The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

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Dear Hannah

Thank you for the opportunity to comment on the agenda of the 57th meeting of the Medicines Classification Committee (MCC) of Medsafe

General practice and the College

General practice is the range of values, knowledge, skills, and practices required to provide first level medical services in both community practice and hospital settings. General practice includes the provision of both first contact and continuing care for all ages and both sexes that is comprehensive, person-centred, and takes into account the roles of family, whānau, community and equity in achieving health gains.

GPs comprise almost 40 per cent of New Zealand's specialist workforce and their professional body, the Royal New Zealand College of General Practitioners (the College), is the largest medical College in the country. The College provides training and ongoing professional development for GPs and rural hospital generalists, and sets standards for general practice. The College is committed to:

- Ensuring that New Zealand has a GP workforce that contains sufficient vocationally trained GPs to: ensure appropriate service provision; enable sustainable, safe, high quality primary health care; meet the increased demands of an ageing population and higher rates of co-morbidity; and to meet the Government's expectations of care that is sooner, better and more convenient.

- Improving patient outcomes with regard to continuity and access to quality care by: promoting better integration between primary care, secondary care and social service; and encouraging innovation and the development of new models of care.

- Achieving health equity in New Zealand through: a greater focus on the social determinants of health; reducing the rates of smoking and increasing healthy food options for low-income families; better integration of health and social services; and ensuring that funding for primary care is targeted to the most disadvantaged.

- Improving health outcomes for rural communities through the work of high quality, well trained medical generalists working within multidisciplinary teams.

- Achieving health equity for Maori. Health equity for Māori will be achieved when Māori have the same health outcomes as other New Zealanders. For this to occur, service delivery to Māori needs to be appropriate and effective and ensure equity of access. This does not mean a reduction in service delivery to other New Zealanders, but rather improving service delivery to Māori to ensure fairness.

The MCC Agenda

The College wishes to comment on the following four agenda items for the 57th meeting of the Medicines Classification Committee;

5.3 Updating the Guidance Document

6.2 Melatonin

6.4 Oral contraceptive

7.1 Betaine

We would also have liked to have been able to comment on item 5.4 Medicine reclassification – proposed process when considering the reclassification of prescription medicine to restricted medicine. However as this item was not accessible on the Medsafe website until the afternoon of September 19th, we are unable to do so. This is an important item and we will have comments to make regarding this. We would appreciate the opportunity to respond to this item at a later date and we wish to request this. The guidance states that 6 weeks are usually available for the consideration of agenda items. We are sure that you will appreciate that four days is not sufficient time to consult with College members and prepare a response to a document of such ongoing importance. The College is very keen to see improvement to the process around determining what additional skills and resources are required to enable safe down scheduling of medication, and disappointed that this will not be able to be debated and progressed at the current meeting.

Submission

5.3 Updating the Guidance Document

The College response on this agenda item has been submitted separately using the template provided as requested. A copy is also attached as appendix 1.

6.2 Melatonin

The College does not support the exclusion of melatonin from scheduling when for oral use in 1mg or less, in order for it to be classified as a dietary supplement. In Australia Melatonin is a prescription only medication and it should remain so in New Zealand. Although proposed to be sold in sachets of "1 mg or less" consumers can readily take amounts in excess of this. Melatonin is not without risks and only appropriate for short term use in specific situations. There is continuing debate as to the safety of its use as a dietary supplement.[1] At the very least it should only be supplied to patients under specific circumstances and with the involvement of a pharmacist trained in its use. This would facilitate the identification of people whose sleep disorder is secondary to other underlying problems and enable them to be referred for assistance with the management of those underlying problems.

[1] http://www.huffingtonpost.com/van-winkles/the-dark-side-of-melatoni_b_8855998.html accessed 23/9/16

6.4 Oral contraceptive

The College has previously responded to a number of MCC agenda which included items on the supply of selected oral contraceptives by specially trained pharmacists. The content of these submissions remains relevant and these previous responses are included as Appendix 2 in order to again be taken into consideration.

