GREEN CROSS HEALTH

Product Regulation,
Medsafe,
PO Box 5013,
Wellington 6145

15th January 2018

Re: How to change the legal classification of a medicine in New Zealand

Thank you for the opportunity to provide feedback on the consultation document relating to how to change the legal classification of a medicine in New Zealand.

While we are broadly supportive of the process we have concerns around a number of the points within the consultation document.

1. We are concerned that all the supporting documents and or appendices are being made publicly available. This is IP developed for the purpose of the submission and for the committee to review. We would like to suggest that providing major medical organizations with the supporting documents would be a preferred option and they would be able to comment based on this however we see no benefit for all the documents to be made publicly available. We re-iterate that we have no concerns with all documentation being available for the committee to review.

2. The other alternative is for supporting documentation to be publicly available on the Medsafe website for a limited period of time and then removed. While this is not a preferred option it could mitigate the risk to IP with having the information retained publicly.

3. We note training detail and screening tools are classed as sensitive information and would encourage you to consider that other supporting documentation and appendices be classed in the same way.

4. We have commented on a separate document regarding the importance of retaining applicants as observers in attendance at the MCC meetings.

5. In Appendix 1 under Part B point 10 – Mitigating Circumstances we note that a question raised: Is the Proposal supported by the Professional bodies? While we are strongly supportive of collaboration and discussion with the relevant professional bodies regarding the proposed reclassification, we would like to understand how this will be evaluated. It is our understanding that financial, ethical and moral issues do not form part of the decision-making criteria but rather focus on the quality and safe provision of the product and service and of course the benefits and convenient access for the consumer.

Unichem life Pharmacy

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Ground Floor, Building B, Millennium Centre,
602 Great South Road, Ellerslie, Auckland
Private Bag 11906, Ellerslie, Auckland 1542

We understand the importance of providing as much information on the consultation and discussion undertaken with professional bodies as possible but with some submissions there may be a difference in opinion between professional bodies. Clarity around this impact will be important to understand.

6. We support the process by which the Pharmacy Council and PSNZ will review the submission and make suggestions around appropriate training requirements.

Please do not hesitate to contact the undersigned should you require further information or clarification.

Assuring you of our best attention at all times.

Yours Sincerely,

Green Cross Health

New Zealand Medical Association
Te Hauora mō ngā Iwi Katoa

12 January 2018

Product Regulation
Medsafe
PO Box 5013
Wellington 6140

By email: committees@moh.govt.nz

How to change the legal classification of a medicine in New Zealand

Dear Sir / Madam

Thank you for inviting the New Zealand Medical Association (NZMA) to provide feedback on the above consultation.[1] The NZMA is New Zealand's largest medical organisation, with more than 5,000 members from all areas of medicine. The NZMA aims to provide leadership of the medical profession, and to promote professional unity and values, and the health of all New Zealanders.

We note that the guidance document on how to change the legal classification of a medicine has been updated to include the following changes:

- a template form for reclassification applications
- communal harm has been added to the value-tree framework of benefits and risks
- parameters considered by the MCC when reviewing a medicine for reclassification have been more clearly defined
- complete applications will be published on the Medsafe website unless a request is made under the Official Information Act 1982
- objections will be published on the Medsafe website
- the proposed process from the Pharmacy Council /Pharmaceutical Society has been included.

The NZMA is broadly supportive of the changes that are being proposed. We have previously expressed our view that the MCC needs to take into account contextual factors beyond the direct effects of a medicine when considering reclassification.[2] Accordingly, we welcome the addition of the parameter 'communal harm and / or benefit'. This addition should enable the MCC to take

[1] http://www medsafe.govt nz/consultations/LegalClassification/Updating%20the%20Guidance%20Document%20on%20Classification.asp

[2] NZMA submission on the agenda for the 57th meeting of the Medicines Classification Committee. 23 September 2016. Available from http://www.nzma.org.nz/__data/assets/pdf_file/0003/51465/NZMA-Submission-on-agenda-of-57th-meeting-of-the-Medicines-Classification-Committee.pdf

Level 13, 39 The Terrace, PO Box 156, Wellington 6140 | Tel: (04) 472 4741 | Fax: (04) 471 0838 | Email: nzma@nzma.org.nz | www.nzma.org.nz

into account the effects of reclassification on aspects such as continuity of care, fragmentation of care and missed opportunities to address other health issues.

We welcome inclusion of the Pharmacy Council / Pharmaceutical Society process to determine whether screening tools/algorithms/education or extra training are required by pharmacists as part of a decision to reclassify a medicine.[3] We also welcome the requirement, as part of this process, for inter-professional collaboration, reflecting the joint Pharmaceutical Society and NZMA's Integrated Practice Framework.[4] We suggest that it may be useful for the medical profession to be actively involved in this process at an early stage.

