PHARMACEUTICAL SOCIETY
of New Zealand Incorporated

12 March 2019

Medicines Classification Committee Secretary
Medsafe
PO Box 5013
Wellington 6145
via email: committees@moh.govt.nz

Dear Jessica,

MEDICINES CLASSIFICATION COMMITTEE (MCC)
COMMENTS TO THE 62nd MEETING AGENDA Thursday 11th April 2019

Thank you for the opportunity to submit comments on the Agenda for the 62nd meeting of the Medicines Classification Committee.

The Pharmaceutical Society of New Zealand Inc. (the Society) is the professional association representing over 3,000 pharmacists, from all sectors of pharmacy practice. We provide to pharmacists professional support and representation, training for continuing professional development, and assistance to enable them to deliver to all New Zealanders the best pharmaceutical practice and professional services in relation to medicines. The Society focuses on the important role pharmacists have in medicines management and in the safe and quality use of medicines.

Regarding the agenda items for the above meeting of the Medicines Classification Committee, The Pharmaceutical Society would like to note the following comments for consideration:

6.1 Reclassification of Ropivacaine up to 10 mg/mL, solution for injection – proposed reclassification from prescription medicine to prescription except classification (Podiatrists Board of New Zealand)

The Society supports the application to reclassify Ropivacaine.

6.2 Reclassification of Bupivacaine up to 0.5% w/v in combination with adrenaline – proposed reclassification from prescription medicine to prescription except classification (Podiatrists Board of New Zealand)

The Society supports the application to reclassify Bupivacaine.
The Society supports the reclassification of Bupivacaine and adrenaline if there are sufficient safety mechanisms in place to reduce any patient risks with the use of these combination products.

Thank you for consideration of this submission. I would be happy to discuss any aspect of this submission further, if required.

Yours sincerely,

[redacted]

Chris Jay
Manager Practice and Policy
[redacted]

19 March 2019

Jessica Lo
Advisor Science
(Secretary for the MAAC and the MCC)
Medsafe
Ministry of Health

Email to: committees@moh.govt.nz

Dear Jessica

Re: Reclassification of a Medicine for Consideration by the Medicines Classification Committee

The New Zealand College of Podiatric Surgery (NZCPS) would like to thank the members of the Medicines Classification Committee for the opportunity to provide feedback upon the Podiatrists Board of New Zealand (PBNZ) submission for the reclassification of Ropivacaine and Bupivacaine.

The NZCPS would also like to thank and commend the PBNZ for the time and effort that it has committed to the writing of this application.

On behalf of the NZCPS I would like to refer directly to and comment on a number of details raised within the Board's document – details which the NZCPS considers may affect the clinical and administrative use of Ropivacaine and Bupivacaine within the New Zealand Podiatric surgical Scope of Practice.

The MCC's agenda for its 62nd meeting refers to:

6.1 Ropivacaine up to 10mg/mL, solution for injection – proposed reclassification for prescription medicine to prescription accept classification (Podiatrists Board of New Zealand), however the PBNZ's request for the reclassification of Ropivacaine is limited to the concentrations ranging from 2mg/ml 0.2% to 7.5mg/ml 0.75%.

Please refer to the PBNZ submission:

Part A

4. Dose form(s) and strength(s) for which a change is sought. Ropivacaine (0.2% 2mg/mL) solution for injection. Ropivacaine (0.75% 7.5mg/mL solution for injection).

5. Pack size and other qualifications. Ropivacaine 2mg/mL, 10mL and 20mL vials. Ropivacaine 7.5mg/mL 10mL and 20mL vials.

The omission of Ropivacaine at a dose concentration of 1%, 10mg/mL solution may be an oversight, however by means of clarification, the NZCPS strongly suggests that the PBNZ Registered Scope of Practice of Podiatric Surgeon requires the ability to effectively facilitate and appropriately manage post-operative pain.

