



15 September 2017

Our Ref: MT17-295

Product Regulation
Medsafe
PO Box 5013
WELLINGTON 6140

Email: medsafeapplications@moh.govt.nz

Dear Sir/Madam

Proposed change to warning statements on labels of oral non-steroidal anti-inflammatory drugs (NSAIDs) available without a prescription

Thank you for providing the College with the opportunity to comment on the proposal to add warnings related to the increased risk of miscarriage to the warning statements required on NSAIDs available without prescription.

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 supports the change to the warning statement as proposed. Members commented that this change was well overdue.

Members also suggested that a wider review of warning statements on over the counter NSAIDs should be considered. In particular it was felt that the warnings related to the use in children should be updated and strengthened in line with guidance to GPs. Current guidance¹ stresses the risk of acute kidney injury (AKI) even at recommended dosages. This is a particular risk in children who are volume depleted and volume depletion can occur when a child is feverish and reluctant to drink or is vomiting. There is some suggestion that overweight children may be at higher risk. Younger children with NSAID induced AKI are more likely than older children to require dialysis.²

In addition the Label Statements Database entries for NSAIDs appear to contain inconsistent warnings regarding the use of NSAIDs in children. For example when Ibuprofen in a solid dose form is sold as a restricted medicine (i.e. by a pharmacist) the required warning label states “do not use in children under 12 years”. However if purchased in a supermarket the label requirement is “do not use in children under 6 years old except on doctors’ advice”.³ It seems inconceivable that Ibuprofen is safer in 6-12 year olds if purchased from a supermarket than it is after discussion with a pharmacist who will be aware of the risk of AKI. For Diclofenac there does not appear to be any requirement for the warning label to mention use in children when sold over the counter.

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
Manager – Strategic Policy

¹ <http://www.bpac.org.nz/BPJ/2013/October/nsaids.aspx> and <http://www.bpac.org.nz/BPJ/2014/July/news.aspx> accessed 14/9/17

² Nonsteroidal Anti-Inflammatory Drugs Are an Important Cause of Acute Kidney Injury in Children [http://www.ipeds.com/article/S0022-3476\(12\)01403-5/fulltext](http://www.ipeds.com/article/S0022-3476(12)01403-5/fulltext) accessed 14/9/17

³ <http://www.medsafe.govt.nz/regulatory/labelling.asp> accessed 14/9/17