We note that sponsors (usually pharmaceutical companies) can submit an application directly to the Pharmacy Council / Pharmaceutical Society for review and endorsement **before** submission to the MCC. We are concerned that this could amount to a joint application when it ultimately goes to the MCC, leading to the potential for a conflict of interest, given that both the profession and industry stand to gain. We seek Medsafe's views on this potential conflict of interest, including how it may be managed.

Finally, as it stands, there is no formalised way to determine whether touted benefits of a reclassification decision actually occur and/or whether there are other non-beneficial effects. As such, we submit that the final step of the reclassification process should entail a formal and transparent evaluation of the effects of reclassification decisions.

We hope that our feedback has been helpful and look forward to learning the outcome of this important consultation.

Yours sincerely

Dr Kate Baddock
NZMA Chair

[3] http://www.medsafe.govt.nz/consultations/LegalClassification/2d-Consultation-How-to-change-the-legal-classification-of-a-medicine-in-New-Zealand-Appendix-2-Pharmacy-Council.pdf

[4] https://www.psnz.org.nz/Folder?Action=View%20File&Folder_id=96&File=IntegratedHealthCareFramework_Final.pdf

Medsafe is seeking comments on the guidance document 'How to change the legal classification of a medicine in New Zealand:

Comments on Phase 1: Application
On page 9, '<u>increased</u> immunisation rates' are given as an example of a possible community harm (8). Is this an error? Potential community harm would come from <u>decreased</u> immunisation rates **In 10) the support of professional bodies for reclassification is identified as a risk mitigation strategy. NZNO needs to know how applicants will engage with us to establish whether we support reclassification. There also needs to be evidence presented with the application of that engagement and the outcomes of that process rather than just a 'yes' or 'no' response.**
Comments on Phase 2: Public consultation

Please include additional pages if necessary.

Comments on Phase 3: Meeting and MCC recommendations

The cost of a medicine is identified as being specifically excluded from the MCC considerations concerning reclassification. While this is appropriate when the MCC is considering applications from pharmaceutical companies, health professional organisations and the Ministry of Health, when the applicant is an individual, the cost of a medicine might be the primary reason that reclassification is sought.

Comments on Phase 4: Noting of the MCC's recommendations by the Minister's Delegate

Please include additional pages if necessary.

Comments on Phase 5: Publication of the minutes and MCC recommendations
Comments on Phase 6: Objection to an MCC recommendation

Please include additional pages if necessary.

Comments on Phase 7: Confirmation by the Minister's Delegate

Comments on Phase 8: Notification in the *New Zealand Gazette*

Please include additional pages if necessary.

Comments on Phase 9: Implementation of a reclassification change

Are there any other comments you would like to make on the guidance document?

It is expected that with the growing number of nurses with prescribing authority in New Zealand (Nurse Practitioners and designated prescribers) there will be an attendant increase in the activity of nurses and organisations such as ours (NZNO) in the process of applying for medicine reclassification and the associated consultation.

Please include additional pages if necessary.

Please include additional pages if necessary.

Introduction

NZSMI is New Zealand's premier organisation representing the importers, manufacturers and distributors of over the counter (**OTC**) medicinal products and complementary healthcare (**CHC**) products in New Zealand. Its membership accounts for over 85% of all OTC and complementary healthcare sales in New Zealand. All members submit to abide by a code of practice and it has a fully constituted board comprising the chief executives of the major pharmaceutical companies in New Zealand. It exists to promote the value of self-care in the community by encouraging health literacy and the safe use of clinically proven product. It seeks to work with the Regulator to ensure the New Zealand public has good ready access to well labelled, well marketed and well researched product manufactured to high standards.

NZSMI has a Regulatory and Technical Affairs Sub-committee that meets six times a year to consider proposed changes to the regulations affecting the OTC sale of Medicines. This committee is made up of employee regulatory specialists from member companies and private/ consultant member regulatory specialists.

Please include additional pages if necessary.

Medsafe is seeking comments on the guidance document 'How to change the legal classification of a medicine in New Zealand:

Comments on Phase 1: Application

As a pre amble NZSMI notes the following proposed changes to the guidelines and makes comment accordingly:

We note:

- Inclusion of a template form for reclassification applications
- communal harm has been added to the value-tree framework of benefits and risks
- parameters considered by the MCC when reviewing a medicine for reclassification have been more clearly defined
- complete applications will be published on the Medsafe website unless a request is made under the Official Information Act 1982
- objections will be published on the Medsafe website
- the proposed process from the Pharmacy Council has been included.

There is concern that these changes/additions add complexity to the process and duplication of work by the MCC and Medsafe when considering applications. From a purely practical point of view the timing allowances for applications will prove challenging, due to the need to align meeting times of the Pharmacy Council and the MCC if the process is not to become hugely elongated. All parties agree that improved "Public Safety and Benefit" is the goal, and efficiency must be a component of these considerations.

We note the comments: Communal harm/benefit arguments need to take into consideration;

- What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)? We comment, the term "Community Harm" needs to be more specifically defined. Is abuse by a minority a community harm?
- What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity because of improved access to a communicable disease vaccine)? As per communal harm definition, what would be considered community benefit? Is improved access to modern medicine a community benefit?

