harms of oral contraceptives in the application and the focus on safety and contraindications.

I also note that New Zealand has had experience with training pharmacists in the prescribing and supplying the emergency contraceptive pill and this seems to have been a successful approach although no audit has been undertaken to support this impression.

In summary, there are three options possible

1. Pharmacy supply for all oral contraception using a screening tool to identify any women with possible contraindications at the time of first supply. The medical history could be updated every 12 months.
2. Pharmacy prescribing only after a consultation and provision of first prescription by an authorized health practitioner (doctor, nurse) who has assessed the suitability of the woman for oral contraception. Women would be able to receive repeat prescriptions from the pharmacy without need to see a doctor again and the medical history could be updated every 12 months.
3. No change to current arrangements.

I support the first option of women being able to see a pharmacist for her first and ongoing supply of oral contraception. There are a number of reasons for my recommendation. Firstly, this approach is likely to remove one of the barriers to contraception which is the need to see a doctor or nurse. Secondly, it is likely to be as safe as contraception prescribed by primary and family planning doctors. Pharmacists are possibly better placed to assess drug interactions as they usually have access to prescribing records and are knowledgeable about drug interactions. Further, adolescents who wish to avoid seeing their family doctor and who may not have access to a Family Planning Clinic the local pharmacy may be an easier option for them to get advice and provision of oral contraception. Finally, it may result in lower costs to some women although this will depend on the region and general practice.

The second option above has some merit in that it would overcome some of the safety concerns expressed by the medical profession and perhaps acclimatize the medical profession before the next greater step of allowing women to receive their first prescription from a pharmacist. Incremental changes are sometimes more acceptable.

A number of the concerns were raised in the response from the MCC to Green Cross Health. One of these was the loss of opportunity for cervical screening. This may not be such a major issue as stated as there is a currently a consultation underway by the NCSP about replacing cytology with HPV screening and reducing the frequency of screening to every 5 years in low risk women. STI tests are also likely to be self collected in the future as well. It is possible for pharmacies to provide written information to women at the time of supplying contraception on a number of sexual health measures including screening and also HPV vaccination. I understand that some work has been already undertaken about information sheets for women at the time of supply of oral contraception.
The concern about the lack of access to medical records, while valid, of course do not mention that this occurs all the time in both the primary and secondary health sector as patients move around the country and even within DHBs have different providers according to their needs. The proposed health screening tool should identify any areas of major concerns in the absence of the health record.

As mentioned above, the information that has been provided is not independent and it may be necessary for an independent review of the literature to be undertaken by Medsafe with a focus on safety in order alleviate the concerns raised.

I wish the Committee well with your deliberations.

Yours sincerely

Professor Cindy Farquhar
Department Obstetrics and Gynaecology and National Women's Health
University of Auckland

PHARMACY GUILD OF NEW ZEALAND

28 September 2015

Advisor Science (Secretariat for MAAC & MCC)

Product Regulation

Medsafe

Sent via email to: committees@moh.govt.nz

Dear Andrea

RE: AGENDA FOR THE 54th MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE

Thank you for making available the agenda for the 54th meeting of the Medicines Classification Committee (MCC), to be held on Tuesday 24 November 2015, and for the opportunity to provide feedback on the agenda.

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation representing the majority of community pharmacy owners. We provide leadership on all issues affecting the sector.

Our feedback covers three agenda items. These are:

- Agenda item 5.1: Objections to recommendations made at the 53rd meeting
- Agenda item 6.1: Influenza vaccine – extension of influenza vaccination by pharmacists (Green Cross Healthcare)
- Agenda item 7.1: 1,3-dimethylamylamine (DMAA) - proposed classification as a prescription medicine (Medsafe)

Each of these agenda items is discussed below.

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Agenda item 5.1: Objections to recommendations made at the 53rd meeting

We have previously submitted this information to the MCC Secretary as requested on 22 September 2015.

We have included a copy of our submission as an Appendix for completeness.

Agenda item 6.1: Influenza vaccine – extension of influenza vaccination by pharmacists (Green Cross Healthcare)

The Guild **strongly supports** the extension of influenza vaccination by pharmacists.

