MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY
A BUSINESS UNIT OF THE MINISTRY OF HEALTH

Comments on Agenda Items for the 51st meeting on 8 April 2014

Medicines Classification Committee Public Consultation

Medsafe

April 2014

MINISTRY OF HEALTH
MANATU HAUORA

New Zealand Government

NZMA
New Zealand Medical Association

25 March 2014

Laurence Holding
Advisor Science (Secretariat for MAAC & MCC)
Committee & Support Services
Product Regulation
Medsafe
PO Box 5013
Wellington 6145

By email: committees@moh.govt.nz; laurence_holding@moh.govt.nz

Agenda for the 51st meeting of the Medicines Classification Committee

Dear Laurence

The New Zealand Medical Association (NZMA) wishes to provide comment to the Medicines Classification Committee (MCC) regarding the agenda for the 51st meeting scheduled for 8 April 2014. Our comments are limited to items 5.1.1 and 6.1.

The NZMA is the country's largest voluntary pan-professional medical organisation with approximately 5,000 members. Our members come from all disciplines within the medical profession and include general practitioners, doctors-in-training, specialists, and medical students. The NZMA aims to provide leadership of the medical profession, and promote professional unity and values, and the health of New Zealanders.

Item 5.1.1: Sildenafil – proposed reclassification from prescription medicine to restricted medicine (Silvasta, Douglas Pharmaceuticals Limited)

We understand that an objection has been received regarding the Committee's previous recommendation that sildenafil should not be reclassified as a restricted medicine when supplied by a pharmacist who has successfully completed the approved training programme and is accredited to supply sildenafil, for the treatment of erectile dysfunction in males aged 35-70 years. We note that Douglas Pharmaceuticals Limited felt that some of the submission was not fully portrayed to the Committee and some of the safety features may have been

overlooked. We also note that the company will provide an updated original submission to include additional information that specifically addresses the concerns raised by the Committee.

The NZMA has requested a copy of this updated submission in order to be able to evaluate how well previously expressed concerns have been addressed. We have been advised that this updated submission is being withheld from public submission on the grounds of commercial sensitivity. This is deeply regrettable. We are very disappointed that commercial sensitivity is being cited as grounds to withhold information that is intended to address concerns about patient safety. We contend that in the interests of transparency and patient safety, such information should be made available in the public domain. Accordingly, while we are unable to comment on the updated submission, we wish to reiterate our position regarding the Committee's original decision.

The NZMA strongly supports the Committee's original decision made during the 50th meeting to not reclassify this erectile dysfunction (ED) drug from a prescription medicine to a restricted medicine. Our primary opposition to the proposed reclassification of sildenafil stem from concerns about patient safety. Erectile dysfunction is a red flag for underlying vascular disease. All patients being offered treatment for ED require a comprehensive cardiovascular assessment that includes laboratory tests for fasting serum lipid profile, fasting plasma glucose and glycated haemoglobin.[1] Our understanding is that the original proposal seeking reclassification of sildenafil did not stipulate the need for these laboratory tests. Furthermore, merely making these tests a 'tick box' requirement now in an updated submission would not satisfactorily address our concerns around possible co-existing cardiovascular disease. We believe that the interpretation of these tests and any decisions about the subsequent management of any co-existing cardiovascular risk factors/disease should be made by the patient's doctor.

Establishing the cause of ED is not always straightforward. Differentiating between psychogenic and organic erectile dysfunction can be challenging, requiring a detailed history, focussed examination and a number of laboratory tests.[2] We believe that these diagnostic aspects of ED are best performed by a doctor. Indeed, diagnosis remains at the core of the role of the doctor.[3] We understand that the original proposal for the training of pharmacists who would dispense sildenafil was envisaged to be approximately three hours in duration. This suggests that only a superficial level of knowledge and skills in the management of ED would be attained, leaving serious concerns about the possibility of misdiagnosis and/or mismanagement.

There are a number of contraindications to sildenafil, with potentially fatal drug interactions associated with the concomitant use of nitrates.[4] The risks of drug interactions with sildenafil are of particular concern if the patient is seeing a pharmacist who may not be aware of their

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[1] Muneer A1, Kalsi J, Nazareth I, Arya M. Erectile dysfunction.BMJ. 2014 Jan 27;348:g129; British Society for Sexual Medicine. Guidelines for the management of erectile dysfunction 2007. Available from: www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2009.pdf; European Association of Urology. Guidelines on male sexual dysfunction. 2013. Available from: www.uroweb.org/gls/pdf/14_Male%20Sexual%20Dysfunction_LR.pdf

[2] Ibid

[3] NZMA. Consensus Statement on the Role of the Doctor in New Zealand. 2011. Available from www.nzma.org.nz/sites/all/files/ps_RoD.pdf

[4] Gur S, Kadowitz PJ, Gokce A, et al. Update on drug interactions with phosphodiesterase-5 inhibitors prescribed as first-line therapy for patients with erectile dysfunction or pulmonary hypertension. Curr Drug Metab. 2013 Feb;14(2):265-9.

concurrent medications. This risk is amplified if the pharmacist is not the patient's usual pharmacist. We believe that the awareness of these risks is best at the GP interface. The recreational misuse of ED drugs is also of concern.[5] It is likely that the proposal to reclassify sildenafil such that a prescription is no longer needed could exacerbate the recreational misuse of this drug.

The NZMA also takes the view that the proposed reclassification would diminish the prospect for opportunistic contact by general practice with a group of patients who would benefit from a thorough cardiovascular risk assessment and, more broadly, from healthy lifestyle advice. 'Well checks' are best provided by a patient's usual doctor and continuity of care is important. Removing the need to see a doctor to obtain a prescription for sildenafil removes a strong motivation for a group of men, many of whom are at increased risk of cardiovascular disease, to see their GP. We have not seen any evidence to support the notion that requiring a prescription by a doctor constitutes a significant barrier to accessing treatment for ED. As such, we do not believe that this claim should be used to support the proposal to reclassify sildenafil. Finally, fragmentation of information is already problematic across the health system. The NZMA has concerns that the current proposal could exacerbate the fragmentation of patient information, particularly in the absence of a universally available shared electronic health record.

Item 6.1: Oral Contraceptives - reclassification from prescription medicine to restricted medicine for selected oral contraceptives

We note that item 6.1 includes proposals for the reclassification from prescription medicine to restricted medicine for selected oral contraceptives, by a pharmacist accredited to supply oral contraception, in accordance with the approved protocol for supply. We note that a 40 page submission has been provided to support these proposals. However, while the submission appears to contain a number of citations in support of the claims that are made, no list of references is given.

We have been advised that the submitter has requested that the reference list not be made publicly available on the grounds of commercial sensitivity and intellectual property. We understand that Medsafe are currently seeking legal advice as to whether these grounds are a legitimate reason to withhold such information from public consultation. We are extremely disappointed that the submitter has elected to withhold the reference list to its submission. This has made it impossible to ascertain the strength or quality of the references and hence, in our view, undermines the credibility of the submission itself.

The NZMA remains strongly opposed to the reclassification of oral contraceptives to restricted medicines that can be supplied by a pharmacist in accordance with an approved protocol. We are not convinced that the requirement for a prescription constitutes a significant barrier to accessing oral contraceptives in New Zealand. In the absence of a reference list, it is impossible to evaluate the 'evidence' in support of this claim. However, we note that the statement about a prescription requirement constituting a barrier is attributed to a single obstetrician and gynaecologist in the United States. It is certainly not a view that is shared by our General Practitioner Council. Furthermore, it is our contention that any existing concerns about access to the oral contraceptive pill can be satisfactorily and safely addressed via a

[5] Bechara A, et al. Recreational use of phosphodiesterase type 5 inhibitors by healthy young men. J Sex Med. 2010 Nov;7(11):3736-42; Fisher DG, et al. Recreational Viagra Use and Sexual Risk among Drug Abusing Men. Am J Infect Dis. 2006;2(2):107-114.

delegated collaborative model of prescribing, available following the assent of the Medicines Amendment Act 2013.

One of the most important aspects of prescribing the oral contraceptive pill is the advice and counselling about its use and about sexual health in general, particularly for young adolescent females. It is difficult to envisage how this can be done well in a pharmacy setting. It can sometimes be difficult even for experienced clinicians to broach sexual health when dealing with a young patient. In some cases, the patient will present asking for advice on contraception or sexually transmitted infections (STIs), but in the majority of cases, opportunistic intervention will be necessary. Yet on average, teenagers are seen at general practice less than once a year. As such, the potential for opportunistic medical interactions, as well as the act of forming a therapeutic relationship with a medical practitioner at a time of personal change, is already low. It is our view that the proposed reclassification would undermine the opportunity for opportunistic intervention and screening for at risk behaviours in an important patient group.

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.[6] 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.[7] 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 (e.g. when there is a suspected STI). Finally, we fear that the proposed reclassification of selected oral contraceptives from prescription to restricted medicines is likely to further fragment patient care with potentially serious consequences for patients, including unintended pregnancy or life-threatening adverse events.

We hope that our feedback to the Committee on these items is helpful and that our comments will be given careful consideration during its deliberations at the upcoming 51st meeting. We look forward to learning the outcomes from this meeting.

Yours sincerely

Dr Mark Peterson
NZMA Chair

[6] Roberts H. Combined oral contraceptive: issues for current users. BPJ April 2012(12):21-9 Available from: www.bpac.org.nz/BPJ/2008/April/docs/bpj12_contraceptive_pages_21-29.pdf
[7] Ibid

Medicines Classification Committee
Ministry of Health

1 April 2014

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

School of Pharmacy
The University of Auckland
Private Bag 92019
Auckland
New Zealand,

85 Park Road, Grafton
www.health.auckland.ac.nz

[redacted]

Dear Committee Members

Re: Submissions for reclassification – oral contraceptives and sildenafil

In consideration of the proposed reclassifications of certain oral contraceptives and sildenafil from prescription medicines to restricted medicines, I offer the following information on the educational preparation of pharmacy undergraduate students to undertake the appropriate assessment and counselling roles associated with these medicines.

While these comments relate specifically to the Bachelor of Pharmacy degree at The University of Auckland, there are similar arrangements in the pharmacy programme at the University of Otago.

During the Auckland programme, students receive a considerable amount of training in physical assessment, screening and monitoring, and patient counselling.

In respect of cardiovascular risk assessment, the following aspects are covered:

- Performance of health assessments related to cardiovascular risk factors including: Body mass index; Waist circumference; Blood pressure; Lipid levels; Glucose levels; Smoking status
- Gathering of pertinent patient information including past medical history, family history and smoking history
- Use of the New Zealand Cardiovascular Risk Assessment and Management Guidelines
- Assessment of cardiovascular risk factors and calculation of absolute cardiovascular risk
- Counselling and education of patients and/or caregivers on cardiovascular risk

These items are taught in a variety of settings, for example in pharmacotherapeutics workshops, pharmacy practice laboratories, communications workshops, ethics workshops, and for the physical assessments at the multidisciplinary Clinical Skills Centre (CSC). In Years 3 and 4 of the programme, students undertake modules in Clinical Skills run by the CSC.

By the time they graduate, students will have been assessed on measuring blood pressure using both sphygmomanometers and automated devices, and on their counselling of patients on the parameters and interpretation of blood pressure recordings. They will also be familiar with of a variety of point-of-care testing devices and their application.

They will also have received extensive training in patient counselling throughout the programme, including the discussion of sensitive or potentially worrying information. Such counselling is framed in

the context of clear ethical practice and moral reasoning and students are fully aware of requirements for confidentiality, patient autonomy, and so on.

Clearly, there is no guarantee that, because students have these skills and knowledge at the time of graduation, this will carry through to their subsequent practice. If the above medicines were to be reclassified, appropriate training and revalidation would be mandatory, as currently occurs for the emergency contraceptive pill or trimethoprim, as examples. Recent graduates will have the advantage of having a head start in these areas. Additionally, clear protocols for use of these products would be required.

In my experience, pharmacists are very responsive to the opportunities presented by reclassification and there is considerable evidence that they are very responsible in their approach. I have personally been involved in a number of evaluation studies concerning reclassification of medicines or introduction of new pharmacy services including studies on nicotine replacement therapy, diclofenac, oseltamivir, and anticoagulation management (warfarin). I have appended a few references and can provide more on request. The bottom line from all of these studies is that pharmacists are competent, responsible and safe in their practice regarding reclassified medicines and there are considerable consequential benefits for patients.

Kind regards

Professor John Shaw
School of Pharmacy
The University of Auckland

Selected References

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PHARMACY GUILD
OF NEW ZEALAND

Your Community Pharmacist: the health professional you see most often

PHARMACY HOUSE 124 Dixon Street, Te Aro, Wellington 6011
PO Box 27139, Marion Square, Wellington 6141
Ph (04) 802 8200 Fax (04) 384 8085
enquiries@pgnz.org.nz www.pgnz.org.nz

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Laurence Holding

Advisor Science (Secretariat for MAAC & MCC)

Product Regulation

Medsafe

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

Dear Laurence

RE: AGENDA FOR THE 51st MEETING OF THE MEDICINES CLASSIFICATION COMMITTEE

Thank you for making available the agenda for the 51st meeting of the Medicines Classification Committee (MCC), to be held on Tuesday 8 April 2014, 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. The Guild and our members are very concerned about the risk to the New Zealand public if some of the proposed reclassifications from a pharmacy-only medicine to a general sale medicine go ahead. The Guild has undertaken a survey of our members and incorporated the results into our submission.