On this occasion in order to provide members with an additional opportunity to feed back on the proposal, we conducted a brief electronic survey of GPs which was distributed via our weekly electronic newsletter ePulse. To assist members we provided a summary of the conditions under which the OCP could be supplied, after gaining agreement from Green Cross that the summary was accurate. This summary stated;

Women requesting the oral contraceptive pill (OCP) can be supplied without prescription with one of the specified formulations of the combined oral contraceptive pill (COCP) or progesterone only pill (POP) by a specially trained pharmacist if;

1. *The woman has been prescribed an oral contraceptive in the past three years (based on prescription or first dispensing date)*
2. *The same formulation is continued, unless either;*
    - *The woman is from overseas and that formulation is not available in NZ or*
    - *there has been a gap in therapy e.g. where a woman stopped treatment, had a baby and now is post-partum and breast-feeding*

    In either of these circumstances the therapy may be changed.
3. *Supply can only occur if the woman is eligible for supply in accordance with the screening tool consistent with World Health Organisation's Medical Eligibility Criteria for Contraceptives, and approved by the MCC (or Pharmaceutical Society of New Zealand, as the MCC sees fit)*
4. *Doctor referral occurs where the woman is ineligible according to the screening tool*
5. *Women will be screened for contraindications using the full screening tool at the first visit to the pharmacy and every 12 months. In intervening occasions at the same pharmacy they will be asked if any conditions have changed since the last dispensing. If the woman visits another Pharmacy the full screening tool is automatically undertaken*
6. *A maximum of 6 months' supply can be provided on any one occasion*
7. *The woman's GP is informed of the supply unless the woman opts out of this process Women are strongly encouraged to consent to having the GP informed of the supply.*
8. *Verbal and/or written information is supplied on the need for smear tests, sexually transmitted infection checks (if necessary), contraceptive options including long-acting reversible contraception, compliance, adverse effects, and what to do if a tablet is missed or diarrhoea or vomiting occur.*

The Pharmacy Council Protocol for the Sale and Supply of Pharmacist Only Medicines for Chronic Conditions would apply to the pharmacist supply of oral contraceptives. This states that a private area must be provided for consultations.

Of the 118 members who answered the survey only 29 (25%) supported pharmacist supply. Only 7 of these supporters, (6% of respondents overall), also supported initial supply by the pharmacist. We note that the current proposal before the MCC excludes initial supply (supply to OC naïve patients). These findings establish the extent of the concern from GPs around the ability for women to receive good quality care around the choice of contraceptive method and associated best practice women's health care in a pharmacy environment.

Of the 25% who supported pharmacist supply under the proposal, the majority of those who gave their reasons mentioned the need to increase access to contraception, however it was clear from many of their responses that they were assuming that there would not be a cost to the woman for this. In fact one respondent stated “Will the pharmacist charge a fee for their time taken to administer the questionnaire? If so this may negate some of any improvement gained re access”. The current MCC guidance document does not require applicants to state whether there will be a cost for the time that the pharmacist spends establishing whether the medication is appropriate for the symptoms or need, establishing whether the customer has contraindications to supply, and explaining how to take the medication and the precautions to follow. Neither is there a requirement in the guidance to give an indication of the cost to the customer of the medication itself. We will mention cost further later in our response.

Those respondents who did not support the proposal were asked to identify any of a list of suggested changes to the proposal that would address their concerns, and 61 of them did so. The most frequently selected of the options was changing to 12 months between prescriptions. The proposal currently suggests that there be 3 years allowable between prescriptions.

Respondents were provided with the options of changing this to 24 months, 18 months or 12 months between prescriptions. Around a third of respondents indicated that a change to 12 months between prescriptions would address their concerns. The numbers selecting the 24 month and 18 month options were very small. Respondents were also able to provide free text responses which gave an indication of their concerns although many of them would not be easily able to be addressed by a change in the proposal. One fairly typical response was “I fully support women having better/wide access to contraception. However, I still think GP's are best placed to provide this care - (in the context of the patient’s wider health). Ideally, all contraception visits/care/prescriptions should be fully funded...”. Others specifically mentioned the effect on continuity of care, the risk (and possible GP liability) “when problems occur due to a script being issued elsewhere and something is scripted that might interfere with the pill or if she has a consequence of being on the pill (e.g. DVT) and it is not picked up as such.” Although there may be a perception that GPs are engaging in patch protection the only mention of any effect on GP income was the comment that it was unfair that GPs would still be required to achieve health targets (e.g. smoking cessation advice) even if they no longer had the opportunity to address these issues during routine appointments. Respondents were also concerned at the effect that such a change would have on detection and hence prevalence rates for sexually transmitted infections (STIs). These are already considered to be at epidemic proportions in New Zealand. Women who are referred to their GP or family planning for testing will be much less likely to actually receive this testing than will women who are able to have STI testing carried out at the time of prescription.