In relation to parameters considered by MCC some of the new additions or more formalised considerations now include;

Product presentation: In relation to the presentation of the product the proposal needs to address; What disposal considerations need to be made for the medicine?
What storage considerations need to be made for the medicine?
How practical and easy to use is the proposed presentation?
Again, product presentation is something that Medsafe takes into consideration during evaluation of the medicine- what is MCC reviewing that would not have been considered or would be considered by Medsafe?

What are the benefits from a consumer viewpoint? Does this mean that each submission will require a consumer survey about the perceived benefits should switch be successful

Please include additional pages if necessary.

or is this a comment from consumer advocacy group? It's not clear how this needs to be addressed or how it will be considered.
Efficacy /Benefit: NZSMI understands that one of Medsafe's roles is to consider efficacy. We maintain MCC should not reassess efficacy of a product as this would have been done by Medsafe at the time of registration. Why has MCC included this here and what will they be assessing?

Risk mitigating strategies –it is our supposition that most switches are not likely to require this. How is this to be addressed by more lower risk medicines that are switching? What type of risk mitigation strategies would be considered acceptable by MCC? There is concern that the same level of Risk Mitigation Strategy that is required for "Prescription Only Medicines" would now be applied to OTC medicines which we contend is inappropriate. Clarity in relation to this would be appreciated.

We note the increased role of the Pharmacy Council in the classification process. We believe more discussion is required around the mechanics, purpose and benefit of this initiative.

Concern was expressed that a whole new level of submission is being required and there is questionable value attached to this from a consumer and patient safety point of view. Concern was also expressed over the balance of decision making authority, MCC versus the Pharmacy Council. There is a feeling that the Pharmacy Council will, if history is to be considered, strongly resist any changes from the "pharmacy" to "general sale" and that if this is the case, it will be difficult to get such a change through MCC if it does not have Pharmacy Council endorsement. So, members are seeking clarity around the various weightings of each organisation in relation to the other.

Our sub-committee was confused about the "Pecking Order" and their relative importance and significance in gaining acceptance of a reclassification. An example postulated was the analysis of specific staff training protocols, which would only appear necessary when a "Pharmacist Only" schedule is being sought.

Please include additional pages if necessary.

Public consultation

NZSMI wishes to express (again) its deep concern regarding the existing and proposed protocols around the broad publication of fine details of medicine applications.

We are happy to provide examples to the MCC where highly developed, unique intellectual property has formed part of a medicines classification submission only to be “appropriated” by competitors for subsequent applications. Some cases relate to distinct scientific processes involved in formulation and some involve specific training programmes around SWITCH applications.

Collectively these isolated, but highly contentious, examples are creating a global perception that New Zealand is not the place to innovate or progress when it comes to bringing improved formulations, new molecules or new administration techniques to the public. NZSMI members fully understand and applaud the need to present research, evidence and proposed protocols to the MCC and Medsafe when seeking medicine classification, but not at the unreasonable cost of full public disclosure of highly developed intellectual property to all and sundry.

It is important to note that considerably less disclosure is sought by the TGA in Australia and companies are preferentially seeking medicines registration in Australia over New Zealand for this reason.

Also in other jurisdictions such as the UK – MHRA, the public can only view the actual proposal that is issued by the MHRA to change the classification of a particular product with very limited information about the product such as the proposed product, active ingredient information, the indication, the mode of action of the actives and who made the submission. The actual submission is not disclosed to the public.’

NZSMI contends that the current detail requirements around the Official Information Act requests for non-disclosure are nebulous and somewhat insecure.

There is concern that actions may be taken after the horses have bolted and members find their information no longer able to be secured. The alternative is to withdraw an application before publication. There is no doubt that this is a stumbling block for innovation and product development.

The suggested changes require greater disclosure of pack size, labelling, label content, etc. While this was seen as more work, members did not disagree with this initiative as it was not unreasonable and could add to patient safety and better understanding of the risk reward equation of a classification request.

NZSMI regards this as a serious issue and suggests that alternative pathways should be discussed that better meet the needs of all parties; including the idea of submitting a redacted application that puts sensitive commercial data in front of committee members only

Please include additional pages if necessary.

Comments on Phase 3: Meeting and MCC recommendations

NZSMI agrees with the proposed meeting times and protocols, particularly the aspiration to improve harmonisation with Australia.

We re-iterate our concern, however, over the necessity to co-ordinate meeting times with the Pharmacy Council to avoid extended delays in process.

We also would like discussion on the make-up of the MCC and suggest it could be enhanced by broader representation.

Are there any other comments you would like to make on the guidance document?

NZSMI appreciates the opportunity to discuss the future improvement of regulatory processes with the MCC, Medsafe, Medicines New Zealand, the Pharmaceutical Society and the Pharmacy Council.

Overall, NZSMI supports the thrust of where Government and Regulators wish to take our regulatory environment.