Our feedback covers five agenda items. These are:

- Agenda item 5.1.1: Sildenafil – proposed reclassification from prescription medicine to restricted medicine
- Agenda item 5.2: Review of the classification criteria
- Agenda item 5.5: Oxymetazoline – proposed reclassification from pharmacy-only to general sale medicine
- Agenda item 6.1: Oral contraceptives
- Agenda item 6.2: Diclofenac - proposed reclassification from general sale medicine to pharmacy-only medicine

Each of these agenda items is discussed below.

Agenda item 5.1.1: Sildenafil – proposed reclassification from prescription medicine to restricted medicine

The Guild **supports** the reclassification of sildenafil from a prescription medicine to a restricted medicine.

The Guild was disappointed in the MCC recommendation from the 50th agenda meeting that sildenafil would not be reclassified from a prescription medicine to a restricted medicine. The minutes of the 50th meeting stated that eight out of a total of thirteen pre-meeting comments were in favour of the reclassification. Of the five pre-meeting comments that did not support the reclassification, we feel that the issues raised were valid, but manageable.

The individual comments opposed to the reclassification are addressed below:

a. Reclassification to a restricted medicine would mean the Medsafe Investigation and Enforcement team would no longer be able to stop the importation of sildenafil at the border.

We have confidence that Medsafe would be able to provide appropriate wording, such as requiring supply to be in approved packaging or using the exemption from prescription status as suggested below. However, we note, it is likely that a reclassification would result in a decrease in the importation of this drug, once men are made aware of a safe, easier and legitimate way to access sildenafil. Customs agents intercepting the drug arriving by post currently send a letter to the purchaser including a statement that the purchaser can have the sildenafil sent on to them, on presentation of a prescription from their doctor. Despite the fact that the letter notes the risks of purchasing via the internet, a significant number of patients still present a prescription written by their doctor. By reclassifying sildenafil as pharmacist-only the letter could include the added option of going to their pharmacist for a consultation and purchase of sildenafil. This is certainly a safer option than supply of a potentially counterfeit drug via the internet.

Further to the above concern, the Guild suggests that if it is a high priority to reduce the importation of unregulated sildenafil, MCC could consider reclassifying sildenafil from prescription medicine to "prescription medicine, except when supplied by a pharmacist who has successfully completed the approved training programme and is accredited to supply sildenafil, for the treatment of erectile dysfunction in males aged 35 to 70 years".

b. A thorough assessment by a clinician should be conducted before sildenafil is prescribed.

The second issue raised was that a thorough assessment by a clinician should be conducted before sildenafil is prescribed. To provide context for how the planned pharmacy screening compares to current practice, there is unfortunately little data about doctor work-up in erectile dysfunction (ED), and no such data specific to NZ to our knowledge. A conference abstract reported a survey of 1594 doctors and sex therapists at a European Association of Urology Conference about their management of men when first presenting with ED. Most respondents (85%) saw at least 5 new ED patients per month. A third of respondents reported conducting an ED-specific patient interview, 19% undertook an assessment of cardiovascular risk factors, 15% did laboratory tests, 12% conducted a physical examination, and 7% reported doing a BP/heart rate check at some time before supply. We are unable to find where this research has been published as a peer-review paper, so it needs to be read with caution. Additionally, it may not reflect

behaviour of GPs in NZ who should be more focused on cardiovascular risk assessment given national targets. However, this research does suggest that the proposed pharmacist screening and referral is at the best practice end of the spectrum.

c. There are contraindications with other medications such as nitrates and alpha-blockers.

Pharmacists currently provide advice to patients on contraindications and interactions with other medicines including when a prescription is presented for sildenafil. This is at the core of pharmacists' professional knowledge and practice. The additional pharmacist training to supply this medicine will include a thorough knowledge of these contraindications, and this can also be incorporated within the screening tool. Should a patient be taking any medicine that is contra-indicated, the pharmacist would refer the patient to their GP.

We wish to reiterate the study undertaken by infectious diseases experts (Associate Professor Mark Thomas and Dr Rosemary Ikram), and pharmacy expert, Natalie Gauld. The study investigated how pharmacist-supply of trimethoprim impacted on the overall management of patients with urinary tract infections. This was an extensive study with over 80% of pharmacies agreeing to undertake the baseline data collection. While the results of the trimethoprim study are not yet available, anecdotal feedback from pharmacists around trimethoprim suggests that a conservative, responsible approach has been taken, with pharmacists working within guidelines, and referring patients to their GP as required. The same sort of highly professional attitude and a clear 'following of the rules' were shown when Tamiflu was released for sale by pharmacists. There is no reason to expect that the same would not be true if sildenafil is reclassified.

In the Guild survey of community pharmacists undertaken in September 2013 on their opinions regarding the agenda items for the 50th meeting, the majority of pharmacists agreed or strongly agreed with the reclassification of sildenafil to a restricted medicine. New Zealand pharmacists and pharmacy organisations are embracing opportunities as a result of medicine reclassifications and are taking their responsibilities very seriously. The overwhelming response to the data collection mentioned above was absolute testament to pharmacy's desire to help the NZ public achieve 'better, sooner, more convenient' healthcare with new health initiatives. Should sildenafil be reclassified, the Guild believes pharmacists will embrace this as well and be mindful of the high level of trust that has been placed in their professionalism. The reclassification of sildenafil to a restricted medicine provides an opportunity for pharmacists to work at the top of their scope of practice as the medicines experts in their communities. This medicine has a good safety margin and is well tolerated. While there are clear interactions and contraindications, pharmacists who have received extra training in this specific medicine will have these top of mind. They will be very capable of safe and considered screening of patients, and referral to the GP as necessary. Pharmacists are mindful of the Code of Ethics which restricts them to only provide services to patients in which they are competent.

d. Reclassification to a restricted medicine would put New Zealand out-of-sync with the Australian Schedule unless the same change is also sought in Australia.

This should not be a reason to stop a potential reclassification. There will be no need for differences in labelling requirements between the two countries if sildenafil is reclassified

as a "prescription medicine, except when supplied by a pharmacist who has successfully completed the approved training programme and is accredited to supply sildenafil, for the treatment of erectile dysfunction in males aged 35 to 70 years". The reclassification would provide the opportunity for Australia to follow New Zealand's lead, and also reclassify sildenafil. The Australian classification of Schedule 3 medicines are those that are considered substantially safe in use but require professional advice or counseling by a pharmacist, require pharmacist advice, management, or monitoring, are for ailments or symptoms that can be identified by the consumer and verified by a pharmacist and do not require medical diagnosis, or only require initial medical diagnosis, and do not require close medical management. Sildenafil would appear to meet these requirements.

e. The monetary incentives for pharmacy owners would lead to some promoting themselves as sildenafil suppliers rather than medical professionals

The concern that monetary incentives would lead pharmacy owners to promote themselves as sildenafil suppliers rather than medical professionals is a matter of professional ethics; as discussed above pharmacists have in the past shown they have very high ethical standards. The Guild works with pharmacy to ensure they are well aware of their professional responsibilities, including those defined in the Pharmacy Council Code of Ethics. One of the ethical responsibilities is that a pharmacist must not compromise their duty of care to patients by a commercial interest. Supply criteria are clear, and where these are not met, men will be referred to the doctor. Every day in pharmacies all around New Zealand consumers are triaged and referred to their doctor in line with the professional ethics of the pharmacist, rather than being sold a medicine. In our survey of members conducted last year, pharmacists told of their experiences turning down inappropriate use, such as with omeprazole, naproxen and oxymetazoline, and advising against using paracetamol and ibuprofen liquids in children to help them sleep. Pharmacists frequently turn down requests for all sorts of medicine sales where they have concerns about inappropriate use or misuse. In New Zealand we can be commended for leading the way in helping consumers to access medicines, and working together to take a responsible approach to medicines access.

f. The proposed screening process for cardiovascular risk is not thorough enough.

We believe that amendments can be made to the proposed screening tool to allay any further concerns the MCC may have.

<u>MCC discussion topics:</u>

Equipment used for checking blood pressure:

The MCC discussed the equipment that would be used by pharmacists for checking blood pressure and whether it would need to be audited and recalibrated annually. This is a valid query as pharmacists will be making clinical decisions based on blood pressure measurements.

Under Section 51 (d) and (e) of the Medicines Act 1981 a pharmacy is required to have all the equipment necessary for the services they provide. Pharmacies receive their Licence to Operate Pharmacy on the condition that every responsible person, as named on the licence "has a sufficient knowledge of the obligations of a licensee and of the

hazards associated with the medicines in which it is proposed to deal". The licensee must ensure that the premises and equipment within the pharmacy are suitable and adequate for the purposes for which the licence is sought.

Community pharmacies are audited by Medicines Control, Ministry of Health every three to five years. These audits check the validity of the pharmacy equipment, whether the pharmacy has current Standard Operating Procedures, and if the pharmacy staff follow these procedures. Medicines Control ensures that pharmacies are adhering to the criteria defined in the Health and Disability Services Pharmacy Services Standard. This Standard requires any equipment used should be thoroughly cleaned, maintained and adequately stored. Equipment must be calibrated and checked at defined intervals by appropriate methods, with adequate records of such tests maintained. The Guild agrees with the MCC that calibration of electronic blood pressure monitors must be undertaken every two years. If MCC are concerned about the regular calibration of blood pressure monitors they could recommend to Medicines Control that this is added to the quality audits that they already undertake in community pharmacies.

Greater access to the medicine

Committee members stated that "most men who are too embarrassed to talk to their general practitioner would also be too embarrassed to talk to their pharmacist". The Guild would argue that time is a more significant issue that contributes to patients using the internet to source medicines than embarrassment. Pharmacies give the public walk-in access to qualified health professionals, are open longer hours than medical centres and are generally more accessible to the public. A recent study undertaken by the University of Otago on the uptake of the flu vaccine as administered by community pharmacists showed people accessed the vaccine because of the ease of visiting a pharmacy[i]. Forty-two per cent of patients surveyed stated they had not been immunised the previous year, with one of the main reasons for this being they were "too busy". By increasing the access to immunisation, uptake of the vaccine was demonstrated. This shows that pharmacy has the ability to capture patients who may not normally visit their GP because of being too busy or cannot easily get time off work for 'non-essential' doctor visits.

Should this reclassification be successful, it is likely that there will be men identified who currently under-attend their GP. There is potential for pharmacists to refer patients to the GP when health concerns are identified, or when conditions that require treatment are discovered. This will increase the health benefits to the men who utilise a pharmacy service, and provide another safety net of health screening for patients.

Conclusion

The Guild provides tools for our members to help them, for example providing them with SOPs for pharmacy vaccinations and Emergency Contraception consultations. SOPs are reviewed by the appropriate specialists in the field before being released. The Guild has developed an SOP on the use of blood pressure monitors which is currently being reviewed by the Heart Foundation, and a draft is attached at the end of the submission. A finalised version will be forwarded as soon as this becomes available.

The company submission emphasises the requirement for pharmacists to have adequate training and the Guild supports the need for this training to be thorough. We understand Associate Professor Rhiannon Braund from the University of Otago will be overseeing the

development of this training, and we support that this occurs. We will also be recommending to our local branches that they run blood pressure monitoring training as part of their regular continuing education to ensure our members are fully competent and confident in providing blood pressure checks.

The Guild believes pharmacists have demonstrated their professionalism with previous reclassifications and we are confident that they will take a responsible and cautious approach to this reclassification also.

Agenda item 5.2: Review of the classification criteria

The Guild **supports** the change in the Medsafe paper that states comments received on agenda items will be published on the Medsafe website.

We have no objection to our own comments on agenda items being made public, and feel this change would increase the transparency of the decision-making process.

Agenda item 5.5: Oxymetazoline – proposed reclassification from pharmacy-only medicine to general sale medicine

The Guild **strongly opposes** the reclassification of oxymetazoline from a pharmacy-only medicine to a general sale medicine.

The Guild is disappointed to see that the MCC will reconsider the submission to reclassify oxymetazoline for nasal use, when labelled for use in adults and children over 6 years of age, from pharmacy-only medicine to general sale medicine. Further data has been submitted by Pharmaceutical Solutions in consultation with the New Zealand Retailers Association. We have not seen any data for this resubmission so cannot comment specifically on the arguments they raise.

The Guild stands by our statement in our previous submission that reclassifying this medicine to general sale is not in the consumers' best interests due the reasons listed below:

- Inappropriate or prolonged use can cause rebound congestion
- The risk of cardiovascular and central nervous system effects
- There are significant contra-indications (e.g. glaucoma, cardiovascular conditions)
- There are a number of drug interactions (e.g. beta-blocker, monoamine oxidase inhibitors)
- There are a number of precautions (e.g. hypertension, pregnancy)
- Risk of use in children under 12 years without professional advice
- Risk of use in children under two years
- Current pack size of 20ml permits in excess of 18 day's supply
- Little expected benefit to patients by having it available in supermarkets.