We believe that lowering the age of recipients of an influenza vaccine from a minimum age of 18 years to 13 years would be of benefit to the New Zealand public with no added safety concerns. The interactions with other medicines, contraindications and precautions, as well as the potential for adverse reactions remain the same in this age group, as for those aged over 18 years.

There are now over 500 accredited vaccinator pharmacists in New Zealand and this number is steadily increasing. Some of these pharmacists have now had experience in administering vaccinations throughout four flu seasons and have had a positive impact on flu vaccine uptake. Green Cross Limited reported in the 2013 flu season that over 8500 flu vaccinations were given in their pharmacies[i]. In 2014 the number of doses given by Green Cross pharmacists increased to 10,000 and to 17,000 in the 2015 flu season.

Pharmacists are the most accessible of all health professionals and this reclassification would open access even further with the potential to increase the uptake of flu vaccinations. A New Zealand study undertaken in 2012 found that of the patients vaccinated against influenza by a pharmacist for the 2012 flu season, 42% had not been immunised the previous year.[ii] The main reason that these patients gave for not being immunised the year before was that they were too busy. The study stated that "on-demand community pharmacist immunisation will reduce the barrier for individuals who report finding the time for immunisation or forgetting to be immunised an issue". An English study had similar findings in that a pharmacy-based vaccination service gave access to patients that would not normally have accessed medical services.[iii] In this study, pharmacists administered flu vaccines to patients aged over 12 years and it was found that a key attribute of the service provided for all patients was accessibility. Patients stated there was no waiting, no queue, no appointment and the service was convenient, leading them to choose to have their vaccination at a pharmacy over their medical practice.

As an extremely accessible healthcare hub, community pharmacists are in a pivotal position to be able to increase awareness about the importance of all vaccinations and identify those patients who may benefit from specific vaccinations. A Japanese study found that when community pharmacists personally advocated the influenza vaccine to people aged 65 and over, vaccination rates increased.[iv] By continually increasing awareness about the availability and importance of vaccinations, patients can make informed decisions to protect themselves and their family members. Our Guild member pharmacies who offer vaccinations report that they are often asked by patients why they are unable to administer flu vaccinations to their children. There appears to be significant patient support for pharmacists having a broader role in flu vaccinations.

In the US, pharmacist vaccination has been accepted as routine.[v] In the United States there are 41 states (more than 80%) that permit pharmacists to administer any vaccine. Thirteen US states permit pharmacists to vaccinate patients of any age and a further twenty states allow pharmacists to vaccinate children over the age of five years.[vi]

An American study, published in 2013 examined parents' experience of pharmacist administered influenza vaccinations for their children.[vii] Approximately 97% of the responding parents felt confident about the pharmacist providing influenza vaccinations to their children.

Increasingly around the world, it is becoming the norm for pharmacists to vaccinate children.

The Guild supports the extension of influenza vaccination for similar reasons to those we gave to support the original submission for reclassification of the vaccine back in 2012:

- Further improving access to immunisation supports the Government's policy to deliver better, sooner, more convenient health services to the public.
- Increasing the number of individuals vaccinated has the potential to reduce the number of people who contract the influenza virus and the likelihood of spreading the virus to others, with an overall decrease in the burden of flu in the community. Influenza infection rates are generally highest in children and otherwise healthy children are the major cause of the spread of influenza viruses in the community.[viii]
- Certified pharmacists have been successfully vaccinating patients for many years in other countries such as the United States, Ireland, Japan, United Kingdom and Canada.
- The increasing number of pharmacists that are choosing to undertake training to become a vaccinator means there is a greater pool of vaccinators to call upon at short notice during any potential pandemics.

In addition to the points raised in 2012, another reason the Guild is in support of this proposed extension is that:

- the number of potential sick days for teenagers (and any possible associated days off work needed by their parents to care for them) may reduce due to teenagers being vaccinated and therefore protected from the influenza virus.