When speaking to Alison Van Wyk of Green Cross we were told that the customer would only be charged if the medication was supplied. We considered that this gave an incentive to supply when a considerable amount of time had been spent in discussion with the customer even when the medication may not be in the customer’s best interest. She responded that pharmacists can structure their conversations in a way that enables them to identify patients for whom the medication is not suitable early in the conversation.

The College continues to be concerned at the perverse incentives that exist in a situation where the ‘prescriber’ receives income only in the event that medication is dispensed.

In summary the College does not support the reclassification of the oral contraceptive to allow supply under the conditions outlined in the proposal. In particular the College considers that the proposed interval between prescriptions of 3 years is much too long. If this was to be shortened to 12 months there would be considerably less concern at the safety of the proposal.

7.1 Betaine

Very few people are unfortunate enough to have the metabolic errors that are mentioned in the submission as benefiting from Betaine. Those who do will already be receiving medical care and be able to obtain Betaine via this channel if necessary. Hence the demand for Betaine as a restricted medicine will be small. We do

note however that Betaine is marketed to athletes looking to boost muscle strength, power, and mass.[2] This indication is not mentioned in the proposal but is likely to be a much larger potential market. The College does not support this proposal and considers that Betaine should be classified as a prescription medicine. We also note that the opinion of paediatricians would be useful here.

We hope that you find this submission helpful. If you have any questions or would like to discuss our views further, please contact us at policy@rnzcgp.org.nz.

Yours sincerely

Michael Thorn
Manager Strategic Policy

[2] http://www.bodybuilding.com/fun/ask-the-supplement-guru-whats-the-word-on-betaine.html

Appendix 1 Copy of the response to item 5.3

Medsafe consultation submission

Update to Medicines Classification Committee Processes

Name and designation	Michael Thorn, Manager Policy
Company/organisation name and address	Royal New Zealand College of General Practitioners (RNZCGP)
Contact phone number and email address	04 496 5999 michael.thorn@rnzcgp.org.nz

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* (Reasons for requesting confidentiality must meet the Official Information Act 1982 criteria)	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	☐ Yes ☒ No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	☐ Yes ☒ No

It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:

☒ New Zealand ☐ Australia ☐ Other (*please specify*):

I am, or I represent, a: *(tick all that apply)*

☐ Importer ☐ Manufacturer ☐ Supplier ☐ Sponsor

☐ Government organisation ☐ Researcher ☒ Professional body ☐ Industry organisation

☐ Consumer organisation ☐ Member of the public ☐ Institution (eg, University, hospital)

☐ Regulatory affairs consultant ☐ Laboratory professional

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

Please return this form to:

Email: committees@moh.govt.nz including "MCC Process Consultation" in the subject line

Or Post: MCC Secretary
Medsafe
PO Box 5013
Wellington 6145

Medsafe is seeking comments on the following:

1. Reference lists for all applications will be made publicly available.

   - Do you have any comments on this clarification?

   The College supports this change as it assists in the understanding and assessment of proposals.

2. Supporting documents and/or appendices for applications will be made publicly available, and will only be treated as confidential when the applicant specifically requests this, and only to the extent permissible under the Official Information Act 1982.

   - Do you have any comments on this proposal?

   The College supports this change as it assists in the understanding and assessment of proposals.

3. Reclassification applications will now be received electronically via email (file size permitting). Alternatively, applications can be provided with a hard copy of the cover letter along with the application on a CD.

   - Do you have any comments on this change?

   No

4. Feedback provided on applications will be made publicly available, and will only be treated as confidential when it is specifically requested, and only to the extent permissible under the Official Information Act 1982.

   - Do you have any comments on this clarification?

   The College supports this change as it promotes transparency.

5. The proposed criteria for valid objections are:

   - The MCC did not consider all the safety issues correctly (for example a new safety concern may have been identified since the start of the consultation)
   - The MCC did not consider all the benefits, or
   - There was a breach in the appropriate process.

   Financial or commercial reasons are not acceptable grounds for objection.

- Do you have any comments on these criteria?

These criteria appear reasonable.

6. The determination of whether an objection is valid could be made by:

   - Medsafe Group Manager on advice from the MCC Secretariat
   - MCC Chair
   - MCC committee via teleconference
   - Director General of Health on advice from the MCC secretariat.

   Given the short timelines involved it is noted that the first option is likely to be the quickest and avoids any perception of conflict of interest which would accompany a determination made by the MCC or the chair of the MCC.