Topical nasal decongestants have long been identified as causing rhinitis medicamentosa (rebound congestion). Rebound congestion is caused by prolonged use of topical decongestants which stimulate alpha adrenergic receptors causing vasoconstriction.[ii] A search revealed over 70 papers in the Medline database related to the use of these medicines and rebound congestion. Prolonged use results in reduced efficacy and

shortened duration of effect,[iii] which encourages an increased dosing amount and frequency. For example, users may dose as often as two-hourly. The nasal mucosa develops a cobblestone appearance with redness. There is loss of cilia, ulceration, mixed inflammatory cell infiltration, goblet cell hyperplasia and increased submucosal glands. On electron microscopy, gaps between capillary endothelial cells are enlarged, and this may be why this medication becomes ineffective. Rebound congestion can cause nasal septal perforation.[iv]

Rebound congestion is treated by stopping the topical nasal decongestant with help from oral decongestants, topical antihistamines or corticosteroids, or oral corticosteroids. Where all medical treatment fails, turbinate surgery is required. However, rebound congestion predisposes patients undergoing turbinate surgery to profuse bleeding that is not responsive to standard surgical treatment to control mucosal bleeding (of which oxymetazoline is the treatment agent) may result in the need to abort the surgery.[v] Graf and Hallen advise that patients who have had rebound congestion who stop using topical decongestants need to be careful when later using these medicines, even one year later, rebound congestion has a fast onset.[vi]

Pharmacists and pharmacy assistants are well aware of the problems associated with rebound congestion and counsel accordingly both in terms of prevention (highlighting a maximum of three days' treatment – as directed on the box), and identifying when it has occurred and how to manage it. Clearly the product label warning to not use for more than three days is inadequate, as pharmacists and pharmacy staff still find rebound congestion occurs in practice despite pharmacy staff intervention and current labelling requirements. Pharmacists and pharmacy staff frequently counsel patients when supplying these medicines, so as to avoid this problem, yet some patients will still overuse oxymetazoline and pharmacists follow up with the patient at a future visit to try to change their behaviour or refer them for medical treatment. Supermarket availability will significantly exacerbate this problem. It would mean that some people could deliberately avoid the pharmacy where they know they would be questioned and moved onto alternative and more appropriate treatments. Other patients would remain completely unaware of the existence of topical nasal decongestant overuse syndrome until they finally visit their GP with advanced rebound congestion.

There is currently a range of classifications of Oxymetazoline in developed countries. While the MCC noted that oxymetazoline is already available as a general sale medicine in the United Kingdom, the United States and Canada, topical nasal oxymetazoline requires a prescription in some countries, e.g. France and Japan.[vii]

Of the 242 New Zealand pharmacists answering a survey undertaken of Guild members in September 2013, 95% reported finding inappropriate use of topical nasal decongestants in their practice. Furthermore, some pharmacists reported finding other concerns such as nasal infection that resulted in doctor referral. One pharmacist outlined a case in which their doctor referral led to a diagnosis of nasal cancer. It is clear that referral and diagnosis benefits also accrue from the pharmacy-only supply of oxymetazoline.

The interventions made by pharmacy staff contribute to quality use of medicines and protect our most vulnerable patient groups such as the very young and the elderly. Upon a patient request for an oxymetazoline product, there is often a discussion that will establish the cause of the problem. A more appropriate treatment (e.g. nasal or oral antihistamine) or referral to a doctor or ENT specialist is often the result of an interaction

in the pharmacy arising from a request for a topical nasal decongestant. In particular, when nasal corticosteroids first became available this reduced the problem of overuse of nasal topical decongestants. Pharmacists were able to move patients with on-going nasal congestion to a safe long-term treatment.

The recommendation of the MCC as stated in the 50th minutes was that the pack size should not exceed 20ml. The Guild does not agree with this. This seems in conflict with the recommendation that the label should state that oxymetazoline should not be used for longer than three days. The recommended dose of nasal spray is for two to three sprays to be used in each nostril every 12 hours. For a three day supply this would be 36 doses, a five day supply would be 60 doses in total. On testing two different 20ml bottles of oxymetazoline nasal spray we found that one delivered 220 doses, and the second delivered 218. For both bottles this is enough to provide the patient with an 18 day supply, i.e. six times the recommended treatment course. Should this reclassification go ahead, the Guild requests that a bottle size that limits the treatment to no more than a five day supply be enforced. We also feel that the bottle should have a permanently sealed cap to prevent poisonings from oral ingestion.

At the recent Australian Pharmacy Professional (APP) conference held in Queensland Professor Scott Koslow from Macquarie University Department of Marketing and Management was a guest speaker. Professor Koslow has undertaken studies on consumer selection processes using data from focus groups, questionnaires and actual real in-field eye tracking measurement. His studies have found that for the average consumer, purchasing medicines is difficult and complex. Eye-tracking research showed that the consumer looked at brand names and prices first, brand name again, then turned the item over and looked at the brand name for a third time. None of the general public who were studied actually read the product information on the back of the medicine pack. Feedback from consumer questionnaires was that there were so many little and confusing words on the back of the pack, and they felt they should be looking, but did not know what at or why. Eye-tracking also showed that once the pharmacist was involved, the patient looked at the pharmacist and listened to what they said.

Professor Koslow reinforced that the consumer is a limited processor and if there is information that regulators want them to read, it needs to be on the front of the pack near the brand name in the same size font. Ordinary people don't chose a product based on ingredients, dose, or safety, they choose a product because they recognise the brand name.

The availability of oxymetazoline in supermarkets offers little potential benefit to the public while significantly increasing the possibility of inappropriate and over usage. Consumers generally make the assumption that because a medicine is available from a supermarket, it is safe. As you can see above, you can expect that many consumers will use this medicine without looking at the instructions or warnings. Independent research from markets where these medicines are available in the supermarket is needed to show whether inappropriate use is higher with supermarket availability or not.

The information provided by Professor Koslow is important in illustrating why oxymetazoline should remain as a pharmacy-only medicine. Important advice needs to accompany the sale of this medicine, advice that will not be provided in a supermarket and advice that will generally not be read even if it is displayed on the medicine

container. Bolder labelling instructions will not replace the professional advice available in a pharmacy. There is a risk that, regardless of the recommendations of the MCC for improved labelling requirements, oxymetazoline will be used longer than three days, it will be used in children under two years of age, and those under 12 without the advice of a health professional, and it will be used by people with other medical conditions or taking other medicines.

The public trust government bodies like MCC to ensure that only safe medicines are available for them to purchase. The general public should be able to trust that only those products that cannot harm them or their families are available in a supermarket where there is no health professional intervention. Given concerns about misuse and overuse, this medicine is not appropriate for general sales supplies.

Agenda item 6.1: Oral contraceptives

The Guild **supports** the reclassification of desogestrel, ethinylestradiol and norethisterone from prescription medicine to restricted medicine.

The Guild **supports** the proposed changes to the restricted medicine classification conditions for levenorgestrel.

The Guild believes that pharmacist provision of hormonal contraceptives is long overdue. The oral contraceptive pill has been available in New Zealand since the 1960's and world-wide has proved to be a safe and effective form of contraception, however unintended pregnancy remains a public health and social issue in New Zealand. Teenage pregnancy rates are considered high by OECD standards[viii]. For the young women involved, the on-going effects such as the failure to reach educational potential, decreased career prospects and decreased earning potential have long-lasting effects. Unintended pregnancy also has considerable costs for taxpayers.

To the year ended December 2012, there were 14,745 abortions performed in New Zealand. Women aged between 20 and 25 years old had the highest abortion rate. By decreasing the barrier to access for contraception, it is likely that this will impact the unplanned pregnancy and abortion rates in New Zealand.

Oral contraceptives are a common medicine that pharmacists dispense as an emergency supply to those women who have lost their medicine, forgotten it while travelling or run out of tablets over the weekend. Not all women are aware that a limited emergency supply is possible from a pharmacy, and many risk treatment failure by missing tablets. Should this proposed reclassification go ahead, the potential for treatment failure as a result of discontinued supply will be alleviated.

Pharmacists are increasingly adding to the range of services they provide to patients, from monitoring of warfarin therapy, the provision of the emergency contraceptive pill, influenza vaccinations and the supply of trimethoprim for uncomplicated urinary tract infections. Pharmacists have embraced these new services and are keen to work at the top of their scope of practice for the benefit of their patients.

Pharmacists have played a role in the supply of the emergency contraceptive pill (ECP) for many years and have proved to be safe providers of this medicine. They are enthusiastic participants as shown by the number of pharmacists who have completed

the training. Pharmacists are comfortable with talking to their patients about sexual health issues such as sexually transmitted diseases and smear tests. The Guild is aware that pharmacies are using the tools developed for ECP as the patient assessment forms are available through the Guild, and these are continually being reordered.

Should oral contraceptives be reclassified to pharmacist-only, this will provide the patient with a complete solution for a pharmacy-held ECP consultation. Currently there is much opportunity lost for the provision of healthcare at the time of the patient visit to the pharmacy for the ECP. With the reclassification of oral contraceptives a pharmacist would be able to consult with the woman over the supply of the ECP, provide advice on contraception, and then recommend and possibly provide a suitable oral contraceptive for on-going contraception. Currently pharmacists often recommend that the patient taking the ECP should visit their doctor and talk about regular contraception. There is no way to know how many women take up this suggestion but it is likely to be somewhat less than 100%.

Pharmacist supply of oral contraceptives is happening already in Australia, Canada, the United States and the United Kingdom. There is data available to show that women are able to safely "self-screen" their suitability for an oral contraceptive. A US study[ix] showed that women seeking oral contraception from outside of a typical healthcare setting were just as knowledgeable of contraindications and side effects as their counterparts seen in a health clinic. The submission by Pharmacybrands Limited (PBL) adds a layer of safety by proposing that specially trained pharmacists will screen women to ensure only those who are low-risk will be eligible for supply.

The Guild fully supports the PBL and Pharma Projects Limited submission for reclassification of progestogen-only pills and the second-generation combined oral contraceptives due to their lower risk of venous thrombosis. It is imperative that the screening of patients, safe supply of medicine and provision of counselling is undertaken with the utmost of care. The submission has provided assurances that a comprehensive screening tool and strict criteria for supply will be used and that the service delivered to patients will only be undertaken by pharmacists qualified to do so. Those patients found to fall outside of the criteria for supply will be referred to their doctor. Pharmacists are used to referring patients with risk factors to their GPs. As stated above pharmacists have shown themselves to be highly ethical in their attitude to the supply of reclassified medicines and strictly follow the criteria.

Pharmacists will have to undergo mandatory training and assessment before being permitted to supply oral contraception without prescription. They will also need to undertake on-going accreditation by means of an online refresher every two years in order to carry on providing the medicine. Initial pharmacist initiated supplies will be audited to provide reassurance that inappropriate supplies are not being made. The Guild is aware that both Natalie Gauld and Dr Christine Roke will be involved in the training and feel comfortable that the training will be professional and thorough.

The Guild has played a role in ensuring pharmacists are prepared for the responsibilities that come with medicine reclassifications. We have recently undertaken a proactive role around vaccinations, developing a set of comprehensive Standard Operating Procedures for the administration of vaccinations. We will continue to support our members in preparation for a positive outcome of the proposal to provide oral contraceptives through the provision of our Standard Operating Procedure for Blood Pressure Monitoring and blood pressure monitoring training at local branch events.

This proposal fits the government model of "better, sooner, more convenient" health care by removing the barriers to access a medicine that has a similar safety profile to other non-prescription medicines.

Agenda item 6.2: Diclofenac – proposed reclassification from general sale medicine to pharmacy-only medicine

The Guild **supports** the reclassification of diclofenac in transdermal preparations for topical use containing 140mg or less of diclofenac from general sales to pharmacy-only medicine.

Diclofenac has been available as a general sales product in topical form for many years. It is well tolerated, has a good safety profile, and has low systemic absorption, making it a valuable alternative to those patients who may not be able to tolerate oral NSAIDs. Patients are familiar with diclofenac and are able to self-select a wide range of treatments for the short-term relief of localised pain in acute soft tissue injuries.

While topical diclofenac has a low safety risk, it makes sense to classify this novel product as pharmacy-only so that patients will receive appropriate advice from pharmacies about how to use transdermal patches. Patients will be able to discuss with pharmacy staff how to use this new product and be able to compare it to the treatments that are currently available and therefore select the most appropriate form for them. Discussions with pharmacy staff provide a valuable interaction and a screening for anything that may need referral to a pharmacist, doctor or a physiotherapist.

We agree with the company submission that is makes sense to harmonise the New Zealand classification with that of Australia, to allow for common packs to be marketed in both countries especially in light of the future alignment of the medicine regulatory agencies.

[redacted]

Yours sincerely,

Lee Hohaia
Chief Executive

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[vii] OTC Ingredients. 2012; http://www.aesgp.eu/facts-figures/otc-ingredients/. Accessed 7 August 2012.

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[ix] Kaskowitz AP et al; Online availability of hormonal contraceptives without a health care examination: effect of knowledge and health care screening. Contraception 2007; 76:273-7.

Measuring Blood Pressure in Pharmacy - Standard Operating Procedure

Blood pressure can be taken only by pharmacists or pharmacy technicians who have been trained in using a blood pressure monitor. Training must include hands-on training, and may occur in under-graduate training, a formal training session or ad hoc training. For ad hoc training, e.g. by representatives from companies supplying BP monitors, supplementary independent credible training must be accessed, e.g. from the British Hypertension Society website: http://www.bhsoc.org/files/6413/3517/2224/BHS-DVD.avi Training must be documented. Where a pharmacy technician takes the blood pressure, this must be over-seen by the pharmacist who will provide advice.

An arm blood pressure monitor suitable for clinical use (e.g. as listed on the British Hypertension Society website) must be used, with standard and large cuffs available.