The First Aid training that vaccinators currently undertake is equivalent to NZ Resuscitation Council Level 4 and includes administration of adrenaline in anaphylaxis as well as maintenance of airways and the provision of oxygen. This Level Four training covers both children and adults. The vaccinator training that pharmacists undertake also covers adults and children.

We have reviewed the changes that have been made to the pre-vaccination checklist and consent form written by Green Cross Limited. We are pleased to see that it highlights the Intanza vaccine that can only be given to those patients aged between 18 and 59 years so that pharmacies are reminded to use the alternate flu vaccines. The new checklist also includes an information sheet for managing adverse events in children post-vaccination which is important.

The Pharmacy Guild supports our member pharmacies that provide vaccination services. We have a full suite of vaccination Standard Operating Procedures (SOPs) covering topics such as receipt and storage of vaccines, managing anaphylaxis and faint to dealing with needle-stick injuries. Our SOP for "Administration of vaccines in adults and adolescents" would require minor updating should this reclassification go ahead, in order to reflect the lowered age of administration. We would make such a review a priority should the MCC support the proposal. We note that our SOP for "Managing Anaphylaxis or a faint" already states that the recommended dose of adrenaline for an adult is 0.3 to 0.5ml, and this is the recommended dose for children over 11 years of age.

Agenda item 7.1: 1,3-dimethylamylamine (DMAA) - proposed classification as a prescription medicine (Medsafe)

We support the Medsafe submission proposing to reclassify 1,3-dimethylamylamine from a general sale to a prescription medicine.

We believe that the proposed reclassification would be in the best interests of the New Zealand public and we support Medsafe's approach to make medicines safer.

Thank you for considering our feedback. If you have any questions about our feedback, please contact our Guild Pharmacist, Professional Services and Support, Tracey Sullivan at t.sullivan@pgnz.org.nz or 04 802 8209.

Yours sincerely,

Lee Hohaia
Chief Executive

Appendix

RE: RECLASSIFICATION OF ORAL CONTRACEPTIVES – OBJECTION TO THE RECOMMENDATION MADE BY THE MEDICINES CLASSIFICAITON COMMITTEE AT THE 53RD MEETING ON TUESDAY 5 MAY 2015

Thank you for your letter dated 31 July 2015 stating that the Guild's objection to the recommendation made by the Medicines Classification Committee (MCC) not to reclassify oral contraceptives as restricted medicines, has been accepted as valid.

Our objections that were accepted as valid are as follows:

1) **The decision appears to be in contrast to the objective of the MCC which is to foster self medication where safe and appropriate. International evidence was provided to demonstrate that with pharmacist support the provision of oral contraceptives (OCs) to eligible women is safe and appropriate. The provision of OCs as a follow-up to a supply of ECP is also safe and appropriate for eligible women.**

We believe that the evidence presented in the two applications by Green Cross Health Limited (previously Pharmacybrands Limited) and Pharma Projects Ltd (now known as Natalie Gauld Limited) regarding the safety profile and lack of serious side effects of OCs was more than sufficient to prove that these medicines are safe.

Dr Samantha Murton of the Royal New Zealand College of General Practitioners' recently stated in the media that "The contraceptive pill can be risky for some women". She went on to say "The college is concerned about safety and continuity of care and if we keep prescribing as it currently is we can ensure that" [ix]. While there are known risks associated with OCs, the risks are manageable. The relationship between OC use and blood-clot risk and stroke is well-documented, and that risk increases when a woman is smoker, particularly a smoker over age 35. However the inclusion of a pharmacist screening tool will ensure that unsuitable patients will be referred on to medical practitioners. Pharmacists have proven well versed in using screening tools and have a professional responsibility to ensure they are safe to supply any medicine. If the Committee was of a view that mandated training would further increase the safety profile for pharmacist supply of OCs, the Guild would support such training.