[redacted]

Post-operative pain is often the predominant post surgical symptom, it can be considered an important outcome of surgery. Patients may relate improved pain control to improve post-operative outcomes. [3, 4, 5, 6, 7, 8]

Bonnet et al 2004 explained, "post-operative symptoms and complications can be prevented by a suitable choice of anaesthetic and analgesic techniques for specific procedures. The aim of analgesic protocols is not only to reduce pain intensity but also to decrease the incidence of side-effects from analgesic agents and to improve patient comfort." [1]

The NZCPS respectfully suggests that the PBNZ's request for the reclassification of Ropivacaine for registered podiatrists should include the Ropivacaine concentration of 10mg/mL (1%). The use of this higher concentration, form/dose of Ropivacaine is appropriate for surgery that requires an anaesthetic effect upon larger neurological structures that are positioned deep within the mid foot and at the rear foot. These deeper positioned neurological, larger structures are often tightly positioned between muscular fascial compartments that are difficult to infiltrate with larger volumes of fluid/anaesthetic. The NZCPS further argues that a restriction to the parenteral, use of the lower concentrations of 2mg/mL (0.2%) and 7.5 mg/mL (0.75%) will have a reduced analgesic effect on these structures and are neither optimal or suitable for cases requiring efficient mid to rear foot analgesic effect.

The NZCPS would therefore recommend that the PBNZ's submission to the MCC should include the reclassification of Ropivacaine at a concentration of 10mg/mL (1%).

The NZCPS would also draw the attention of the MCC to the PBNZ's Consultration Document for Prescribing Authority for Registered Podiatrsists (Feb 2019) which does include the higher concentration of Ropivacaine 10mg/mL (1%).

The NZCPS understands the need for the surveillance of any medication that is newly introduced to the market, however it is widely accepted that the use of Ropivacaine has a 23 year history of international use within the Podiatric surgical field.

It is deemed to be an effective and safe alternative to other local anaesthetics, including but not limited to Lidocaine, providing analgesia for cases/surgeries that require an extended analgesic effect.

Ropivacaine can be used effectively as a local anaesthetic for digital nerve blocks. It can be used for prolonged operations (greater than 1.5 hours) without additional injections and provides long-lasting post-operative analgesia. [2]

The NZCPS notes with interest that New Zealand registered Podiatrists are not be required to submit an anaesthetic log book for their ongoing administration and use of local analgesia utilising Lidocaine which is an anaesthetic that shares the same pharmacological risks as Ropivacaine. Therefore the PBNZ's proposed requirement for a post-market surveillance activity that is limited to New Zealand Podiatric Surgeons through the provision of providing an annual local anaesthetic log book is considered by the College to be unjustified, inequitable and onerous.

The NZCPS believes the reclassification and availability of Ropivacaine should be available to all PBNZ Registered Podiatrists. We understand this provision has been requested within the NZPBs list of medications for Podiatric prescribing authority document (February 2019).

Thank you once again on behalf of all PBNZ Registered Podiatric Surgeons for being given the opportunity to offer this feedback to the MCC and on behalf of the NZCPS, I look forward to being of further assistance to the MCC should that be requested.

With Kind Regards

[redacted]

Mr Stefan R Edwards, FNZCPS
PODIATRIC SURGEON
President, New Zealand College of Podiatric Surgery

References:

1. Bonnet F, Marret E, Influence of anaesthetic and analgesic techniques on outcomes after surgery, Br J Anaetts 2005;95:52-8.
2. Keramidas EG, Rodopoulou Sg, Ropivacaine versus Lidocaine in digital nerve blocks: a prospective study, plast reconstr surg 2007 Jun;119(7):2148-52.
3. Barden J, Edwards J, Moore A, McQuay H. Single dose oral paracetamol (acetaminophen) for post-operative pain, Cochrane Database Syst Rev 2004;I:CD004602
4. Block BM, Liu SS, Rowlingson AJ, Cowan AR, Cowan JA, Wu CL, Efficacy of post-operative epidural analgesia : meta-analysis JAMA 2003:290:2455-63.
5. Hyllestted M, Jones S, Pedersen JL, Kehlet H. Comparative effects of paracetamol, NSAIDs or their combination in post-operative pain management: a qualitative review. Br J Anaesth 2002;88:199-214.
6. Romsig J, Moiniche S, Dahl JB, Rectal and parenteral paracetamol and paracetamol in combination with NSAIDs to post-operative analgesia. Br J Anaesth 2002;88:215-26
7. Subramanian K, Subramaninan B, Steinbrock RA. Ketamine as adjuvant to opioids: a quantitative and qualitative systemic review. Anesth Analg 2004;99:482-95.
8. Walder B, Schafer M, Henzil, Tramer MR, Efficacy and safety of patient –controlled opioid analgesic for acute post-operative pain. A quantitative systemic review. Acta Anaesthetist Scand 2001;45:795-804.