The blood pressure monitor will be serviced and calibrated at least once every two years, or more frequently if manufacturer's guidelines have a shorter service period.

Taking a blood pressure:

1. The person should sit for five minutes.
2. The arm is supported at the level of the heart, with no constriction from clothing. Use the same arm the person normally has measured, and document the arm used.
3. Use an appropriate cuff:

Arm circumference	**Cuff size**	**Notes**
<23 cm	Small adult/child	Refer to medical practice if no small cuff available
23-33 cm	Standard adult	
33-50 cm	Large adult	Particularly large adults should be referred for BP measurement

4. The cuff is applied directly to the skin with no clothing in between. The centre of the bladder is placed over the brachial artery. Two fingers should be able to be slipped under the cuff before inflation.
5. The person should stay still and not talk while the readings are carried out.
6. Take two readings one minute apart
7. If the readings vary by >10 mmHg, do more readings until measurements are stable, aiming for two stable readings. Refer to the doctor if difficulties with readings occur.
8. Document each reading, and use the average of the last two BP readings
9. If BP or pulse readings are difficult or erratic, refer to the doctor for a reading
10. A high BP reading is communicated carefully to the patient – noting that BP can rise with recent caffeine intake, recent cigarette smoking, recent physical and mental stress, talking, high alcohol intake, NSAIDs, and sympathomimetics. With a high reading, check if the person has recently had a caffeinated drink, smoked a cigarette, been stressed or had physical

exertion, and if so repeat later. Repeating the BP on another occasion will often give different results.

11. Adults fitting the criteria in Appendix 1 who have not had a heart health and diabetes check with their GP will be referred to the GP for this check, regardless of their BP reading (see Appendix 2)
12. Adults with BP above [what levels should I include here, e.g. 180/110 mmHg?] will be referred immediately to their GP with a written document (see Appendix 2). The pharmacist should offer to make the appointment and fax the document to the GP as well as providing a copy to the patient.
13. [what other referral points are desirable?]
14. Provide advice to all – written and/or verbal on keeping their BP low and heart healthy – dietary advice, stopping smoking (advise strategies if applicable), limit alcohol intake, exercise for 30 minutes on most days (check with doctor first if significant cardiac history), and maintain a healthy weight.

Template letter to Doctor

Dear Doctor,

In our blood pressure check taken today, _____[name] had a reading of _____ mmHg, based on the average of two stable readings. We have recommended follow-up with their General Practice.

_____[name] may not have had a heart health and diabetes check in the last five years, and has been recommended to attend their General Practice to have this. [strike out if not applicable]

Yours sincerely,

_____ [Pharmacist's name] _____[date]

_____ [Pharmacy name and Phone number]

Table 1: The recommended age to offer cardiovascular risk assessment

Group	Men	Women
Asymptomatic people without known risk factors	Age 45 years	Age 55 years
Māori, Pacific peoples or Indo-Asian* peoples	Age 35 years	Age 45 years
People with other known cardiovascular risk factors or at high risk of developing diabetes Family history risk factors • Diabetes in first-degree relative (parent, brother or sister) • Premature coronary heart disease or ischaemic stroke in a first-degree relative (father or brother <55 years, mother or sister <65 years) Personal history risk factors • People who smoke (or who have quit only in the last 12 months) • Gestational diabetes, polycystic ovary syndrome • Prior blood pressure (BP) ≥160/95 mm Hg (taken as a clinic BP), prior TC:HDL ratio ≥7 • HbA1c 41–49 mmol/mol • BMI ≥30 or truncal obesity (waist circumference ≥100 cm in men or ≥90 cm in women) • eGFR<60 ml/min/1.73 m^2 †	Age 35 years	Age 45 years
People with diabetes (type 1 or 2)	Annually from the time of diagnosis	Annually from the time of diagnosis

* Indo-Asian peoples: Indian, including Fijian Indian, Sri Lankan, Afghani, Bangladeshi, Nepalese, Pakistani, Tibetan.

† eGFR estimated glomerular filtration rate.

Source: Cardiovascular disease risk assessment (updated 2013) New Zealand Primary Care Handbook 2012. Wellington: Ministry of Health. [need to get permission to use]

References:

Cardiovascular disease risk assessment (updated 2013) New Zealand Primary Care Handbook 2012. Wellington: Ministry of Health.

British Hypertension Society website http://www.bhsoc.org/ [accessed 6 Mar 2014]

PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

27 March 2014 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 51st MEETING AGENDA April 2014

Thank you for the opportunity to submit comments on the Agenda for the 51st 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.

5 MATTERS ARISING

5.5 Oxymetazoline - proposed reclassification from pharmacy-only medicine to general sale medicine (Pharmaceutical Solutions in consultation with the New Zealand Retailers Association)

The Pharmaceutical Society reiterates the concerns expressed in it's submission (reproduced below) to this agenda item when presented at the 50th Meeting of the Medicines Classification Committee. We believe the proposed changes do not adequately address these concerns and remain **strongly opposed** to the reclassification of oxymetazoline to General Sale Medicine.

> **6.5 Oxymetazoline - proposed reclassification from pharmacy-only medicine to general sale medicine (Pharmaceutical Solutions in consultation with the New Zealand Retailers Association)**
>
> The Society **strongly opposes** the proposed reclassification of oxymetazoline from Pharmacy-Only Medicine to General Sale. The use of oxymetazoline nasal spray must be used for short periods only or people risk rebound congestion which can be confused with ongoing symptom presentation. With no controls in place to question use, many consumers self-selecting will continue to purchase and treat themselves without recognising their ongoing symptoms reappearing with stopping treatment are likely due to rebound congestion. Furthermore, pharmacists have told us of situations

Level 10, Grand Arcade Tower, 16-20 Willis Street, PO Box 11640, Manners Street, Wellington, 6142, New Zealand
TEL 04 802 0030 **FAX** 04 382 9297 **EMAIL** p.society@psnz.org.nz **WEB** www.psnz.org.nz

where customers ask about oxymetazoline treatment, but when questioned it is found that symptoms are more allergy related and are directed to more appropriate treatment options such as corticosteroid nasal sprays or oral antihistamines. We strongly believe the general public do not understand the aetiology of nasal congestion and the potential for inappropriate treatment.

The submission is inconsistent in seeking reclassification for ages from 6 years, yet states the labelling "directs consumers to seek medical advice and consult doctor or pharmacist before use if taking any other medicines to treat cough and cold and before use in children aged 6 to 12 years". If professional advice is required to determine appropriateness and/or potential clinical risks in a specific age group, then it is unreasonable to expect this to be enforced in a supermarket environment and a reclassification is inappropriate.

We are concerned at the lack of acknowledgement expressed in the submission with respect to contraindications and precautions with pre-existing hypertension, coronary heart disease, hyperthyroidism, diabetes, narrow angle glaucoma or urination difficulty due to prostatic enlargement. We strongly object to the addressing of interactions with MAOIs, tricyclic and tetracyclic antidepressants or β-blockers by labelling requiring people "to consult a doctor if you are taking any other medications to treat cough and cold". All pharmacy staff are expected to ask about current medications with the sale of any medicine from the pharmacy.

As mentioned earlier, we do not accept opening hours of pharmacies versus supermarkets to have any relevance to why this medication should be available general sale. We do not believe customers will travel to a supermarket outside of a pharmacy's opening hours, late at night in order to purchase an oxymetazoline spray. Oral decongestant products are already available general sale, therefore we believe oxymetazoline, with its added clinical management issues, potential for inappropriate use and medication interactions, should remain under the supervision of a pharmacy-only sale.

6 SUBMISSIONS FOR RECLASSIFICATION

6.1 Oral Contraceptives

The comments below relate to the proposal to reclassify the following oral contraceptives, as described in the agenda:

6.1.1 Desogestrel - proposed reclassification from prescription medicine to restricted medicine
6.1.2 Ethinylestradiol - proposed reclassification from prescription medicine to restricted medicine
6.1.3 Levenorgestrel - proposed changes to restricted medicine classification conditions
6.1.4 Norethisterone - proposed reclassification from prescription medicine to restricted medicine

The Pharmaceutical Society **supports** the reclassification of the above oral contraceptives and endorses the evidence and arguments for reclassification as outlined in the submission by Pharmacybrands and Pharma Projects.

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 Pharmaceutical 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 working with the Family Planning Association of New Zealand in delivering education and training for pharmacists through the Emergency Contraceptive Pill training, and also through continuing education sessions on contraception and women's health. The National Medical Advisor of Family Planning has expressed her support 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 other methods of contraception available that an individual may wish to consider. Should the proposal to reclassify be accepted, the Pharmaceutical Society will work with Family Planning to develop and deliver this training and could supply a detailed 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.

6.2 Diclofenac – proposed reclassification from general sale medicine to pharmacy-only medicine (Novartis Consumer Health Australasia Pty Ltd)

The Pharmaceutical Society **supports** the proactive submission from Novartis Consumer Health Australasia in singling out transdermal diclofenac preparations for topical use containing 140 mg or less to be reclassified to pharmacy-only medicine.

Thank you for consideration of this submission.

[redacted]

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Laurence Holding
Advisor Science (Secretariat for MAAC & MCC)
Product Regulation, Medsafe
Clinical Leadership, Protection & Regulation
Ministry of Health
WELLINGTON

Email: committees@moh.govt.nz, laurence_holding@moh.govt.nz

Dear Laurence

Re: Agenda for the 51st meeting of the Medicines Classification Committee

Thank you for the opportunity to comment on the agenda for the 51st meeting of the Medicines Classification Committee

The College is the professional body and post-graduate educational institution that sets the standards for general practice, providing research, assessment, post-graduate training, and on-going education and support for general practitioners and general practice. College Fellows provide advice and expertise to government and within the wider health sector. The College aims to improve the health of all New Zealanders by supporting and strengthening high quality care and standards in general practice.

The College has a focus on ensuring high quality patient centred clinical care is delivered in CORNERSTONE® accredited general practices by vocationally registered general practitioners.

The College has over 4,000 members. In developing this submission we sought feedback from members on the agenda items via the College's weekly electronic newsletter and via email to members of the relevant professional interest groups.

The College would like to comment on the following three agenda items:

- Item 5.1.1 Sildenafil
- Item 5.2 Review of the classification criteria
- Item 6.1 Oral contraceptives

Item 5.1.1 Sildenafil

The agenda for the 51st meeting states:

> Sildenafil – proposed reclassification from prescription medicine to restricted medicine (Silvasta, Douglas Pharmaceuticals Limited)
>
> An objection has been received regarding the Committee's recommendation that sildenafil should not be reclassified as a restricted medicine when supplied by a pharmacist who has successfully completed the approved training programme and is accredited to supply sildenafil, for the treatment of erectile dysfunction in males aged 35-70 years.

Level 3, 88 The Terrace, P O Box 10 440, Wellington, 6143 New Zealand
Tel: +64 4 496 5999, Fax: +64 4 496 5997
Email: rnzcgp@rnzcgp.org.nz, Web: www.rnzcgp.org.nz

> Douglas Pharmaceuticals Limited felt that some of the submission was not fully portrayed to the Committee and some of the safety features may have been overlooked. The company will provide an updated original submission to include additional information that specifically addresses the concerns raised by the Committee. This recommendation will be reconsidered now that further data has been provided.

The College has not been able to view the 'further data' mentioned, this being classified as commercially sensitive.

We did obtain a copy of the 17 January 2014 letter from Mike Siermans of Douglas Pharmaceuticals to the Medicines Classification Committee requesting reconsideration of the decision of the 13th November meeting regarding Sildenafil. In the letter he suggests that the fact that "pharmacists would be advising all men who had not discussed their erectile dysfunction with their doctor to do so"had been overlooked. He considered that this was an additional safety feature. He also wished to clarify that "pharmacists would be ascertaining when the customer had last had a full check-up at the doctor" ...and "that men who had not had this check up in the recommended time frame for their age be referred for this".

Douglas Pharmaceuticals have provided the College with a copy of the Draft Algorithm for Sildenafil Supply and GP Referral. From this it would appear that men could still be supplied with Sildenafil even if they have not had a full cardiovascular risk assessment. We agree that some men may go ahead and organise a risk assessment as a result of the advice of the pharmacist, but it is likely that many will not. By contrast, if they had requested treatment for erectile dysfunction from their GP then a risk assessment could have been commenced or arranged during that consultation.

The College continues to oppose the reclassification of Sildenafil.

Item 5.2 Review of the classification criteria

The College would like to commend the committee on publishing the guidance document "How to change the legal classification of a medicine in New Zealand".

We do, however, have concerns around some of its content, particularly in relation to withholding of information on the grounds of commercial sensitivity. The guide states:

> Submissions may contain commercially sensitive information. In such cases, the commercially sensitive information should be included as an appendix to the submission and clearly marked as confidential. Justification for confidentiality must also be provided. Parts A and B for publication must include sufficient detail so to inform the consultation process.

This has relevance for the two other agenda items for the 51st meeting on which the College provides comment in this submission. We do not consider that the published material in relation to these items contained sufficient detail to inform the consultation process. Nor could we understand why references to articles in publically available journals could be considered "commercially sensitive". The submission document relating to oral contraceptives contained over 140 citation numbers in the text but without the references to the actual articles supporting the statements made. This severely restricts the ability to critique the evidence, determine its robustness and assess whether it supports the claims made.