Please include additional pages if necessary.

We are concerned, however, that the “Devil lies in the detail” and that, as we have expressed, access to modern medicines and formulations is being restricted by unnecessarily liberal disclosure requirements and expensive, time consuming (and possibly duplicated) processes.

Please include additional pages if necessary.

Medsafe is seeking comments on the guidance document 'How to change the legal classification of a medicine in New Zealand:

Thank you for the opportunity to provide feedback on the guidance document 'How to change the legal classification of a medicine in New Zealand.

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

Comments on Phase 1: Application

While we support the content of what an application for a medicine reclassification should include, we are **strongly opposed** to the application, reference lists, training or other supporting material being made publicly available on the Medsafe website.

We are concerned that updating the guidance document titled 'How to change the legal classification of a medicine in New Zealand' will result in a disincentive for companies and organisations submitting proposals for the reclassification of medicines in New Zealand. This will have future implications on the access of medicines for New Zealanders.

It is our understanding that submitters do not wish for some of their information to be publicly published on the internet as this can be commercially disadvantageous to them. We understand that other medicines regulatory authorities respect the intellectual property of the applicants and publish very little of the application.

Reclassification applications contain intellectual property and require a tremendous amount of background research and resource. Allowing applications to be publicly available on the Medsafe website exposes this intellectual property on an international scale. This transparent process has already resulted in plagiarised reclassification applications being submitted to the MCC, and other applications being withdrawn. Should multi-national pharmaceutical companies be discouraged from making new applications, there is potential for beneficial prescription to restricted or pharmacy-only reclassifications to cease. We believe this would limit improved access to medicines for patients in the future and be to the detriment of the New Zealand health system.

We feel that an executive summary of the reclassification application is sufficient information to publish on the Medsafe website. We believe that the members of the MCC have the skill sets required to make decisions on the material provided with the applications or alternatively the MCC could seek confidential specialist input where required.

We **support** the requirement for submitters to submit their proposal for reclassification for either restricted or pharmacy-only medicines to the Pharmacy Council (the Council) for review by the Council and the Pharmaceutical Society (the Society).

There are several aspects to consider when a medicine is suggested for reclassification to restricted or pharmacy only, consistency forms an important part of this process. We believe the Council and the Society are best suited to advise the MCC on whether there is a need for additional pharmacist training, and to provide or approve screening tools and algorithms when considered necessary.

This joint framework between the Council and the Society enables robust reclassification process, that ensures both those applying for a reclassification, as well as pharmacists who will be affected by the outcome of any future reclassifications, will have a thorough understanding of the process involved in reclassifications from prescription to restricted or pharmacy-only medicines. Having this framework in place should also prevent any duplication of training or educational tools required as a condition of the reclassification.

We hope that having this clear and robust reclassification framework in place will result in more reclassifications of appropriate prescription medicines and improve consumer access to beneficial medicines in the safest way possible.

Please include additional pages if necessary.

Comments on Phase 2: Public consultation For our reasons mentioned in our comments on Phase 1: Application we have concerns around the content of applications including reference lists, training or other supporting material being made publicly available on the Medsafe website. We believe an executive summary of the application is sufficient information for public consultation.
Comments on Phase 3: Meeting and MCC recommendations We have concerns surrounding potential recommendations of the MCC based on Harmonisation with Australia. We **support** harmonisation of labelling and packaging harmonisation of safety directions, warning statements and first-aid instructions, and common nomenclature of drugs and poisons. We are however **opposed** to the harmonisation of equivalent scheduling for drugs and poisons. We believe New Zealand drugs and poisons should be scheduled to meet the needs of New Zealanders, not Australians.
Comments on Phase 4: Noting of the MCC's recommendations by the Minister's Delegate No comment.
Comments on Phase 5: Publication of the minutes and MCC recommendations No comment.
Comments on Phase 6: Objection to an MCC recommendation No comment.
Comments on Phase 7: Confirmation by the Minister's Delegate No comment.
Comments on Phase 8: Notification in the *New Zealand Gazette* No comment.
Comments on Phase 9: Implementation of a reclassification change No Comment.
Are there any other comments you would like to make on the guidance document? No comment.

Thank you for considering our feedback. If you have any questions about our feedback, please contact [redacted]

Yours sincerely,

[redacted]

Nicole Rickman
General Manager – Membership and Professional Services

Please include additional pages if necessary.

Medsafe is seeking comments on the guidance document 'How to change the legal classification of a medicine in New Zealand:

Comments on Phase 1: Application

The Society supports the draft application process, including the introduction of a reclassification framework for medicines moving from prescription to pharmacist only medicine.

Please could part B of the application be streamlined to clarify the sections that will need to be completed for full applications (e.g. new active substance or up-scheduling) and those that will now follow the proposed Pharmacy Council (PCNZ) and Pharmaceutical Society of New Zealand (PSNZ) reclassification framework?