- Do you have any comments on these options?

The College agrees that there is a need to avoid actual or perceived conflict of interest. This could be a risk with all options but the option of Medsafe Group Manager on advice from the MCC Secretariat carries reduced risk without also imposing and administrative hurdle that may result in delay.

7. It is proposed that the supporting data for valid objections will be published on the Medsafe website as per the normal submission process.

- Do you have any comments on this proposal?

The College strongly supports this proposal. For the processes to be robust and to guard against regulatory capture there is a need for open transparent communication.

8. Ten days are allowed for objections to be lodged and the supporting data must be available for the next MCC consultation phase.

- Do you have any comments on these timings?

As above the supporting data needs to be available to allow robust consideration.

9. A maximum of three individuals representing the applicant are able to observe the opening discussion of the agenda item for which they submitted the reclassification proposal. Applicants may also have the opportunity to answer any queries posed by the MCC, which may have arisen following the receipt of comments on the application, and provide explanations which would help make a final recommendation. However, applicants are not able to provide any new data or information that was not included in the original application, in the interests of transparency. Observers are not able to be present for the final recommendation made by the MCC.

- Do you have any comments on the format for observers?

The College is concerned that allowing only those making the application to observe the opening discussion of the relevant agenda item, increases risk of regulatory capture by the pharmaceutical and pharmacy retailing industries, who are the most frequent applicants. The applicants get the opportunity to respond to questions from the committee but there is no opportunity for those opposed to the application to critique their response or present an alternative interpretation.

The guidelines already recognise the need for the evidence presented to be open to scrutiny in that new "data" is not able to be presented by the applicants during the meeting. To allow observers to answer questions while at the same time not allow them to provide any new data, is somewhat contradictory and relies heavily on the interpretation of the word "data". The College considers that the current situation has the potential to unfairly bias the decisions of the committee in favour of the applicant.

We suggest that any information or opinion provided by applicants at the time of the meeting should be open to scrutiny before being relied on by the committee in forming its recommendations.

We also note the new proposal that the discussions with the applicants are to be held under Chatham House Rules[3], hence while what was said may be recorded who said it may not be. Given the commercial implications of reclassification decisions it is important to assess statements and responses in the light of who they are made by. The College is concerned that this degree of anonymity may not be appropriate in this situation. Chatham House rules do not allow the degree of accountability and transparency that is required for robust decision making in a situation where there are commercial implications if the committee is to fulfil its role of protecting the public.

[3] https://www.chathamhouse.org/about/chatham-house-rule accessed 19/9/16

In summary the College agrees that the observers should not be present for the final recommendation, but suggests that the opportunity to observe (and answer questions) prior to the final recommendation should be available to both applicants and to those opposing the application. We also believe that for the purposes of transparency the discussions at meetings between the MCC and applicants should be minuted in full.

10. An update and amendment to the current Decision Criteria has been proposed, and a set of parameters developed.

- Do you have any comments on this change?

The College considers that the changes to the guidance document proposed in the consultation document will not fulfil the aims expressed in the minutes of the 55th meeting or those and stated under the heading of purpose and scope on page 3 of the consultation document.

We are rather surprised to see the rearrangement of the decision criteria, and their interspersing with such details such as dose forms and strengths that are required under part A and part B of the current guidance. This format allows similar issues to be grouped together but there are some problems associated with it in its current form.

1. There is no longer a concise list of the decision criteria. There were previously 10 of these, however they are now mixed in with the items of detail previously in Parts A and B to produce a list of 40 items.

2. Despite this increase in the number of criteria a quick glance reveals that some things that we would have considered important have dropped off the list of requirements. For example there no longer appears to be mention of the need for inclusion of the following information:

    - The present classification of the medicine
    - The classification sought
    - International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine.
    - Proprietary name(s).
    - Name of the company / organisation / individual requesting a reclassification.
    - Local data or special considerations relating to New Zealand
    - Consideration of potential communal harm or benefit.

3. It is very difficult to see what actual changes have been made to the decision criteria apart from a reorganisation of how they are to be grouped and presented. The presentation of the consultation documents does not clearly state what has been added to the criteria, what removed, or alert readers to changes in the wording of existing criteria so these can be assessed.

4. The College has for some time been concerned that there are important criteria that are not currently taken into consideration, in particular the effect of reclassification on fragmentation of care. This remains absent, and we will discuss this further later.