We would urge the Committee to ensure that in future material for publication does include sufficient detail so to inform the consultation process.

Item 6.1 Oral contraceptives

The application proposes changes to the classification of oral contraceptive pill (OCP) ingredients Desogestrel, Ethinylestradiol, Levonorgestrel and Norethisterone. The submission in support of this proposal considers all of these together, as does our response. The proposed changes would allow

accredited pharmacists to supply oral contraception to women aged 16 to 39 in accordance with the approved protocol for supply. Initiation of supply and continuation of supply would both be covered.

The College opposes this proposal. While our members frequently mentioned the need for women to have easy access to appropriate contraception and to minimise the number of unplanned pregnancies, the majority of respondents did not consider pharmacy supply as the only or the best method of achieving better access.

Issues raised by members include the following:

Initiating contraception and range of options

When done properly, initiating an OCP is a complex, time consuming consultation. Knowledge of the patient's previous medical, contraceptive and family history is very important. Women need to be informed of the options available and there needs to be a discussion of what might be appropriate in their particular circumstances and of the advantages and disadvantages of various options with respect to effectiveness, cycle control, possible side effects etc. The OCP may not be the best contraceptive option.

Pharmacists may refer women to a medical practitioner for other options. However, not all women will make that second attempt to obtain contraception. This is all the more likely in the case of women not entitled to free sexual health care from their GP who would then be required to make a second payment. This would effectively raise rather than lower barriers to access.

The submission implies that long acting reversible contraception (LARC) is an unpopular option but this is at variance with recent New Zealand reports of 'skyrocketing' rates of use of contraceptive implants with "13,500 women getting an implant last year" [1] LARC may well be a better option for many women, especially those at risk of missing pills, and many young people fall into this category. Rather than comparing the safety of the oral contraceptive with the health risks of pregnancy it may be more realistic to compare the risks of pregnancy when on the oral contraceptive with the risks of pregnancy on LARC.

Quality health care

Many of the women who see their GP for contraception rarely visit general practice. By visiting for contraception they have opportunity to become familiar with the practice and to develop a trusting relationship with their GP and practice staff. This assists patients in maintaining enrolment and their entitlement to a patient subsidy and in knowing how to access appropriate care rather than attending ED when unwell. Patients who have a general practitioner, or in American parlance have a 'medical home', are likely to receive better quality health care.

Particularly in the case of adolescents and younger women a request for contraception signals the onset of a major life-stage. A consultation with a GP provides an opportunity to enter into discussion over matters such as safe sex, risk taking and risk of partner violence and to screen for mental health issues. Our members expressed surprise that there should be a suggestion that this could be done properly in a pharmacy situation.

The consultation also provides an opportunity to address general and women's health-related issues as well as preventative care. We know that brief interventions made by a GP can be very effective, as can opportunistic screening, and these are encouraged under current Ministry of Health policies. This proposal would lessen the opportunities for both to occur.

Sexually transmitted infection (STI) checks and cervical smears

The submission repeatedly states that STI checks and cervical smears are not necessary for contraceptive prescription. This appears to suggest that these are currently a barrier to the provision of contraception. We

[1] http://www.stuff.co.nz/national/health/8860716/New-contraception-slows-abortion-rates

are not aware of any members refusing to prescribe contraception to any women declining to have a STI check or cervical smear, though GPs may note in the patient record that the patient had declined this examination. We would support contraception being prescribed if required.

Nonetheless, when women are seen by their GP there is the opportunity to encourage women to get STI checks and cervical smears while they are at the surgery. Should the proposal go ahead there is therefore a potential for both a reduction in cervical screening rates and an increase in the rates of STIs.

Fragmentation of care

It is well known that the more providers that are involved in the care of an individual the more potential there is for error. When pharmacists supply contraception the patient's full record will not be available and some information relevant to contraception may be too sensitive to be appropriate for a shared record. This will result in reliance on patients' recall of their medical, family and contraceptive history. However, patients' recall is often incomplete and they may not always disclose everything that is relevant.

There is also a likelihood that women will attend a different pharmacy each time they need a new supply of the OCP with a corresponding disruption in continuity of care.

Conflicts of interest

Financial incentives have the potential to influence practice. Not only may it be in the pharmacists' interest to promote oral contraception over other methods but they may also have an incentive to supply the brand with the largest mark-up. The separation of prescribing and dispensing is a safeguard of best practice. Although this proposal concerns supply rather than 'prescribing, the incentives to promote what can be sold at a profit are similar. While promotion of contraception generally is highly desirable, the same does not apply to the promotion of a particular type of contraception over options that may be more suitable and effective.

Pharmacist supply of oral contraceptives in emergencies

The effectiveness of the oral contraceptive is reliant on it being taken regularly. Women who run out of pills are therefore at risk of unintended pregnancy. It is important that women are able to access a supply of medication as soon as possible, even if it is at the weekend or if they are away from home. In New Zealand, women are already able to purchase the pill from a pharmacy in such circumstances. Pharmacists are allowed to provide an emergency supply of up to 72 hours of medication. Reclassification is not required to allow emergency supply as is suggested in the submission for reclassification.

Comparison with the supply of the emergency contraceptive pill (ECP)

While the College supports the supply of the ECP by suitably trained pharmacists there are significant additional considerations involved in the supply of the oral contraceptive pill. It is important the ECP is taken within a few hours of unprotected intercourse, and having it available from pharmacists facilitates this. By comparison, the OCP is not effective immediately and additional methods such as condoms should be used until it is.

BP threshold

Feedback from members also suggested that a lower BP than the suggested 140/90 should lead to referral to the GP for women requesting Ethinylestradiol containing medicines.

Training and 'screening'

It is not possible to comment on the adequacy of the intended training or of the methods of identifying women with contraindications – termed screening in the submission document, as the information about these has been withheld as being commercially sensitive.

Other comments

Rather than moving to pharmacist supply of oral contraceptives it may be preferable to further develop the role of the practice nurse prescribing under standing orders but still within practices. Here the prescribing nurse would have ready access to past medical history and screening information, and would be able to document what was prescribed and the required follow up directly into the patient's notes, and the GP would be able to be involved when necessary.

Should, however, the proposal be supported we consider it important that pharmacist supply should first be piloted. Evaluation of this pilot would reveal how effective and practical pharmacist supply of the OCP would be in the New Zealand context.

We would also emphasise the need for the GP to be informed of the pharmacist consultation, including which contraceptive was supplied and whether the women was advised to see a doctor for further investigations, screening or follow up. Communication with the GP should be the norm and the women should not have to request this (opt in). Women who are hesitant should be reassured that the GP will keep this information confidential and in particular will not inform her parents. If the woman does not have a GP then this is an opportunity for her to be assisted to locate one.

We hope you find our comments helpful. If you would like any further information or clarification please do not hesitate to contact the College's policy team (policy@rnzcgp.org.nz).

Yours sincerely

Jeanette McKeogh
Group Manager Strategy and Standards

CoupleWork

Nic Beets & Verity Thom Relationship Psychology Sex Therapy

8 Crossfield Rd • Glendowie • Auck 1071 • Email info@couplework.co.nz • Fax (09) 575-5833 • Tel (09) 575-5798 •

25 March 2014

Laurence Holding
Medicines Classification Committee Secretariat,
Medsafe
PO Box 5013
Wellington 6145

Dear Laurence Holding,

We are again writing in support of Douglas Pharmaceuticals' application for the reclassification of sildenafil. Again, we were approached by the company for comment, and in the interim since we last wrote to your committee they have discussed our becoming involved in the design of training of pharmacists but to date we have done no work for them and are motivated to write out of our professional concerns around this issue. As previously stated we are relationship and sex therapists with 50 years of experience between us, who strongly support the reclassification to make it more accessible to the men who need it.

We will not reiterate points made in our previous letter of 26 July 2013, but wish to address concerns that were raised by by the committee in its rejection of the initial application for reclassification.

We strongly agree with the committee's concerns about the dangers of young men (in particular) over-using medication or using it unnecessarily when their problem is primarily psychological. This is exactly what is happening at so-called Men's Clinics (who advertise on radio stations such as The Edge, aimed squarely at an under 35 audience) and with the drugs bought over the internet. However we believe that making sildenafil available without prescription will lessen this risk, not increase it.

In our experience of talking with doctors about it, men rarely make an appointment to see the doctor about ED. Men seem to think the problem too trivial, from a medical point of view, to want to bother the doctor with it. So they either don't seek treatment at all or wait until they have a different problem that they need to see the doctor about and then tack it on to the end of the consultation (“door-knobbing” is how we have heard it referred to). This aligns with our experience that men don't want to see their erectile problems as a medical issue – they see it as a sexual, a personal and a relationship issue.

This is why we believe men will be willing to talk to their chemist more readily than their doctor. It is normal to talk to your pharmacist about awkward life problems, and get solutions for them in the chemist shop. We are all used to going to the chemist to buy things that are a bit embarrassing – from nit shampoo to haemorrhoid ointment and sexual things - from condoms and lube to the emergency contraceptive pill. This is a normal part of life. It would be very normalising for men and fit better with how they see their erectile

problems if asking for help with improving their sexual functioning could just be added to this list.

We certainly believe it is possible for pharmacists to be trained to screen for and deal with ED that has a purely psychological origin. It will only take a handful of screening questions regarding erectile functioning and their life circumstances (E.g. do they experience morning erections? Are the difficulties they are having recent or long-standing? Does their erectile functioning change across situations particularly partner sex vs solo sex? Are their stresses in their life and/or relationship that might be affecting, distracting or worrying them?).

Obviously it will depend on the comfort and skill of the pharmacist to determine how effective this screening is – but this is also true of doctors. At least the pharmacists will be choosing to opt-in to having to do this questioning. Our anecdotal experience suggests there are a number of doctors out there who are very uncomfortable talking about the psychological and relationship aspects of sexual functioning but they get no choice in the matter, so both they and their patients suffer.

In the discussions we have had with Douglas about training pharmacists we have talked about providing pharmacists with a written guide to asking these sorts of questions, plus video material that explains their importance and how to vary them for differing situations and presentations, and a further video with a role play modelling talking with different individuals with different presentations (e.g. different ages, different kinds of problems – notably physical vs psychological). We have also discussed the importance of cultural appropriateness in how sexual issues are raised with people.

Also looking at the issue of medicating a psychological issue, it must be noted that a brief course of a PDE5 inhibitor sometimes can be a useful adjunct to the effective treatment of ED with psychological origin (especially to deal with the secondary anxiety re erectile functioning that is laid over a primary cause such as relationship difficulties or work stress). Furthermore such a medical intervention can increase the likelihood of patients accepting a referral for psychological help. Rosen (2007)[1] puts it strongly: "...most men (and their partners) are more likely to accept a referral for psychological or couple counselling when it is combined with medical treatment of the disorder"

We have suggested, and Douglas has agreed to support, the establishment of a register of suitably qualified and trained psychological and counselling professionals who are experienced in talking about sexual matters to act as a referral list for pharmacists who asses that the patient's presentation is more requiring of psychological intervention. Nic is the coordinator of a well-established network of professionals with an interest in sex therapy with a membership distributed across NZ that could provide a basis for this.

Again, we would be happy to discuss these issues further, should that be required.

Yours sincerely

Nic Beets & Verity Thom
Clinical Psychologist Registered Psychologist

1 Rosen, R C (2007), Erectile Dysfunction; Integration of Medical and Psychological Approaches. Chapter 10 in Principles and Practice of Sex Therapy 4th Edition; Leiblum, SR (Ed).

UNIVERSITY of OTAGO

Te Whare Wānanga o Otāgo

NEW ZEALAND

28th March 2014

To the Members of the Medication Classification Committee

This letter is to reiterate my support for the reclassification of Sildenafil, subject to supply being from accredited pharmacists.

There are many reasons for this, but importantly, access to this medication is vitally important to patients with ED and given the safety profile of this medication, combined with the proposed substantial cardiovascular risk screening, patients will not only receive timely access to this medication, but potentially early CV risk detection.

I want to take this opportunity to inform the committee that the post-marketing surveillance aspect of this proposal has now been given conditional approval (pending the reclassification and Māori consultation). All men will be given an information sheet and consent form. The reference for this is the Human Ethics Committee H14/034, University of Otago.
As the committee will be aware my role in the proposed reclassification is to ensure that all training is of a robust, well informed nature and that patient focused care is paramount at all times.

The proposed research aspect will provide valuable information on real-life usage in a non-prescription setting with all data sent in - deidentified in the case of men who do not consent. In this way detailed information can be gained regarding multiple areas such as:

- who uses the product,
- what risk factors they have based on the screening,
- how long the problem has occurred for,
- how frequently they purchase it,
- is there ongoing use in certain age groups,
- reasons for referral,
- whether pharmacy sees men who have not discussed their ED with their doctor before or repeat users.

New Zealand's National School of Pharmacy
Te Kura Mātauraka Wai-whakaora
Adams Building, 18 Frederick Street, PO Box 56, Dunedin 9054, New Zealand
Tel +64 3 479 7275 • Fax +64 3 479 7034 • Email pharmacy@otago.ac.nz
www.otago.ac.nz/pharmacy

Additionally, this study has the potential to look for CV events in those patients that have consented.