The 2014 document (Part B) lists various questions around the reasons for requesting a classification change. The 2017 document (Part B) lists ten different sections, but it is not clear if all of these sections need to be completed for "switching/reclassification" or only completed for "new active" substances. Some of the questions appear to be specific to "new active" substances and others for "switching". Potential clarity may help applicants meet MCC's requirements. We are happy to provide specific examples, if that would be useful.

Some applicants may have concerns about making their training materials and screening tools publically available as part of the reclassification application.
Complete training packages may not be available at the initial time of application, as the applicant may be waiting for MMC's final recommendations before developing their full training. Also, the issue of intellectual property associated with the training may arise if all the information is made freely available in the public domain.
With PCNZ and the PSNZ providing the governance and recommendations around the training requirements for any new reclassification we would like to suggest that the training materials and screening tools do not need to go through to MCC as part of the application. We would like to propose that these are considered by PCNZ and PSNZ and then any approved training recommendations are delivered to MCC as part of the new combined reclassification framework process.

Comments on Phase 2: Public consultation

The Society supports the changes to the public consultation section of the document.

Comments on Phase 3: Meeting and MCC recommendations

The Society supports the changes to Phase 3 of the consultation document and also the opportunity for observers to answer questions and provide explanations to help the committee reach a final recommendation.

Comments on Phase 4: Noting of the MCC's recommendations by the Minister's Delegate

The Society supports the content of this section and it appears that there are no significant changes from the 2014 document.

Comments on Phase 5: Publication of the minutes and MCC recommendations

The Society supports the content of this section and it appears that there are no significant changes from the 2014 document.

Comments on Phase 6: Objection to an MCC recommendation

The Society supports the changes to this section.
Please can the MCC clarify if the electronic grounds for objection will follow the same format as the 2014 document and include a hard copy with the submission? This is not clear in the 2017 document.

Please include additional pages if necessary.

Comments on Phase 7: Confirmation by the Minister's Delegate The Society supports the content of this section and it appears that there are no significant changes from the 2014 document.
Comments on Phase 8: Notification in the *New Zealand Gazette* The Society supports the proposed clarification around electronic notifications that are documented in this section.
Comments on Phase 9: Implementation of a reclassification change The Society supports the changes proposed in this section of the consultation.
Are there any other comments you would like to make on the guidance document? The Society welcomes the opportunity to respond to this guidance document and we look forward to working with MCC to also progress the use of the new reclassification guideline and framework.

Please include additional pages if necessary.

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

HMB18-347

16 January 2018

Laurence Holding
Team Leader
Committee & Support Services,
Medsafe
Ministry of Health.

Email committees@moh.govt.nz Cc Laurence_Holding@moh.govt.nz

Dear Mr Holding

Updating the guidance document How to change the legal classification of a medicine in New Zealand.

Thank you for providing the Royal New Zealand College of General Practitioners (the College) with the opportunity to comment on this consultation.

Introduction to general practice and the College

General practice is the medical specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent 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 has a commitment to embed the three principles (participation, partnership and protection) of Te Tiriti o Waitangi (Treaty of Waitangi) across its work, and to achieving health equity in New Zealand.

Health equity is the absence of avoidable or remediable differences in health outcomes and access to health services among groups of people, whether those groups are defined socially, economically, demographically, or geographically (WHO). To achieve health equity, we advocate for:

- A greater focus on the social determinants of health (including labour, welfare, education, housing, and the environment).
- Funding and support to sustain the development of a GP workforce of sufficient capacity to meet population need for access to quality primary medical care, particularly in rural and high need areas.

- Sustained focus on measures to reduce smoking and to increase healthy food options for low-income families.
- Improved integration of primary, community, and secondary care health and social services which ensures the provision of high quality services.
- Universally accessible free primary health care for children and low-income families, because health inequities begin early and compound over the life course.
- A review of the funding model for primary care to ensure that resourcing is allocated equitably across diverse populations with differing needs.

Submission

The College welcomes the changes to the guidance document. We are particularly pleased to see that consideration of communal harm has been restored to the guidance and that it now is more prominent than in the 2014 version of the guidance. Specifically that it is included in the value tree tool used to produce the integrated benefit risk statement.

The guidance document includes useful information on the background and legislative context of the Medicines Classification Committee (MCC). We note the additional information in the background and legislative section, that the composition of the MCC is determined in the Medicines Act 1981. We acknowledge this Act is currently under review. As a part of this review we would like to see consideration of changes to the membership of the MCC. Specifically, as the organisation representing almost all general practitioners the College would appreciate having a greater role in nominating at least one of the medical members of the MCC.

The inclusion of risk mitigating strategies, and in particular the mention of post mark surveillance activities is also welcomed. We note an item in the October 2017 Pharmacy Council newsletter that indicates a need for continued vigilance.