Because it is unclear what changes have been made to the decision criteria, we consider that further work is required. In particular the following need to be produced;

1. A draft of the proposed new guidance. This will show what it is proposed to look like. The current consultation document contains both discussion of changes and an outline of the draft itself. It refers to the current documents in a way that makes it unclear what sections of the current documents will also be included unchanged in the new guidance document.

2. An accompanying brief consultation document. This would outline the changes that are being proposed to both the criteria and to the information required to be included in every application. This will enable the current wording and its proposed replacement to be clearly and unambiguously identified and compared, and the rational for the changes to be presented.

Currently it is very difficult to assess what has been changed, removed or added, and what has simply been relocated. Consequently it is not possible to provide useful feedback on the changes, as these are unclear - as is the content of the proposed guidance.

<u>Additional criteria needed.</u>
The College considers that there are some important additional criteria that need to be considered when reclassification decisions are made. In particular,

- The effect on continuity of care and the potential for introducing fragmentation of care of a nature that will have significant negative effects on patient safety and the quality and efficacy of patient care. It is well known that the greater number of health providers involved in the care of a patient the more opportunity for error. As Ron Paterson commented in 2010 when he was the Health and Disability Commissioner: “Fragmented care looms large in complaints about

medical care."[4] Looking specifically at prescribing, there is evidence, particularly in the case of older people, that multiple prescribers are associated with an increased risk of adverse drug reactions.[5] There is an emerging body of research revealing that a greater breadth of services provided in primary care is associated with lower costs and fewer hospitalisations[6], and also improved health outcomes[7]. The reclassification of some medications has only a minor effect on continuity of care but for others, such as the oral contraceptive pill, the effect of down scheduling on continuity of care is significant. The College considers that the *magnitude* of the potential consequences of fragmentation of care brought about by a particular proposed reclassification, on the health of the target population, should be one of the factors able to be considered by the MCC in the assessment of any proposed reclassification.

- The effect on health equity. The effect that a proposed change in practice or policy will have on heath equity is taken into consideration in most decisions that affect healthcare. For example Pharmac in its factors for consideration takes into account "The impact [of its decision] on the health outcomes of population groups experiencing health disparities. The College considers that this should also be considered by the MCC.

- The potential for drugs to be approved for one indication but widely used or marketed for another. We have concerns that this may apply to one of the items on the agenda for the 57th meeting.

We note that the MCC provides recommendations to the Minister of Health. Our view is that the Minister needs to be advised of these impacts before making any decision about reclassification. It is important that there is the ability of assess changes with a whole health system view. A narrow "pharmaceutical" view risks foreseeable but unintended consequences to public health. If the MCC takes only a narrow view of the impact of proposed changes there is no process to inform the Minister of Health of the wider impacts.

Decision criteria

- Do you have any comments on these parameters?

Decision parameters.
The current wording of the principle used by the MCC has been retained, and these have been termed parameters in the new version. We suggest that a change to the wording would enable them to more accurately reflect the role of the Committee. This change would emphasise that regardless of whether the condition or symptoms

[4] http://www.nzdoctor.co.nz/in-print/2010/march-2010/march-24-2010/window-into-world-of-care-gone-awry.aspx
5 http://www.bpac.org.nz/BPJ/2012/october/elderlyMedicines.aspx
[6] More comprehensive care among family physicians is associated with lower costs and fewer hospitalizations. Bazemore A, Petterson S, Peterson LE et al. Ann Fam Med. May/June 2015; 13(3):206-13.
[7] Living in a country with a strong primary care system is beneficial to people with chronic conditions. J Hansen, P Groenewegen et al. Health Affairs, September 2015; Vol 34, Issue 9

are able to be diagnosed by the patient themselves or require the assistance of the pharmacist the medication itself must “show substantial safety”. It is not acceptable to down schedule a medication that has significant safety risks, even if it is for a condition that is easily diagnosed.

The current wording is;

The MCC uses the following principle when considering a medicine for suitability for non-prescription sale: Medicines which may be available without prescription shall be able to either:

a. show substantial safety in use in the prevention or management of the condition or symptom under consideration
b. be for conditions or symptoms that can be diagnosed and managed by a pharmacist
c. be easily self-diagnosed and self-managed by a patient.

Our suggested wording is;

The MCC uses the following principles when considering a medicine for suitability for non-prescription sale: Medicines which may be available without prescription shall be able to show substantial safety in use in the prevention or management of the condition or symptom under consideration and be for conditions or symptoms that can be either

- diagnosed and managed by a pharmacist or
- easily self-diagnosed and self-managed by a patient.