Pharmacists are familiar with making referrals to other health professionals and do this already for other restricted medicines when they appear to be unsuitable for a specific patient. With the patient's consent pharmacists also already inform the patient's doctor of any vaccination they have administered to the patient which ensures continuity of care. Pharmacists have reported that in general patients are happy for pharmacists to pass on information to GPs and in fact it is the patients expectation that this is done. We

know of occasions where patients have checked with the doctor that the information e.g regarding a recent pharmacist vaccination has been passed on. This system of referral and notification to the GP will work just as effectively for the supply of OCs.

Since the pill was first introduced there have been hundreds of major studies on risks and benefits. Most women can use OCs without safety concerns. It is safe for non-pregnant women past menarche and up to the age of 40 years old (and usually safe after age 40), with or without children, and in women of any weight including obese women. Women can use the pill if they have mild headaches, varicose veins, anaemia, a history of diabetes during pregnancy, painful or irregular menstrual periods, malaria, benign breast disease, thyroid disease, or if they carry viral hepatitis.[x]

In the minutes of the 51st meeting it is recorded that the MCC agreed that the risk: benefit profile of OCs was similar to other restricted medicines. Hormonal contraception has been widely studied and shown to be safe, so safe that the American College of Obstetricians and Gynecologists has recommended that it be available over the counter.[xi]

There are certain women who should not use oral contraceptives under any circumstances. These include women who are pregnant, have a greatly increased risk of cardiovascular disease, are both over age 35 and smoke heavily (more than 20 cigarettes a day), and have certain pre-existing conditions that could be worsened by OCs. These pre-existing conditions include current breast cancer, benign liver tumours, liver cancer and active viral hepatitis. High risks for cardiovascular disease include blood pressure greater than 180/110mm Hg, diabetes with vascular complications, complicated valvular heart disease, and a history of any of the following conditions: deep vein thrombosis, blood clotting in the lung, heart attack, stroke, or severe recurrent headaches with vision problems. As previously stated all of these conditions can effectively be screened for by a pharmacist.

As long ago as 1994 a U.S. Agency for International Development panel of experts identified procedures that needed to be followed by health providers in order to distribute OCs safely. They believed that the only essential procedure is "good counselling on efficacy, side effects, changes in menstrual patterns, correct use, problems that require seeing a health-care provider and STD protection".[xii] Their view was that distribution of oral contraceptives did not need to be confined to medical clinics and that community-based distribution systems can easily follow these recommended procedures. Pharmacists have the knowledge and training to effectively deliver this kind of counselling for OCs.

2) **There is an MCC principle for considering a medicine for suitability for non-prescription sale that states "Medicines which may be available without prescription shall be able to either:**
    a. **show substantial safety in use in the prevention or management of the condition or symptom under consideration**
    b. **be for conditions or symptoms that can be diagnosed and managed by a pharmacist**
    c. **be easily self-diagnosed and self-managed by a patient."**

    We believe that the application for reclassification submitted by Green Cross Health Limited and Pharma Projects Limited met the above criteria and there is nothing in the minutes to suggest that this principle has not been met.

The MCC principle gives three options that a medicine suitable for non-prescription sale should meet. Even though the principle states that only one of the three options needs to be met, we believe that two of the criteria have been met. Oral contraceptives show substantial safety and a patient can themselves decide their contraception needs and safely manage any treatment they choose to use or that has been prescribed for them.

3) **Our other concern is that the minutes note that "In the absence of support from the major medical representative bodies it could not support this request for reclassification". We are unable to understand how lack of support from another agency would impact on the MCC decision making process. If an organisation wanted to object to an MCC decision it would be our expectation that the objection would be expected to demonstrate why the guidelines of the MCC have not been met by the application.**

There have been previous reclassifications of prescription medicines to pharmacist-only medicines where there has been a distinct lack of support from other agencies. Trimethoprim, sildenafil and the emergency contraceptive pill are all examples of this. In all cases the MCC applied the principle for reclassification, and ultimately viewed these medicine reclassifications to have public benefit with an associated a lack of harm and the reclassifications went ahead.

A reclassification should not be rejected on the basis of a lack support from medical bodies. If other agencies have reason to believe that a medicine is not suitable for reclassification there must be robust reasoning and evidence to show it does not meet the MCC guidelines. What must remain at the forefront of the decision-making process are the questions regarding safety and patient benefit.