If the committee has any questions, please contact me

[redacted]

Johnson & Johnson Pacific

507 Mount Wellington Highway
Mount Wellington, Auckland 1060
PO Box 62-185, Sylvia Park, Auckland 1644
Phone: (09) 523 8700

MCC Secretary
Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145
NEW ZEALAND

28 February 2014

Dear Sir/Madam,

RE: Comment on Oxymetazoline – proposed reclassification from pharmacy-only medicine to general sale medicine to be considered at the 51st Meeting of the Medicines Classification Committee (MCC) on 8 April 2014.

Johnson & Johnson (New Zealand) Limited welcomes the opportunity to provide comment on the proposed reclassification of Oxymetazoline from pharmacy-only medicine to general sale medicine as proposed by Pharmaceutical Solutions in consultation with the New Zealand Retailers Association.

Johnson & Johnson (New Zealand) is a manufacturer and marketer of a wide range of OTC medicines and consumer products which includes Sudafed® nasal decongestant sprays containing the active Oxymetazoline (as Oxymetazoline hydrochloride). These products have been marketed in New Zealand since 2010. The Australian business also currently markets these products.

We support the submission made by Pharmaceutical Solutions.

In addition we would like to provide the following comment concerning the proposed requirement to have a "child resistant cap" in addition to a "sealed container where the lid cannot be removed".

Given that these products are metered dose and pose minimal risk to children due to the ergonomics associated with actuation of the spray device, the TGA's Therapeutic Goods Order No. 80 *Child-Resistant Packaging Requirements for Medicines* includes an exemption that addresses this:

(g) a liquid preparation in spray presentation if:

- (i) the delivery device is engaged into the container in such a way that prevents it from being removed; and
- (ii) direct suction through the delivery device results in delivery of no more than one dosage unit; and
- (iii) actuation of the spray device is ergonomically difficult for young children to accomplish.

If the Committee believes that there needs to be more protection than a "sealed container where the lid cannot be removed" then the TGA's approach to spray presentations may be an effective solution that addresses the Committee's concerns.

Again, we thank you for the opportunity to provide comment on the proposed reclassification of Oxymetazoline and we support the submission made by Pharmaceutical Solutions to change the classification from pharmacy-only medicine to general sale medicine.

Regards,

[redacted]

[redacted]

[redacted]

March 17, 2014

Dear Sir or Madam

I would like to make a submission regarding one of the agenda items to be considered during the 51st meeting of the Medicines Classification Committee (item 6.1 oral contraceptives)

I am giving my feedback as a GP of 25 years, with a special interest in sexual assault and family violence.

I feel that it would inappropriate for pharmacists to be prescribing the oral contraceptive pill to women between the ages of 16 and 39 years.

1. The choice and suitability of contraception is dependant on several factors, which vary between patients. An evaluation of these factors involves medical knowledge, informed discussion with the patient, and an ability to advise based on a variety of parameters. Some of this discussion include such things as number of sexual partners, likelihood of STIs, evaluation of risk of partner violence, family history (& an ability to unravel bits & pieces of patient knowledge regarding the latter) and ability to further investigate if necessary.

2. A general practice consultation to discuss and prescribe contraception provides an opportunity to explore other health issues, particularly for young people, whom we know do not necessarily spontaneously raise concerns around mood, sexual health issues or risk taking behaviour. These evaluations are more appropriately performed within a traditional health consultation, by someone with particular skills in this area of healthcare.

3. Similarly, a consultation to discuss and prescribe contraception provides an opportunity to explore other health issues for women in their late 20s and 30s. Again mood and risk-taking, as well as relationship issues are commonly discussed during consultations ostensibly about contraception. Often decisions about method of contraception are re-visited at this stage of life and choices may change.

4. Consultations about contraception allow review of "well woman" parameters such as blood pressure, smoking, alcohol and drug use as well as review of cervical screening results. In our practice, a recent audit identified young women in their late 20s & early 30s as the group who are most likely to be missing out their smears. Hence, the opportunity to improve uptake in this group relies on the ability to offer screening at other consultations, such as when they attend for contraception. It would be a disaster to lose this opportunity.

Yours sincerely

pharmacycouncil
OF NEW ZEALAND
Te Pou Whakamana Kaimatu o Aotearoa

File ref: P10

17 March 2014

Andrea Kerridge
Secretary, Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145

Email: committees@moh.govt.nz

Dear Andrea

Pharmacy Council comment on MCC 51st meeting agenda items

The Pharmacy Council of New Zealand was established under the Health Practitioners Competence Assurance Act 2003 (HPCAA) and has a duty to protect the public and promote good pharmacist practice. The Pharmacy Council is responsible for the registration of pharmacists, the setting of standards for pharmacists' education, scopes of practice and conduct. The Pharmacy Council's vision is *Safe Effective Pharmacy Practice*.

6.1 Oral contraceptives

Thank you for the opportunity to comment on the submission by Pharmacybrands Limited for the reclassification of selected oral contraceptives from prescription medicine to restricted medicine; when supplied for oral contraception by a pharmacist accredited to supply oral contraception, in accordance with the approved protocol for supply.

The Pharmacy Council makes the following comments:

a) The Pharmacy Council agrees that, with appropriate training, on-going professional development and monitoring, pharmacists ought to be able to offer pharmacist-only supplies of progestogen-only and second generation oral contraceptives.

b) While the submission makes reference to the Council's Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic Conditions (POMCC) this was not originally intended to apply to consultation and supply of oral contraceptives. However, Council agrees that the requirements proposed for the supply of these medicines is appropriate.

c) Council notes that the Executive Summary indicates that pharmacists must become accredited and comply with approved guidelines. The terms 'accreditation' and approved' training appear to be interchangeable within the submission document. There is a need for an approved programme capable of certifying pharmacists to provide the service. It is not clear who will approve this training, set standards, maintain records, and audit consultations. It needs to be established how approval or certification of a pharmacist to supply oral contraceptives will be granted, monitored and, if necessary, revoked. Council staff will meet with representatives from the MCC this month to find a solution to these issues as they relate to medicine reclassification.

PO Box 25137, Wellington 6146
Ph: +64 4 495 0330 Fax: +64 4 495 0331
enquiries@pharmacycouncil.org.nz
www.pharmacycouncil.org.nz

d) Council agrees that audit of initial consultations as part of their training is appropriate. Recording the supply of oral contraceptives electronically would provide a mechanism for routine reporting and enable a high level audit of the outcomes of oral contraceptive supply by pharmacists.

e) Appendix 7 *Safeguards for Supply* states that ongoing accreditation will be dependent on the pharmacist completing a short on-line refresher every two years; having provided their consultation documents for auditing as required. The Council expects that pharmacists offering oral contraceptive supply would acknowledge the importance of, and fully participate in, continuing professional development in this area. An agreed recording mechanism for pharmacists who complete training and refreshers would enable the Council to confirm whether pharmacists have undertaken appropriate training as part of their CPD.

c) The submission outlines the need for pharmacists to measure blood pressure at each consultation and comments that many community pharmacies in New Zealand already offer blood pressure checks. Council considers that that the training proposed should include interpretation of blood pressure readings for the purpose and that equipment used is suitably calibrated.

Council believes the issues above need to be resolved before it can give full support to this application for reclassification and trusts these comments have been helpful.

Yours sincerely

Claire Paget-Hay
Chief Executive and Registrar

PO Box 25137, Wellington 6146
Ph: +64 4 495 0330 Fax: +64 4 495 0331
enquiries@pharmacycouncil.org.nz
www.pharmacycouncil.org.nz

Regarding making oc’s available OTC from the chemists: totally stupid idea. Chemists are going to check the BP, wt, discuss the patient’s sexual history, menstrual history, general medical and family history, the pros and cons of various methods of contraception and then which OC would be right for the patient if at all the OC is right for her?? In privacy and with the knowledge and clinical/communicative skills required?? And sort out whether a smear or STD examination is required??

Yeah, right.

Ron Baker, MD

Medicines Classification Committee
Name of the meeting = 51st
agenda item = 6.1 Oral contraceptive

Subject: Proposed supply of OCs by pharmacists

[1] I believe that this is a further **fragmentation of primary care** and added to the expansion of Pharmacies into warfarin monitoring, cholesterol (not lipid profile) testing, 'flu vaccinations and dispensing antibiotics such as chloramphenicol and trimethoprim which have created more frustration for many General Practitioners (GPs) than it has helped (the primary argument for the changes). Will the Committee recommend that GPs can claim dispensing fees and Pharmac refunds for drugs we purchase directly to by-pass the pharmacies?
To quote Dr Tim Malloy (President of the RNZCGP): "We look forward to working with pharmacists to ensure there is an appropriate level of collaboration and co-ordination in order to avoid the inefficiencies, safety risks and poor quality care that can result from FRAGMENTATION". Our current relationship with pharmacists is one of co-operation and a good "back stop" for any unintended errors. Direct supply by pharmacists removes this check (who checks the pharmacist?), undermines their relationship with the medical profession and totally removes GP input from the patient's care.

[2] The second concern here is the lack of evidence based support pharmacists have shown over "pushing" expensive supplements, pro-biotics and unproven arthritis medicines without revealing that these products do not have scientific support for their use, primarily because they provide "added value" to the business. This clear lack of **ethical integrity** becomes very worrying when dealing with contraception.

[3] The most important reason why the medical profession should resist this move [direct pharmacy supply of O/Cs] is that supplying oral contraceptives "over the counter" largely **excludes the ability of the practitioner to adequately check this is safe and will be used appropriately**. Despite attending an "approved training course" a pharmacist does not have the medical training and understanding to adequately look at all the other aspects any competent GP would. This includes STI prevention, co-morbidities and risks (such as smoking), social, psychological and psychiatric aspects of sexuality etc. While our local pharmacy has a "side room" for consultations, it is open for all to see and not appropriate for doing examinations (even if this was in the pharmacist's scope of practice!) and even so, I have not seen this used (mostly people are being asked personal questions in public), so it is doubtful if appropriate advice and care can be provided in this environment.

[4] Furthermore, our experience with pharmacists and interactions is that if the computer indicates a potential interaction, the pharmacist puts out a blanket restriction (such as grapefruit), without even considering if the interaction is significant or even beneficial. The rise in pregnancies in those warned about antibiotics interacting with the oral contraceptive (compared to no significant rise when specifically not warned) is a clear example of how unthinking "rule following" can have adverse outcomes. We get the same in pregnancy when pharmacists refuse a smoking woman NRT when the NRT is far less dangerous than continuing smoking.

In Thailand, the appearance of resistance to a new antibiotic is measured in months primarily because there are no restrictions on dispensing and so indications and appropriate courses are often ignored because of financial considerations. In New Zealand we had the Bactroban resistance problem when this was OTC so we know that pharmacists do not adequately inform patients about appropriate use of topical antibiotics.

Basically it is the same argument with nurse prescribing, **doing things by rote or protocol without understanding underlying dynamics** (not just pharmacological) may be OK sometimes but can often lead to bad outcomes, usually avoided in General Practice.

Alternative option:

It might be better to look at extending oral contraception to **yearly prescribing** with the "best practice" expectation that a thorough medical review of risks and general health (including family planning) is

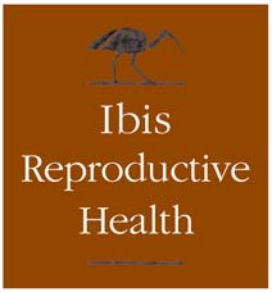
provided by the GP (or Family Planning Clinic) instead of a prescription only "consultation" or a Practice Nurse consultation.

Final Thought:

At the end of the day it is the GP who is responsible for ensuring excellent care is provided for their patients which we do either directly or by delegation to an appropriate provider. Having patients directly **accessing medications from all and sundry is not good medicine**, hard to justify to the Health and Disability Commissioner and in fact I believe this whole concept of what is good for General Practice in New Zealand needs review (and decided by Vocationally Registered GPs alone). If further fragmentation occurs, GPs will feel even **less valued** which is the **major disincentive to enter or stay in General Practice** in New Zealand (not what HWNZ wants!), and is likely to drive up consultation fees in those General Practices that remain as we see more difficult cases ("swings and roundabouts" principle).

Regards,

Dr Keith Blayney



March 26, 2014

Medicines Classification Committee
Medsafe
PO Box 5013
Wellington 6145
New Zealand

Dear Committee Members,

I am writing this letter in support of the reclassification application submitted by PharmacyBrands and Pharma Projects for several formulations of combined and progestin-only oral contraceptives. I am an obstetrician-gynecologist and researcher based in the United States, and I have conducted several studies exploring the safety and effectiveness of over-the-counter access to oral contraceptives, as well as women's interest in accessing this contraceptive method without a prescription. There is a growing body of evidence indicating that women can safely use oral contraceptives obtained without a prescription, and this model of pharmacy provision has also been studied in Washington State.[1] In addition, women want to access contraception without visiting a physician,[2] and studies suggest that uptake and continuation of effective birth control would improve if the prescription requirement were removed.[3] I believe the model proposed under this reclassification application would be safe and would offer more options for women seeking to avoid unintended pregnancy.

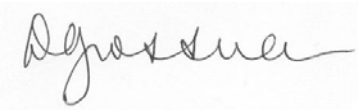
Our research has identified several concerns that both physicians and the general public raise when considering removing the prescription requirement. One is that women will avoid getting recommended preventive screening for cervical cancer or sexually transmitted infections (STIs). Our research of U.S. women obtaining oral contraceptives over the counter in Mexican pharmacies found that a high proportion—over 90%--reported having cervical cancer screening within the prior three years.[4] This figure is above the U.S. national average, and we found similar results for STI screening.