This change would emphasise that the medicine should always be substantially safe.

The College considers that these three parameters do not cover all the factors that need to be considered before the wisdom or otherwise of enabling rescheduling of a medication can be assessed. As just one example the parameters do not cover whether the rescheduling will lead to increased antibiotic resistance – a factor that is of continuing and increasing importance. Such things MUST be stated in the parameters.

In addition to these parameters, explicit decision criteria are needed to establish what should be taken into account to determine whether a medication is “substantially safe”.

The committee may request that the information provided in applications is *presented* under the new headings, but is important that the decision criteria are also available in a separate list so that the principles on which decisions are made are transparent.

11. Do you have any further comments on the MCC process?

The College continues to have concerns around process that the MCC use to alert interested parties to the items on the agenda. We are pleased to see the statement on page 8 of the previous guidance stating that interested bodies are expected to "watch the Medsafe website" has been removed. We do not however see any mention of what process the MCC intends to use in future to ensure that it gets to hear and consider the views of relevant clinicians. The lack of a robust process to publicise proposals results in clinicians sometimes only hearing of the proposal after it is too late to feedback. Pharmaceutical companies and pharmaceutical retailers are focused on issues such as reclassification, have the resources to monitor the activity of the MCC, especially given the high likelihood that the agenda will be of interest to them. Medical practitioners by comparison have to spread their attention and time over a wide range of tasks.

Please include additional pages if necessary.

Appendix 2.

Extracts from RNZCGP submissions to the 55th, 53rd and 51st meetings of the Medicines Classification Committee

Extract from RNZCGP response to the Agenda for the 55th meeting of the Medicines Classification Committee. Item 5.1.1 Oral contraceptives

The agenda item reads:

> *"The Committee's recommendation of reclassifying selected oral contraceptives (desogestrel, ethinylestradiol, norethisterone and levonorgestrel) from prescription medicine to restricted medicine, when sold in the manufacturer's original pack containing not more than six months' supply by a registered pharmacist who has successfully completed a training programme, when indicated for oral contraception in women who have previously been prescribed an oral contraceptive within the last 3 years from the date of an original medical practitioner's prescription."*

The College wishes to reiterate that it strongly supports the ready availability of safe, effective, and acceptable contraception. Our major dispute is with the process that was followed and the precedent it creates for future decision making. As for the decision reached regarding the oral contraceptive pill (OCP) we have only minor changes to suggest.

The College remains opposed to the supply of the OCP without prescription to women who have not previously been prescribed it. The reasons for this have been outlined in the Colleges previous submissions to the MCC in response to the agendas of the 51st and 53rd meetings of the MCC.[8] [9]

However, the College would be supportive of the alternative proposal from Green Cross with some minor modifications. We would have liked to have had the opportunity to raise these issues in a response to the agenda of the 54th meeting. If we had been provided with the information to enable this prior to the meeting, then the delay in progressing pharmacist supply of the OCP in appropriate situations (arising from the need for this issue to be reconsidered by the committee), could have been avoided. The precedent set by the process used must be challenged so that future decisions are made in the public's interest rather than the industry's.

The College considers a repeat supply of a woman's OCP without prescription is reasonable provided that before dispensing, the pharmacist ensures that there has not been a change in the woman's health (or that of her close relatives), that would indicate that she should be advised that the OCP may no longer be the best contraceptive option for her. Additionally the woman should:

- have been prescribed that OCP within the past year
- have been reviewed by an authorised prescriber at least once since starting the OCP for the first time

This differs slightly from the "alternative proposal" put forward by Green Cross at the 54th meeting in that:

- the interval between prescriptions has been reduced from 3 years to 1 year

[8] http://www.medsafe.govt.nz/profs/class/Agendas/agen51CommentsOnSubmissions.pdf p30
[9] http://www.medsafe.govt.nz/profs/class/Agendas/agen53comments.pdf p 70

- a requirement is added that for woman receiving the OCP for the first time (OCP naïve), one follow up appointment with an authorised prescriber is required before further repeats can be provided without prescription.

RNZCGP members considered that an interval of three years between prescriptions is too long and should be shortened, ideally to one year. This would minimise many of the issues around the difference in the level of holistic and comprehensive care that can be provided to the woman by her general practice team, as opposed to what can be provided by a pharmacist in a pharmacy setting.

Reducing the interval between prescriptions from 3 years to 1 year would also would address issues with repeat prescriptions in older women. The submission document does not state the age beyond which supply without prescription will not be permitted. We consider that this is a significant omission.