> "A recent inspection audit pilot of 90 pharmacies in Auckland indicated that many pharmacies were not adhering to the criteria for legal supply of sildenafil. Quantities supplied in excess of the maximum of 12 per dispensing, dispensings not recorded in the patient history and sildenafil supplied to patients with clinical parameters, such as blood pressure, outside of the eligibility criteria are examples of practices identified". [1]

We are pleased to see that a number of the suggestions in the College 2016 submission on the update to the guidance document[2] have been taken on board. We provide further comments on some others under the relevant phase of the response template attached.

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1 http://www.pharmacycouncil.org.nz/Portals/12/Documents/Newsletters/Newsletter%20October%202017.pdf?ver=2017-10-19-163448-033

2 https://rnzcgp1.sharepoint.com/Website_documents/_layouts/15/guestaccess.aspx?guestaccesstoken=EOdYqKuP8XCrIGv2gZiH%2bM3UteEVvkCABCKfLJhPqQA%3d&docid=007f48e764cc24aee88237ef43741d479&rev=1f accessed 15.1.18

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

Please find the College submission containing further feedback on the guidance document attached.

We hope you find our submission helpful. Should you require any further information or clarification please contact the College's policy team at policy@rnzcgp.org.nz.

Yours sincerely,

Michael Thorn
Acting Chief Executive

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Email: rnzcgp@rnzcgp.org.nz, Web: www.rnzcgp.org.nz

Medsafe is seeking comments on the guidance document 'How to change the legal classification of a medicine in New Zealand:

Comments on Phase 1: Application

The MCC uses three principles when considering a medicine for suitability for non-prescription sale. The College has the two comments to make on the principles.

Firstly, the principles are worded in such a way that means that meeting any one of the principles is sufficient for a medicine to be suitable for non-prescription sale. The current wording permits the medication to be available without prescription whether or not it shows substantial safety so long as either principle (b) or principle (c) apply. The College considers that safety should apply whether non-prescribing health practitioner oversight is appropriate, or no oversight is needed.

The wording in the draft states:

> "Medicines available without a prescription should be able to either:
> (a) show substantial safety in use in the prevention or management of the condition or symptom under consideration, or
> (b) be for conditions or symptoms that can be diagnosed and managed by a pharmacist, nurse practitioner, nurse or podiatrist, or
> (c) be easily self-diagnosed and self-managed by a consumer."

The College considers that for a medication to be suitable to be available without prescription, it must always be substantially safe. The College recommends that the above wording of the principles is changed to:

Medicines available without a prescription should be able to show substantial safety in use in the prevention or management of the condition or symptom under consideration. They should also be for conditions able to be either:

- diagnosed and managed by a pharmacist *(in the case of restricted medicines)* or
- easily *(and accurately)* self-diagnosed and managed by a consumer *(in the case of pharmacy only or general sale medicines).*(emphasis added)

The College commented on the implication that any one of the three principles was sufficient in its response to the August 2016 consultation on the *Update to the Medicines Classification Committee Process*. In that draft the 'or' was implicit. We are concerned with the wording in the current draft that 'or' is explicitly stated rather than just implied, which increases rather than resolves the problem.

Secondly, the previous wording of principle (b) mentioned only pharmacists. The proposed wording also includes nurse practitioner, nurse or podiatrist. We suggest that the former wording, where pharmacists were the only practitioner type listed, be retained.

Whilst the particular medication may be for a condition appropriately managed by a health practitioner other than a doctor or pharmacist, the College considers that the professions should be specified for the particular medication. Principle (b) could then read "be for conditions or symptoms that can be diagnosed and managed by a pharmacist, *or other specified appropriate registered health practitioner."*

In addition, the majority of nurse practitioners are able to prescribe. It is therefore unnecessary and confusing to have nurse practitioners named in relation to principle (b).

Communal harm or benefit.

The College strongly welcomes the addition of communal harm or benefit as a benefit and risk consideration. The College has argued repeatedly that the previous decision criteria prevented relevant issues around fragmentation of care from being considered by the Committee. In the

case of some medications, omission of this consideration can result in a decision leading to potential serious unforeseen negative consequences for patients.

Communal harm or benefit was included in the January 2014 version of *How to change the legal classification of a medicine in New Zealand: Guidance Document*. However it was only included as the 10th of 10 criteria.

In the August 2016 *Update to Medicines Classification Committee Processes: consultation document*, communal harm did not appear. In the current draft, consideration of communal harm or benefit is re inserted and is appropriately elevated to become one of the benefit and risk considerations that is factored into the integrated benefit-risk statement.

It is important to consider 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 former Health and Disability Commissioner Ron Paterson commented in 2010 "Fragmented care looms large in complaints about medical care." [1] 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.[2] 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, and also improved health outcomes. The reclassification of some medications has only a minor effect on continuity of care but for others, the effect of down scheduling on continuity of care is significant. The College is pleased to see 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, will now be one of the factors the MCC considers when assessing applications for reclassification.

<u>The potential for medications to be approved for one indication but then marketed for another</u>.