Another concern is that removing the prescription requirement will result in a lost opportunity to counsel about long-acting reversible contraceptive (LARC) methods, such as the IUD and implant. First, I understand that the protocol will include referrals to physician care for routine preventive screening, so women should continue to have contact with a clinical site. Just because a woman starts the pill does not mean she cannot switch later to the IUD. Second, at least in the U.S., while we would like to believe that every physician—or even every family planning provider—counsels women about LARC methods, we know that is not the case. And finally, we have evidence that pharmacists can successfully refer interested women to obtain LARC methods, although few who present to a pharmacy seeking pills are interested in LARC.[5]

In addition to Washington State, California recently passed legislation that will allow pharmacists to prescribe hormonal contraception, as well as well as nicotine replacement products and prescription medications not requiring a diagnosis that are recommended for international travelers. While a few other countries, such as South Africa, Tanzania and Vietnam allow at least some formulations of oral contraceptives to be provided by pharmacists who perform necessary medical screening,[6] New Zealand would be the first high-income country to implement this model nationwide. The experience of New Zealand could serve as a model for other countries to learn from as they work toward addressing the problem of unintended pregnancy.

I would be very happy to answer any questions related to my research on this topic. Please let me know if you would like to schedule a time to talk by phone.

Sincerely,



Daniel Grossman, M.D., F.A.C.O.G.
Vice President for Research, Ibis Reproductive Health
Assistant Clinical Professor, University of California, San Francisco

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[1] Gardner JS, Miller L, Downing DF, Le S, Blough D, Shotorbani S. Pharmacist prescribing of hormonal contraceptives: results of the Direct Access study. J Am Pharm Assoc (2003) 2008;48(2):212-21; 5 p following 221.
[2] Grossman D, Grindlay K, Li R, Potter JE, Trussell J, Blanchard K. Interest in over-the-counter access to oral contraceptives among women in the United States. Contraception 2013;88(4):544-52.
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[4] Hopkins K, Grossman D, White K, Amastae J, Potter JE. Reproductive health preventive screening among clinic vs. over-the-counter oral contraceptive users. Contraception 2012;86(4):376-82.
[5] Parsons J, Adams C, Aziz N, Holmes J, Jawad R, Whittlesea C. Evaluation of a community pharmacy delivered oral contraception service. J Fam Plann Reprod Health Care 2013;39(2):97-101.
[6] Grindlay K, Burns B, Grossman D. Prescription requirements and over-the-counter access to oral contraceptives: A global review. Contraception 2013;88(1):91-6.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Excellence in Women's Health

New Zealand Committee
Level 6, Featherston Tower
23 Waring Taylor Street
Wellington 6011

PO Box 10611, The Terrace
WELLINGTON 6143
Telephone: +64 4 472 4608
Facsimile: +64 4 472 4609
Email: ranzcog@ranzcog.org.nz

27 March 2014

Dr Stewart Jessamine
Chair, Medicines Classification Committee
Medsafe
Ministry of Health
Po Box 5013
Wellington 6011

Dear Dr Jessamine

I write on behalf of the New Zealand Committee of RANZCOG in support of the submissions for reclassification of four oral contraceptives listed under Item 6.1 on your agenda for the 51st meeting to be held 8 April 2014.

We are strongly in support of any responsible development designed to improve access to quality contraceptive advice and service. We 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.

In this case, we 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 listed at Item 6.1 on your agenda.

We 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

National Office
Level 6
203 - 209 Willis Street
PO Box 11-515
WELLINGTON 6142

T: (04) 384 4349
F: (04) 382 8356
familyplanning.org.nz

Charities # CC11104

26 March 2014

Laurence Holding
Advisor Science (Secretariat for MAAC and MCC)
Committee and Support Services
Product Regulation
Medsafe
Ministry of Health
Wellington

1. Thank you for the opportunity to comment on the proposed move to pharmacist supply of selected oral contraceptives.
2. Family Planning is a registered charity which provides high-quality sexual and reproductive health services for all New Zealanders. We run clinics and health promotion activities across New Zealand, and provide training for clinicians, teachers, parents, and public health and community workers. Family Planning is the country's largest provider of sexual and reproductive health services.

Recommendations

1. Allow more primary care nurses to prescribe contraception by reviewing the protocols for nurse prescribing through the Nursing Council.

2. Assess the proposed move to pharmacist supply of oral contraception for its potential effects on health equity and reducing disparities.

3. Ensure high-quality training of non-medical providers of oral contraception, especially in the assessment of risks to women's health, teaching how to take pills correctly, and training in sensitive treatment of women seeking contraception.

4. If the proposed change occurs, we recommend:

- the use of Collaborative Practice Agreements (where a pharmacist works with a doctor who audits their practice)
- the training programme is at least 2 days duration, and
- pharmacists should first supply continuing combined pills only, and progress to the supply of initial combined pills once assessed as competent.

General Comments

1. ***Compared with pharmacists, Family Planning nurses are already trained and well-placed to prescribe contraceptive pills.*** We are disheartened by the unacceptable delays in extending nurse prescribing rights. The Government's recent response to the Health Select Committee report[1] indicates support for nurse prescribing but gives an overly long timeframe of two years.

   A rapid way to improve access to contraception would be to immediately review the protocols for nurse prescribing through the Nursing Council to allow more primary care nurses to prescribe contraception.

[1] Government Response to Report of the Health Committee on Inquiry into improving child health outcomes and preventing child abuse with a focus on preconception until three years of age, released 6 March 2014.

2. ***The proposed move to pharmacist supply of oral contraception is unlikely to reduce costs for contraceptive users.*** There is a need for research into the population groups that currently access the ECP directly from pharmacies. We expect that many motivated women who can afford to pay for their contraceptive pills will use the proposed pharmacist-supplied contraceptive service. In contrast, the priority groups for greater contraceptive access include: young people and marginalised groups including Māori, Pacific, people with multiple problems and those at high risk of STIs.

   Having said this, the proposal may improve access for some women living in rural and isolated communities, e.g. those who lack access to Family Planning clinics and are reliant on other primary health care services. Pharmacies also have potential to help increase youth access to health care by becoming more 'youth-friendly', e.g. consulting with young people and displaying youth health information.[2]

3. ***The proposed move should be assessed for its potential effects on health equity.*** More information is needed on how the proposal could affect disparities, e.g. ethnic and socioeconomic inequalities in health status. A formal assessment tool, such as the HEAT tool (developed by University of Otago researchers for the Ministry of Health[3]) could be used to assess the likely effects on health equity and disparities.

4. ***The proposed move does not encourage uptake of long-acting reversible contraception.*** Internationally and in New Zealand, long-acting reversible contraception (LARC) is increasingly encouraged (within a full informed consent discussion with women). This is because it is much more effective in practice than contraceptive pill use.[4]

   The literature suggests that women who have gone to a pharmacy and are referred for a LARC often fail to access the referred provider and therefore miss the opportunity to receive effective longer-term contraception (e.g. Southwark and Lambeth study referred to on page 36 of the submission). It is preferable that women initially access a provider who can provide a full range of services including LARCs.

Importance of training

5. Family Planning believes that well-trained non-medical staff can safely provide oral contraceptives. However, safe provision requires high-quality training in three vital areas:

   a) ***Accurate assessment of high-risk women*** to ensure they do not receive oral contraception when they are at high risk of complications

   b) ***Accurate teaching of pill-taking*** so that women use the packets correctly and know what to do if they forget pills

   c) ***Training in the need for sensitive, non-judgemental treatment of women seeking contraception.***

   Assessment of risk
   Combined oral contraceptives (COC) have a small risk of serious – and potentially fatal – complications. Pharmacists would need to be adequately trained to assess and recognise the key risk factors. Clear instruction in how to use the combined pill effectively is also important.

   In contrast, the progestogen-only pills (POP) have simple pill-taking rules and no risk of serious complications (a similar risk to the ECP which is already available in pharmacies).

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[2] Horsfield, E., Kelly, F., Clark, T., & Sheridan, J. (2014). How youth-friendly are pharmacies in New Zealand? Surveying aspects of accessibility and the pharmacy environment using a youth participatory approach. Retrieved March 26, 2014, from http://www.unboundmedicine.com/medline/citation/23981912/How_youth_friendly_are_pharmacies_in_New_Zealand_Surveying_aspects_of_accessibility_and_the_pharmacy_environment_using_a_youth_participatory_approach_

[3] http://www.health.govt.nz/publication/health-equity-assessment-tool-users-guide

[4] Winner B., Peipert, JF., Zhao Q., Buckel, C., Madden, T., Allsworth JE and Secura G. (2012). Effectiveness of Long-acting Reversible Contraception. *The New England Journal of Medicine* 2012;366:1998-2007.

Family Planning's experience is that it is common for even well-trained health professionals to find it difficult to ascertain if migraines, for example, are the type that contraindicate a COC. This is contrary to the view expressed in the submission that women recognise their contraindications more often than their health professional.

It is important to assess a range of risk factors in assessing suitability for COC because individual factors can combine to pose an unacceptable risk. For example, simple migraine and smoking are two risk factors which on their own do not contraindicate COC, but together they are contraindications for COC.

Need for sensitive and non-judgemental approach

It is essential that the contraceptive provider is sensitive to the needs of a woman seeking contraception, and is non-judgemental in their approach. This topic must be part of the training programme. It is important for contraceptive providers to promote two-way communication and to understand the needs of women, especially those with poor health literacy skills.

Family violence screening is now routinely practised in Family Planning and most primary health care practices in New Zealand. As this has not been an issue that pharmacists have been involved in, women who see a pharmacist for oral contraception are likely to miss out on this screening and intervention. It is also vital to have good referral mechanisms and procedures for disclosures of sexual coercion and violence.

More broadly, a limitation of pharmacist-supply of oral contraceptives is the missed opportunity for opportunistic screening for a range of other health issues such as STIs, cervical smears, smoking cessation advice, alcohol advice, and discussion about general well-being.

Importance of Collaborative Practice Agreements

6. ***Family Planning supports the use of Collaborative Practice Agreements***. The submission for the proposal mentions that many international pharmacist-supply programmes for oral contraception involve collaborative practice agreements where the pharmacist works with a doctor. It is not clear in the submission document that this is envisaged for New Zealand. We would see a timely initial audit by a doctor, as discussed on page 30, as an essential part of any training programme.

Staged provision

7. If the proposed pharmacist supply of selected oral contraceptives is to go ahead, Family Planning recommends a ***training programme lasting at least 2 days*** followed by ***staged provision*** as suggested below. Family Planning has trained our nurses in a similar programme which works well.

   Recommended staged approach:
   - the pharmacist would provide oral contraception only for those women continuing to take combined contraceptive pills (i.e. not initial supply of pills)
   - a doctor would audit each provision within 5 days for at least the first 20 occasions
   - the pharmacist should then be assessed to ensure they are ready to progress to initial supply of the combined pill.

Thank you for the opportunity to contribute to this decision.

Kind regards

Jackie Edmond
Chief Executive

27 March 2014

Medsafe
PO Box 5013
WELLINGTON 6145

Tēnā koe

51st meeting of the Medicines Classification Committee

The New Zealand Nurses Organisation (NZNO) welcomes the opportunity to comment on the proposed move to pharmacist supply of selected oral contraceptives. NZNO is the leading professional nursing association and union for nurses in Aotearoa New Zealand, representing over 46,000 members, including nurses, midwives, students and allied health workers.

NZNO supports an expanded framework for prescribing and we draw your attention to our position statement on independent nurse prescribing. NZNO proudly acknowledges the experience, expertise and leadership that Family Planning New Zealand (FPNZ) consistently demonstrates in its provision of contraceptive services, and in training nurses and doctors in this field.

Having consulted with members and staff, in particular members of the College of Primary Health Care Nurses and Women's Health Section, and professional nursing advisers, NZNO offers its strong support of FPNZ's submission and recommendations to the Committee to:

- allow more primary care nurses to prescribe contraception by reviewing the protocols for nurse prescribing through the Nursing Council;
- assess the proposed move to pharmacist supply of oral contraception for its potential effects on health equity and reducing disparities;
- ensure high-quality training of non-medical providers of oral contraception, especially in the assessment of risks to women's health, teaching how to take pills correctly, and training in sensitive treatment of women seeking contraception.

Should the proposal go ahead we support FPNZ's recommendations that pharmacists:

- have Collaborative Practice Agreements i.e. work with a doctor who will audit their practice;
- complete a training programme of at least 2 days duration; and
- have a staged approach i.e. the pharmacist would provide oral contraception only for those women continuing to take combined contraceptive pills (i.e. not initial supply of pills); a doctor would audit each provision within 5 days for at least the first 20

occasions; and the pharmacist should then be assessed to ensure they are ready to progress to initial supply of the combined pill.

NZNO agrees the proposal may improve access for some women living in rural and isolated communities, and may help increase youth access to health care, though cost is likely to remain a barrier for this group. Ongoing monitoring and evaluation of outcomes should occur throughout the implementation, particularly in respect of its impact on uptake of long-acting reversible contraception, which has been found to be more effective in practice than the contraceptive pill[1].

Nāku noa, nā

Marilyn Head
Senior Policy Analyst
[redacted]

REFERENCE

[1]Winner B., Peipert, JF., Zhao Q., Buckel, C., Madden, T., Allsworth JE and Secura G. (2012). Effectiveness of Long-acting Reversible Contraception. *The New England Journal of Medicine* 2012;366:1998-2007.