In relation to the upper age limit for the COCP we draw you attention to a recent case highlighted by the Medical Protection Society in which the complainant suffered a stroke. Expert opinion was that a reasonably competent GP would have stopped prescribing the OCP to a woman with her history at the age of 35.[10] The checklist that we were shown by Green Cross in February 2015 had an upper age limit higher than this, although it did also contain advice regarding use in this age group.

We were permitted to share this check list with a small number of GPs. They expressed concerns about some of the content. In our response to the 53rd agenda we commented that, "If the check-lists are to be used, we would expect the College to be further consulted before implementation". There is a need for this information to be made publically available and reviewed.

[10] http://www.medicalprotection.org/docs/default-source/pdfs/casebook-pdfs/new-zealand-casebook-pdfs/nz_book_web.pdf?sfvrsn=6 p13

Extract from the RNZCGP Response to the 53rd meeting of the Medicines Classification Committee

Item 6.2 Oral contraceptives – proposed reclassification from prescription medicine to restricted medicine (Green Cross Health Limited)

The RNZCGP continues to be opposed to the proposed reclassification of oral contraceptives.

Comparison with the 2014 Pharmacy Brands submission

The submission from Green Cross Health in support of reclassification appears to be in large part a copy of the 2014 submission. Key changes between the 2014 submission to the 51st meeting of the MCC and the current submission are;

1. The previous submission was made on behalf of Pharmacy Brands. They have since rebranded as Green Cross Health. Green Cross Health remains a body that represents retail pharmacy, and the commercial advantages to them of reclassification remain.

2. The proposed length of supply has been reduced from 6 months to 3 months (page 4 under pack size and other qualifications).

3. The paragraphs of supporting information have changed in some places. We note for example that the reference to the potential for pharmacist supply to decrease the rate of teenage pregnancy is no longer included. The recent increased availability of Long Acting Reversible Contraceptives (LARCs) has been credited with a significant drop in the teenage pregnancy rate.[11] As LARCs will not be supplied by a pharmacist this proposal may increase the likelihood that those young women for whom LARCs would be the most appropriate option would instead be supplied with the OCP. The OCP is unlikely to be as effective as LARCs in a teenage population.

It would have been helpful if there had been a list of changes to the proposal as there may be other changes that we have missed when comparing the two versions

Meeting with representatives of Green Cross Health and Pharma Projects

We appreciated the opportunity to meet with Dr Natalie Gauld of Pharma Projects and Alison van Wyk of Green Cross Health on February 19th. We also appreciated them making available copies of the draft checklists for OCP and POP and for giving us permission to share these with up to 6 GPs who would undertake to keep them confidential.

While the meeting allowed us to clarify some issues it did not allay our concerns around this proposal and in fact raised further concerns.

GP member feedback

Members felt strongly about this proposal and about 30 members provided feedback as a result of notification in ePulse (the weekly College electronic newsletter), and emails to members with an interest in relevant areas. Member response was overwhelmingly against this proposal.

Members were concerned that the underlying motive for the proposal related more to boosting retail pharmacy profits than to improving access to contraceptives.

[11] http://www.radionz.co.nz/news/national/235957/steep-drop-in-teen-pregnancy-rates

In the College's response to the agenda of the 51st meeting of the MCC a range of concerns were expressed. Member feedback on this occasion reinforced those existing concerns and raised further issues. The 2014 response is included as an appendix to this response and should be considered along with this response.

The key concerns raised by members on this occasion are outlined below

Consultations for contraception

A consultation ostensibly about contraception is seldom limited to this issue alone. Depending on the individual patient and their situation and health needs it can include discussion of sexual health, STI testing, opportunistic risk screening[12], education, follow up of mental health or other health issues, or can provide an opportunity to engage with mothers regarding issues such as immunisation of their children. There is also the opportunity to discuss future child bearing plans and declining fertility with age, and to educate regarding pre conception care.[13]

A request for contraception requires a comprehensive discussion of the options available, assessment of possible contraindications, discussion of the risks and benefits of the various methods, and education on the use of the method selected. Particularly for young women a "pill consultation" often leads to a more complex consultation using the HEADSS[14] model.

Consultations relating to contraception provide an opportunity to engage with hard to reach members of the population who have other issues that require attention or follow up. These consultations also provide the opportunity to establish a therapeutic relationship which enables more effective and appropriate provision of future care whether or not this relates to contraception.