The proposal relating to Betaine considered at the 57th meeting of the MCC is an example of a medication for which a restricted classification was sought on the basis of one indication (which would have affected a very small number of patients). However, the potential market from body builders wishing to use it for a different indication was not mentioned in the application. The College considers that similar issues may arise in future and there should be the ability for this to be covered by the parameters.

<u>Health Equity</u>

The College recommends that the effect of MCC decisions with regard to health equity also be considered by the MCC in its assessment of applications. Some over the counter (OTC) medications carry a price tag that renders them unavailable to those without access to sufficient financial resources. This potentially has a negative effect on health equity. The effect that a proposed change in practice or policy will have on health 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.

<u>Minor issues</u>

We also noted a couple of minor issues in this section. There appears to be a typo under parameter 8, (Communal harm and/or benefit). The current wording implies that increased immunisation causes community harm rather than community benefit which is obviously not the case. The wording is taken from an earlier version where the heading referred to both harm and benefit.

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[1] NZ doctor 24 March 2010 Window into world of care gone awry

[2] http://www.bpac.org.nz/BPJ/2012/october/elderlyMedicines.aspx accessed 15.1.18

There is a further typo in figure 1 where the new version of the value tree framework is missing the arrows between the risk considerations box and the categories (of which there are now six) that were present in the previous diagram containing only 5 categories.

Comments on Phase 2: Public consultation
The College supports the increasing transparency of the consultation process proposed.

Comments on Phase 3: Meeting and MCC recommendations
The College has provided a separate submission on Observers at MCC meetings.
Comments on the principles are included under Phase 1.
The College is pleased to see that further information and clarification supplied by the applicant will be made available for further consultation.

Comments on Phase 4: Noting of the MCC's recommendations by the Minister's Delegate
No comment

Comments on Phase 5: Publication of the minutes and MCC recommendations
No comment

Comments on Phase 6: Objection to an MCC recommendation
No comment

Comments on Phase 7: Confirmation by the Minister's Delegate
No comment

Comments on Phase 8: Notification in the *New Zealand Gazette*
With some reclassifications clinical and eligibility criteria are applied. These are not listed in the Gazette and it is difficult for a GP to advise a patient enquiring as to whether they might be able to obtain medication, (for example a repeat of the oral contraceptive), without prescription. The Gazette may not be an appropriate place for such information but it should be able to be easily accessed elsewhere and this is not current the case.

Comments on Phase 9: Implementation of a reclassification change
No comment

Are there any other comments you would like to make on the guidance document?

The Pharmacy Council process for medicines reclassification Appendix 2.

The College is concerned at the lack of clarity around the underpinning framework mentioned in point 2. This is referred to only as "The Council/PSNZ framework".

For the robustness of the Council process to be assessed, it is necessary for this document to be read. The College considers that the "Council/PSNZ framework" should be referred to by its official title and a link to it provided.

In our April 10th 2017 submission in response to the MCC we stated

> We note that the "Council framework" will be established in collaboration with the Pharmaceutical Society. This framework "will set out any training programme requirements and mandatory patient consultation outcomes.[3]". It is unfortunate that this framework is not already available to allow it to be considered alongside this proposal. It is important that in the development of the framework issues of conflict of interest are dealt with appropriately.

The minutes of the 58th MCC meeting say that the documents (Pharmacy council/Pharmaceutical society process for medicines reclassification) would be released for consultation following the 58th meeting. This meeting was in May 2017. The College is not aware of this consultation having taken place.

The College strongly supports the Pharmacy Council having the responsibility to determine the additional training requirements for pharmacists (if any) rather than the Pharmaceutical or Pharmacy retailing organisation proposing the reclassification.

[3] http://www.medsafe.govt.nz/profs/class/Agendas/agen57PharmacyCouncil.pdf

12 Jan 2018

Medicines Classification Committee and Medsafe Staff

Medsafe

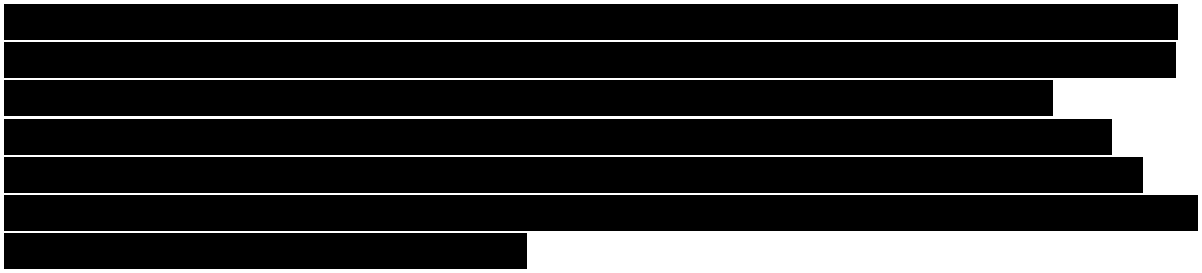
Wellington

Dear Sir/Madam,

Re: Consultation document regarding reclassification guidelines

Thank you for the opportunity once again to respond to changed guidelines for reclassification.