MEDSAFE -: 51ST Meeting of the Medicines Classification Committee 8th April 2014 Wellington NZ

Response regarding proposal to reclassify prescription products Desogestrel, Levonorgestrel, Norethisterone and Ethinyloestradiol <35 micrograms in the oral contraceptive pill (OCP) to restricted medicines available for sale over the counter at pharmacies and dispensed by trained pharmacists

Dear Sir/Madam,

This letter is in response to the request for Medicines Classification Committee review of a proposal to reclassify the above oral contraceptive medicines from prescription to restricted medicinal products[1]. We would like to raise some points regarding the above proposal which in our view are important to a positive benefit-risk profile of OCs in general.

While we do not disregard the important and critical role of the pharmacist in contraceptive counselling and even suggest widening of access to contraceptives be achieved through continued dispensing arrangements (as in Australia)[2], we would like to highlight a few points for consideration. We will discuss combined oral contraceptives (COCs) and progesterone only pills (POPs) separately as we believe they require distinct aspects to be counselled for to ensure safe and effective use.

We will also discuss the implication for a Rx to OTC switch in New Zealand in creating a disconnect ahead of harmonisation activities as we transition to an Australia New Zealand Therapeutic Products Agency (ANZTPA).

<u>COC as a class</u>

Although the applicant to "Reclassify Oral Contraceptives NZ January 2014", argue that OCPs (and amongst them, certain COC formulations) are among the safest medications in the world, they are associated with rare, but serious side effects. With regards to the risk of VTE and ATE that is associated with the whole class of COCs, it is the overall risk increase with use of a COC compared to no-use which should drive the individual benefit-risk assessment. There is an ongoing scientific debate about differences in VTE risk between COC formulations depending on their progestin component.

The available evidence is conflicting, with some studies finding no difference between the progestins regarding risk for VTE[3,4,5] while others have highlighted an increased risk[6,7,8] It is

[1] Application to Reclassify Oral Contraceptives NZ January 2014

[2] Continued Dispensing of PBS Medicines in Defined Circumstances (continued dispensing) initiative - Australian Government September 2013- Department of Human Services/ Medicare Available at www.medicareaustralia.gov.au/provider/pbs/fifth-agreement/medication-continuance.jsp

[3] Dinger JC et al. The safety of a drospirenone-containing oral contraceptive: final results from the EURAS on OCs. Contraception 2007;75:344-354

[4]Seeger JD et al. Risk of thromboembolism in women taking EE/DRSP and other oral contraceptives. Obstet Gynecol 2007; 110:587-593

studies with a methodology that is less susceptible to bias and confounding which have consistently shown no difference between progestins. It remains conceivable that a differential risk observed in case control studies and data base linkage studies has been to a certain extent the result of bias and confounding[9]. The SOGC states that "Women using COCs should be advised that the highest quality evidence available at this time does not suggest a difference in VTE risk based on the type of progestin in the COC"[10].

The choice of COC formulations that are proposed to be made available in pharmacies in NZ is restricted to LNG-containing and NET-containing formulations based on the consideration of the authors that these formulations are safer in terms of VTE risk. While they quote a meta-analysis by Stegemann to show a 1.3 fold risk increase with so-called 3rd/4th generation formulations over so-called 2nd generation formulations, more consideration should be given to the fact that it is the 2-3 fold overall risk increase with CHCs as a class which is well recognized and most important for an individual patient´s risk. We are concerned that making only a selective choice of COCs available in pharmacies would result in a public misconception of false security with these products. Awareness of the risk of VTE and ATE with this class of products is key to ensuring early recognition and appropriate treatment of thromboembolic events.

Thorough and comprehensive evaluation of the individual risk profile of a woman is one of the most essential elements in rendering CHCs safe to use. The company core data sheet (CCDS) for all Bayer COCs as well as the current update of the EU SmPC highlight that not only single risk factors may change the benefit-risk balance in an individual woman, but that there are also factors which may cumulatively enhance a woman´s risk. The WHO-MEC and UK MEC for contraceptive prescribing refers to an extensive list of contra-indications and precautions[11] . A pharmacist would have to be appropriately trained in how to evaluate and assess a woman´s individual risk factors and would have to be prepared to re-assess the risk profile regularly in order to maintain a positive benefit-risk profile for the use of any CHC.

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[5] Dinger Jurgen, Bardenheuer Kristina, Heinemann Klaas,Cardiovascular and general safety of a 24-day regimen of drospirenone-containing combined oral contraceptives: Final results from the internationactive surveillance study of women taking oral contraceptives, *Contraception* (2014) Article in Press (Article in Press Published Online 6th February 2014)

[6] Lidegaard Ø, Løkkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. BMJ 2009; 339: b2890

[7] Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data. BMJ 2011;342:d2151.

[8] Parkin L, Sharples K, Hernandez RK, Jick SS. Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: nested casecontrol study based on UK General Practice Research Database. BMJ 2011;342:d2139.

[9] Shapiro S, Dinger J. Risk of venous thromboembolism among users of oral contraceptives :a review of two recently published studies. J Fam Plann Reprod Health Care 2010; 36: 33–8.

[10] SOGC 19th February 2013 Position Statement Hormonal Contraception and risk of Venous Thromboembolism Available at http://sogc.org/media_updates/position-statement-hormonal-contraception-and-risk-of-venous-thromboembolism-vte/

[11] U.K Medical Eligibility Criteria for Contraceptive Use U.K MEC 2009 Faculty of Sexual and Reproductive Health Care Royal College of Obstetricians and Gynaecologists and WHO 2009 Medical Eligibility Criteria for Contraceptive Use Fourth Edition Department of Reproductive Health.

POPs as a class

The authors have proposed that the POP should also be available over the counter. With this type of hormonal contraceptive counselling on effective use is key for the benefit-risk profile of the products. The progesterone only pill is associated with less tolerance for delays in pill intake than COCs and even 1 missed pill might jeopardize reliable contraception, increasing the importance of missed pill advice for the patient[12].

GENERAL CONSIDERATIONS

From our point of view counselling is key for a positive benefit-risk balance for COCs as well as POPs. There are important elements that determine a successful counselling process. The setting within which patient consultation occurs is critical as many patients view a contraceptive discussion as extremely sensitive. This should include adequate privacy in a face-to-face setting. The HCP should engage in the discussion on contraceptive choice with background medical knowledge about the patient and with the capacity to discuss a full range of contraceptive options. A detailed history may need to be taken to ensure patients are not contraindicated to a particular contraceptive choice. Clinical judgement and skill must be employed to ensure the appropriate risk/benefit decision when a patient has a relative contraindication. Any HCP embarking on this complex counselling process needs to be appropriately trained. While we in principal agree to the necessity to provide easy access to reliable contraception a safe level of patient evaluation and guidance on proper use needs to be maintained. The continued dispensing arrangements as they are already implemented in Australia allow pharmacists to supply oral contraceptives when there is an immediate need for the medicine and the consumer cannot access a prescriber. This provision might allow to close a substantial gap in accessibility in New Zealand by giving the consumer greater access to the product if they cannot reach a doctor and thereby improving adherence and continuity of contraceptive protection.

Possible Public Health Benefits of the Contraceptive Consultation

The contraceptive consultation may allow opportunistic screening for breast and cervical cancer as well as the opportunity when discussing contraceptive methods to discuss barrier contraception and Sexually Transmitted Infection (STI) risk. It may also allow the primary care provider the ability to counsel the patient and promote behaviours to decrease infection risk[13]. With such high rates of chlamydia in western countries, opportunistic screening opportunities could provide enormous public health benefit. Indeed, Rose and colleagues in

[12] Chi I 1993 The Safety and Efficacy of progestin only oral contraception –an epidemiologic perspective Contraception 47(1) 1-21

[13] Petersen R et al Contaception 2004:69 213-217

their research with young New Zealanders highlighted the preference of young people for routinely offered opportunistic chlamydia screening when visiting the doctor for other reasons[14].

ANZTPA

TGA and Medsafe are currently undertaking harmonisation work over the next two and half years to transition to a joint agency, ANZTPA.

Reclassification of the OCPs to OTC in New Zealand will create disconnect between the OCPs classifications between the two countries in the lead up to ANZTPA. While post-marketing safety of OCPs continue to be monitored, as VTE and ATE risks remain a concern for health authorities, healthcare providers and users. It is unclear whether ANTZPA would adopt a harmonised OTC classification of the OCPs without further evaluation of supporting data.

Therefore, no change to the current prescription medicine classification should be considered until commencement of ANZTPA.

[14] Rose S, Camille Smith M, Lawton B 2008 If everyone does it, it's not a big deal –Young people talk about chlamydia testing *NZMJ* 121 1271:33-42

MSD
Merck Sharp & Dohme (New Zealand) Limited
Level 3 109 Carlton Gore Road
Newmarket, Auckland 1023
PO Box 99-851 Newmarket Auckland 1149
T 09 523-6000
F 09 523-6001
msd.co.nz

24 March 2014

The Secretary
Medicines Classification Committee
Medsafe

Via email: committees@moh.govt.nz

To whom it may concern,

Submission for Reclassification of Selected Oral Contraceptives

We note that the agenda for the 51st meeting of the Medicines Classification Committee meeting includes at item 6.1.1 reclassification of the oral contraceptive desogestrel from prescription medicine to restricted medicine. MSD is the Sponsor of a number of desogestrel containing oral contraceptives, however the application in question relates to the progesterone only product marketed in New Zealand under the brand name CERAZETTE.

Having considered the application that is available for download from the Medsafe website and consulted with the applicant, this letter serves to support the application by way of providing further information that may be of interest to the Committee. The information provided below is by no means exhaustive of all publications on the respective subjects since the marketing approval of Cerezette in 1999 however we consider that they provide an appropriate reflection of the overall evidential picture.

Risk of Venous Thromboembolism in desogestrel-only contraception

An increased risk of VTE has been reported in combined oral contraceptives that contain a third generation progestin, including those that contain desogestrel.

Three papers published in 2012 have included an analysis of the VTE risk in progestin only contraceptives:

Rott (Curr Opin Obstet Gynecol 2012, 24:235–240) found in a review titled “thrombotic risks of oral contraceptives” that in patients with a history of VTE and/or a known thrombophilic defect combined oral contraceptives are contraindicated, but progestogen-only contraceptives can be safely used in this patient group.

Blanco-Molina (Thrombosis Research 129 (2012) e257–e262) published a review entitled “Progestin-only contraception and venous thromboembolism”. The review concluded that progestins, in general, do not induce adverse changes in haemostasis factors and that progestin-only preparations may be a good alternative for contraception in women in whom oestrogen use is contraindicated.

Mantha (BMJ 2012;345:e4944) conducted a meta-analysis assessing the VTE risks of progestin-only contraception, including desogestrel only contraception. The analysis, of eight observational studies, found that the use of progestin-only contraception was not associated with an increased risk of VTE compared with non-users of hormonal contraception.

We attach to this letter a copy of each of the above mentioned publications.

The effects on bone

There is little evidence available that specifically addresses the effect of desogestrel on bone mineral density. Etonogestrel (the active metabolite of desogestrel) is the active ingredient in IMPLANON and IMPLANON NXT which has been studied. While routes of administration between oral ingestion and implants clearly are different and with that the pharmacokinetics profile of etonogestrel, the below data may provide some view to the effect of etonogestrel on BMD.

The Product Information for IMPLANON NXT references Beerthuizen et al (2000) who carried out a two year study of 73 women to examine the effect of the etonogestrel implant vs copper (non-hormonal) IUD use on bone mineral density parameters. Forty four women received an etonogestrel implant and 33 received an IUD. The changes in bone mineral density parameters were not different from the comparator IUD group and the mean bone mineral density parameters at several sites of the body were generally higher than those reported for a standard reference population. The product information further states that oestradiol levels were above the threshold for maintaining normal bone mass. Other studies of IMPLANON on BMD have been conducted, largely consistent with the results from the Beerthuizen study.

We attach to this letter a copy of the paper by Beerhuizen as well as those by Bahamondes and Pongsatha who built on this work.

In Summary

We hope that the attached publications are of use the committee in their review of CERAZETTE (desogestrel) in respect of the reclassification application. MSD is supportive of the application of reclassification of this product as per the submission that is to go before the committee at its 51st meeting.

Yours Sincerely,

[redacted]

Medsafe Comment

The following articles were supplied but have not been uploaded:

Rott, H (2012). Thrombotic risks of oral contraceptives. *Curr Opin Obstet Gynecol* 24: 235-240.

Blanco-Molina, M *et al* (2012). Progestin-only contraception and venous thromboembolism. *Thromb Res* 129: 257-262.

Mantha, S *et al* (2012). Assessing the risk of venous thromboembolic events in women taking progestin-only contraception: a meta-analysis. *BMJ* 345: 4944

Beerthuizen, R *et al* (2000). Bone mineral density during long-term use of the progestagen contraceptive implant Implanon compared to a non-hormonal method of contraception. *Hum Reprod* 15: 118-122.

Bahamondes, L *et al* (2005). A prospective study of the forearm bone density of users of etonorgestrel- and levonorgestel-releasing contraceptive implants. *Hum Reprod* 10: 358.

Pongsatha, S *et al* (2010) Bone mineral density in women using the subdermal contraceptive implant Implanon for at least 2 years. *Int J Gynecol Obstet* 109: 223-225