In the minutes of the 51st meeting it is recorded that "One Committee member stated that they acknowledged pharmacists were capable of managing the medicine but they were not convinced that pharmacists could manage the patient completely. The College endorses the view that pharmacists are not in a position to provide comprehensive ongoing care.

Fragmentation of care

An associated issue also mentioned frequently by members was the fragmentation of care that would result if this proposal went ahead. The more providers that are involved in the care of an individual, the more potential there is for error. The advantages of having a "medical home are increasingly acknowledged. Where a therapeutic relationship has already been established with the health provider this leads to increasing efficiency and quality of care.

Barriers to access to contraception

Several GPs commented that they did not consider that pharmacist provision was necessary to solve a problem with access to oral contraceptives. In New Zealand, unlike in many of the countries referred to in the submission, there is both a well-developed and subsidised primary healthcare system and in most cases pharmaceuticals are also subsidised. For many patients sexual health consultations are free, and for many others consultation fees are capped at a maximum of $17.50.

[12] Cervical smears, smoking, alcohol, family violence, cardiovascular risk.
[13] For example check rubella immunity, advise re pre conception folic acid and iodine, and early pregnancy care.
[14] HEADSS stands for a number of categories (Home, Education, Activities, Drugs & Alcohol, Sexuality, Suicide)

On February 19 2015 TV1 news ran an item on the proposal for pharmacist provision of oral contraceptives. We presume that this was initiated by the organisations supporting the proposal. Viewer comments to the TVNZ website did not provide evidence of the existence or of a large demand for this service. On the contrary many voiced support for the OCP to remain available only on prescription.

Costs to women of pharmacist provision of the OCP

Members noted that a contraceptive consultation requires time and skill even when strictly limited to core contraceptive issues alone without opportunistic consideration of wider issues.
It is clear that pharmacists will need to charge the patient for providing a contraceptive consultation and if the woman is to be given adequate informed choice regarding contraceptive methods and appropriate education in their use, the consultation will take some time. As such there will be a commensurate cost for this consultation. This will act as a barrier to provision (as opposed to increasing access) and this barrier will be most significant for already disadvantaged women.

Effect on integration of care between pharmacists and GPs

Members commented on the negative effect that such reclassification proposals may have on the integration of pharmacists into primary health care teams. It was felt that such integration is challenging and that proposals driven by pharmacy retailer organisations have a negative effect on the climate for integration. GPs who contacted the College did not accept that the current proposal was driven by a need to improve access and were adamant that it would not improve the safety or quality of contraceptive care and would have a detrimental effect on holistic care and on access to other health care.

GPs commented that although the current financial climate was challenging for pharmacies reclassifications and hence changes to models of care should not be driven by the need to supplement current or future pharmacy income.

Access to patient records

Members expressed concern that pharmacists would not have access to the woman's medical record and would therefore need to rely on the information remembered and volunteered by the woman. This information can sometimes be inaccurate or incomplete. Although Testsafe and other similar programmes will mean that pharmacists are able to access some of the patient record for some women, safety issues due to incomplete or inaccurate information remain.

Conflict of interest

We note that the researcher engaged by Green Cross Health to manage the application to the MCC is a member of the Board of the Pharmaceutical Society. Under the proposal all responsibility for the content of the training for pharmacists wishing to supply the OCP would rest with the Pharmaceutical Society or its associated NZ College of Pharmacists. We consider that this conflict of interest should have been declared and appropriate mitigation proposed.

Feedback on the checklists for prescribing the POP and OCP

We are unable to provide specific feedback on the content of the checklists at this stage, although GPs who have had the opportunity to view the checklists have expressed some concerns to us about

them. If the check-lists are to be used, we would expect the College to be further consulted before implementation.

Minutes of the 51st meeting of the MCC

We were surprised to see the statement in the minutes:

> "The committee agreed that the risk: benefit profile of oral contraceptives was similar to other restricted medicines"

Especially, but not exclusively, when prescribed to women with contraindications oral contraceptives can lead to serious side effects.

We consider that the argument that a prescription medication could be reclassified because it is no more dangerous than something that is already classified as a restricted medicine is flawed. We are also aware that concerns have been expressed that medicines changes in New Zealand sometimes occur too readily. [15]

[15] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0119011 accessed 1/4/15

Extract from the RNZCGP response to the 51st meeting of the Medicines Classification Committee

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" [16] 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

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

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 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 <u>not</u> 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.