



9 February 2016

Hannah Hoang
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Ministry of Health
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Email: Hannah_Hoang@moh.govt.nz

Dear Hannah

Response to the minutes of the 54th meeting of the MCC

The Royal New Zealand College of General Practitioners (the College) has noted the minutes of the 54th meeting of the Medicines Classification Committee (MCC) held on 24 November 2015 and released on 27 January 2016.

We write to you in order to record our concerns that:

- The minutes are not accurate
- The process followed by the MCC in reaching a decision on the classification of the OCP is administratively unsafe - and may result in a decision that creates a risk-of-harm to patients.

The College submits that the appropriate remedy to these concerns is for the MCC to:

- Append an explanation to the minutes of the 54th meeting to make clear that the MCC was mistaken in its assumption that the alternative proposal submitted by Green Cross Healthcare Ltd had been made publicly available
- Conduct a full and appropriate consultation with all relevant stakeholders, including the College, on the alternative proposal before finalising its decision to reclassify the OCP
- Conduct a thorough review of its consultation processes to ensure that in future these are: transparent; proactive; open; robust and; include safeguards to protect against regulatory capture.

Further information about the College's concerns are outlined below.

MCC's failure to act on previous concerns raised

Before discussing our current concerns, the College draws your attention to the comments it provided to the 49th and 54th meetings of the MCC. In a letter to the MCC dated 31 March 2015 the College stated that:

The MCC has asked for feedback on its consultation process. This is an area where the College has considerable concern. The current MCC process is opaque, and it is very difficult for an outsider to find out: what is being discussed by the MCC; the content of any supporting documentation; when and how to provide feedback; whether further opportunities for

comment will be provided; and how to provide that further comment. It appears to the College that MCC processes are primarily used by those who have engaged regularly with the MCC over a number of years, and that it is very difficult for anyone unfamiliar with the MCC and its processes to provide input. The College has previously expressed concern with the public consultation process.¹

The College is further concerned that there is also a strong risk of regulatory capture² in the MCC processes. On the one hand you have industry bodies that stand to benefit financially and substantially from MCC decisions, and which are therefore willing to invest considerable time and effort into making submissions, following debates and pushing for change. On the other hand you have the public interest, which, if it is represented at all, is represented by a diverse group of organisations – which usually: have a broad range of other interests and responsibilities; have minimal engagement because of competing priorities; have low awareness of MCC issues because of the agency's opaque and complicated processes; and stands to receive no financial or other benefit from the outcome of MCC processes.

The current agenda contains links to over 120 pages of submissions. These in turn reference other documents that need to be read to evaluate the submission. Often organisations commenting on proposals have limited resources and need to spread what resource they have between all the items on the agenda. There is the potential for multiple proposals to be made in the knowledge that organisations will be very stretched to make robust comment on them all.

...

In our opinion, the current MCC consultation processes are not robust and present a high-risk of decisions that favour industry rather than the public interest.

The recent actions of the MCC relating to the reclassification of the OCP only reinforce the College's opinion that its consultation processes are not robust and present a high-risk of decisions that favour industry rather than the public interest.

Further, we are of the view that the processes followed in relation to the decision to reclassify the OCP have been administratively unsafe and may result in a decision that creates a risk-of-harm to patients. The reasons for this view are that:

- The MCC failed to conduct an appropriate consultation
- The MCC failed to provide appropriate information when requested
- The MCC failed to respond to an opportunity to correct its oversight.

Further detail on these failures is noted below.

The MCC failed to conduct an appropriate consultation

The minutes of the 54th meeting of the MCC note (on page 3):

“Green Cross Healthcare Limited submitted a revised proposal for consideration if the objection was upheld. The alternative proposal requested the reclassification of desogestrel,

¹ <https://www.rnzcgp.org.nz/assets/Submissions/Agenda-for-49th-Meeting-of-the-medicines-Classification-Committee.pdf>

² Regulatory capture is the process by which regulatory agencies eventually come to be dominated by the very industries they were charged with regulating.

ethinylestradiol, levonorgestrel, and norethisterone to restricted medicines when indicated for women who had previously been prescribed an oral contraceptive pill (OCP).

...

The Committee then discussed whether to consider the alternative proposal provided by Green Cross Healthcare Limited for this meeting. **The Committee noted that the alternative proposal included in the submission was within the material released for public consultation prior to the meeting** and the Committee had received submissions on the proposal from several organisations. The Committee therefore agreed that it was appropriate to consider the alternate proposal put forward by Green Cross Healthcare Limited."

The highlighted portion of this text is not correct. The alternative proposal was not provided as part of the original information provided for public viewing. The College did not view this information prior to the meeting and, as far as it has been able to establish, no other medical organisation viewed the proposal at this time either.

The MCC failed to provide appropriate information when requested

Further, the alternative proposal was not provided in response to a written request for information submitted by the College to the MCC on 31 August 2015. In fact, the alternative proposal was not provided to the College until 28 January 2016, i.e. almost two months after the MCC decision had been made.

The MCC failed to respond to an opportunity to correct its oversight

The College is further concerned that it has not been provided with a fair and reasonable opportunity to respond to the recommendation of the MCC to accept Green Cross Healthcare Ltd's alternative proposal, as recorded in the minutes of the 54th meeting.

As noted above, the College was not provided with the proposal until 28 January 2016. The College was subsequently advised that it would need to lodge an "intent to object" by 9 February 2016, and that supporting data would be due on 5 April 2016. In accordance with this advice, the College lodged a notice on 1 February 2016 to advise that it intended to object on the grounds of both process and public safety.

At 4.04pm on 5 February 2016 the College received a response advising that its notice had been deemed "invalid" by the Chair of the MCC. No explanation was provided of why the College notice had been deemed "invalid", however an email sent by you stated that the College would be provided with an extension until 11 February 2016 to lodge a revised notice that includes both "a notice of intention to object" and "a summary of the grounds for that objection (including reference to any supporting data to be provided)".

The College can only assume that its notice was deemed "invalid" because it did not include reference to supporting data.

Before the College can provide supporting data, good process dictates that it should: conduct a review of the relevant scientific literature and; as a membership organisation that relies heavily on the expertise of GPs, seek input from its members.

It is not possible for the College to undertake either process in the two working days provided (noting that your email was received at the end of the day on a Friday before a long weekend, and that a response was requested by 9am on the following Thursday morning).

While, at first glance, the position taken by the MCC to allow pharmacists to provide the OCP only after a prescription has been initiated by an authorised prescriber appears to be reasonable, the College is unable to appropriately evaluate the risks to public health and safety because it has not been provided with a fair and reasonable opportunity to comment.

Appropriate remedy

The College submits that an appropriate remedy to these concerns would be for the MCC to:

- Append an explanation to the minutes of the 54th meeting to make clear that the MCC was mistaken in its assumption that the alternative proposal submitted by Green Cross Healthcare Ltd had been made publicly available
- Conduct a full and appropriate consultation with all relevant stakeholders, including the College, on the alternative proposal before finalising its decision to reclassify the OCP
- Conduct a thorough review of its consultation processes to ensure that in future these are: transparent; proactive; open; robust and; include safeguards to protect against regulatory capture.

We look forward to receiving your response, and trust that further action to obtain appropriate remedy will not be necessary. If you have any questions or comments, please do not hesitate to contact the College's policy team (policy@rnzcgp.org.nz).

Yours sincerely

A handwritten signature in black ink, appearing to be 'Michael Thorn', written over a circular scribble.

Michael Thorn
Manager Strategic Policy