We believe the application from Green Cross Health and Pharma Projects Limited shows a wide range of parties have been consulted, crossing all areas of the healthcare sector, from women, nurses, and GPs, to senior consultants and pharmacists. The consultation process has shown the desire for a collaborative approach and this collaborative approach between pharmacists and other health professionals will be continued if OCs were to be reclassified.

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22 September 2015

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington
New Zealand

Email: committees@moh.govt.nz

Dear Secretary,

RE: Public Consultation on Agenda Items of the 54th Medicines Classification Committee (MCC) Meeting

appreciates the opportunity to provide public comment in relation to the 54th MCC meeting agenda scheduling proposal detailed below.

Agenda Item 8.2.2.a – Hydrocortisone

The Schedule 3 (restricted medicine) entry should be amended to hydrocortisone and hydrocortisone acetate, but excluding other salts and derivatives, in preparations for human therapeutic use containing 1% or less of hydrocortisone for dermal use, in packs containing 30 g or less of such preparations, containing no other therapeutically active constituent other than an antifungal substance; for dermal use, in packs containing 2 g or less of such preparations, containing no other therapeutically active constituent other than aciclovir (5% w/w or less) in adults and adolescents (12 years of age and older); for rectal use when combined with a local anaesthetic substance but no other therapeutically active constituent except unscheduled astringents in undivided preparations, in packs of 35 g or less or in packs containing 12 or less suppositories.

Please find following comments in relation to the above agenda item that will be considered by the MCC on Tuesday 24th November 2015.

We support the proposal to amend the Schedule 3 entry for hydrocortisone as described above as this scheduling proposal will result in the harmonisation of the New Zealand and Australian schedules. This aligns with the General Principles of Trans-Tasman Scheduling Harmonisation,

where the underlying principle is to harmonise on the less restrictive schedule while giving due consideration to public health and safety issues and/or specific jurisdictional needs.

The public health and safety issues were considered by the Australian Advisory Committee on Medicines Scheduling (ACMS) at the March 2015 meeting and resulted in the final decision by the Secretary to the Department of Health and Aging in Australia to amend the entry for hydrocortisone.

The harmonisation of schedules for hydrocortisone in Australia and New Zealand is critically important if the sponsor registers the product in both countries. An identical scheduling decision in New Zealand will allow for harmonised labelling and therefore a viable option that will benefit the New Zealand consumer.

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30 August 2015

Medicines Classification Committee

Via email committees@moh.govt.nz

Dear Committee

Concerning Agenda Item 8.2.2.b Ranitidine

The requirement that items be supplied in a manufacturer's original pack seems inappropriate to me, in this instance and the others that already exist in the schedules

If specific warnings or packaging are required, these should be stated and can be reproduced either at the manufacturing level or the retail pharmacy level

In using the requirement for an original manufacturers pack the committee is creating a restricted level of price competition and I believe this often shows in the price retail pharmacy must pay to source items in the specified retail packs compared to the equivalent product for dispensing on prescription. There may be some justifications for this such as the relative volumes involved, but this does not need to be enabled as an unintended consequence of the wordings used in classification decisions.

Some of the products requiring original packs are of low volume in the retail sense, particularly if they are premium priced by the manufacturers and compared to the cost of a subsidised doctor visit and a subsidised prescription. The situation can even arise where a legitimate need cannot be met when the original pack is not in stock, yet adequate amounts of other packs are immediately available

It would be in the customer's advantage to allow pharmacists to supply prescription scheduled product, appropriately packed and labelled.

There has been suggestion in the industry that the original pack stipulation on the scheduling decision is a pay back to the applicant for the costs of making the application. I would hope this is not a factor in the committee's decision, as it should not be.

I hope the wording does not pass through the committee's deliberation purely as it is the preferred option for those making the applications

The orginal pack precedent is a poor one and should be reversed, certainly not perpetuated

I believe a very significant justification should be required before the stipulation of an original pack is applied and its use should be the exception rather than the rule

Your consideration is appreciated

Regards