New Zealanders and the New Zealand health system have benefited from reclassifications of medicines. Even New Zealanders who do not use these medicines can benefit. For example, pharmacists (anecdotally and in research(1)) have reported referrals from general practice or accident and emergency clinics at busy times for women with symptoms of cystitis. Such referrals will benefit the patient, reduce a waiting time in an accident and emergency clinic for other patients, and/or allow a little more time with another patient or reduce the stress for the GP of squeezing in an extra patient on a busy Friday afternoon.



Supplies of sildenafil intercepted by Customs have reduced following an upward trajectory prior to the reclassification, and this is consistent with anecdotal evidence from pharmacy of men saying they have moved from internet supply to pharmacy supply.

To ensure reclassification continues to benefit New Zealanders, there is a need to consider how we can enable reclassification while maintaining safety. New Zealand has been known to be innovative and flexible in this area(3, 4), and such an approach is very desirable here.

1. Consideration needs to be given to best practice internationally that achieves safe reclassifications without providing strong disincentives to companies to apply for the reclassification. There is no evidence that this has occurred.
2. Intellectual property needs to be protected, for example using a similar process to Pharmac. There is no other country in the world that I am aware of where this level of publication of intellectual property occurs with a reclassification. This intellectual property includes the reference list and some arguments made.
3. Increasing the burden on the applicant will further limit applications for reclassifications. For example, requiring commentary about importation of

medicines which internal Medsafe staff are better able to make a recommendation on, have evidence of the risk mitigation strategies, or do post-marketing surveillance for a small market. Some applicants will not have access to data that manufacturers have, e.g. reported medication errors post-market. Inability to provide this data needs to be allowed for. Is there evidence that asking some of these questions will provide better health for New Zealanders?

4. Market exclusivity in New Zealand, for example, for three years for the applicant might incentivise some of this additional work, and should be considered. However, market exclusivity in such a small market may not overcome the commercial difficulties faced by companies with their intellectual property being shared publicly.
5. A scientific advisory meeting between the applicant and regulator has been found useful in other countries, such as the UK. [redacted] It is difficult to see that a one hour meeting between the applicant and Medsafe would be excessive in either resource or conflict of interest. Is it possible to reconsider this?
6. It is difficult to comment on the proposed Pharmacy Council and Pharmaceutical Society of NZ process when there is no indication of the time involved nor the cost.
7. The Pharmacy Council and Pharmaceutical Society of NZ document could usefully include commentary on how these organisations will help support pharmacists to take the correct action for that reclassification.
8. The Medicines Classification Committee needs to be able to choose a different pathway to the Pharmacy Council/Pharmaceutical Society recommendation if desired, with the applicant able to recommend this.
9. Little of the Pharmacy Council and Pharmaceutical Society of NZ document about a reclassification should be made publicly available owing to the commercial sensitivity of the intellectual property involved. Having oversight from these organisations and requiring medical input is sufficient for a simple outline to be provided for consultation.
10. I am pleased to see that the key papers will not be published on the Medsafe website. This is appropriate.
11. Submissions from the public consultation should not all be published. The UK and Australia allow an opt-out for this for submitters, allowing more freedom of comment.
12. Is there an oversight that the Medsafe report sent with the Medicines Classification Committee minutes to the Minister's Delegate is not published while virtually everything from the applicant is?

A number of changes have occurred over the past five years. It is important that with every change the committee considers how will this affect access to medicines for New Zealanders. I strongly recommend a reconsideration of earlier decisions around publication, as they have limited opportunities to widen access to medicines in New Zealand, an example of which is [redacted]

New Zealand is a very small market. If an action in the New Zealand market might negatively influence a larger market, a multi-national will avoid it. For international

pharmaceutical companies, the publication of information that disadvantages them commercially makes doing truly innovative reclassifications in New Zealand unattractive. This has been clear from my work and discussions with multinationals, including during my published PhD research considering this area(3, 4). Medsafe has received communications on this from industry and myself previously noting the detriment to New Zealanders from this move. The last time a multi-national applied for an innovative switch involving important intellectual property was 2009 with famciclovir. From 2004-2009 there were seven innovative reclassifications successfully applied for by multinationals. From 2010 to 2017 action has been extremely limited from multi-nationals. The greatest activity seen was when GSK applied for the hydrocortisone-aciclovir combination for herpes labialis – with two ingredients that were already non-prescription, so little intellectual property was required.

Given the potential benefits of reclassification, and barriers to reclassification, in some other countries, such as the UK, Ireland and Japan, there has been an interest in how reclassification can better be enabled by the regulator and process.

I trust that these insights and comments have been helpful.

Yours sincerely,

[redacted]

[redacted]

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3. Gauld NJ, Kelly FS, Emmerton LM, Buetow SA. Widening consumer access to medicines: A comparison of prescription to non-prescription medicine switch in Australia and New Zealand. PLoS ONE 2015;10:e0119011.
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