

# Medsafe consultation submission



## Proposed change to warning statements on labels of oral non-steroidal anti-inflammatory drugs (NSAIDs)

<b>Name and designation</b>	██████████
<b>Company/organisation name and address</b>	Royal New Zealand College of General Practitioners (RNZCGP)
<b>Contact phone number and email address</b>	██████████
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable. Reasons for requesting confidentiality must meet <a href="#">Official Information Act 1982</a> criteria)</i>	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
I would like my name not to be included within the list of submissions published on the Medsafe website.	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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

<b>I am, or I represent, an organisation that is based in:</b>			
<input checked="" type="checkbox"/> New Zealand	<input type="checkbox"/> Australia	<input type="checkbox"/> Other ( <i>please specify</i> ):	
<b>I am, or I represent, a: (<i>tick all that apply</i>)</b>			
<input type="checkbox"/> Importer	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Supplier	<input type="checkbox"/> Sponsor
<input type="checkbox"/> Government	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Professional body	<input type="checkbox"/> Industry organisation
<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Member of the public	<input type="checkbox"/> Institution (e.g. university, hospital)	
<input type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional		
<input type="checkbox"/> Health professional – <i>please indicate type of practice:</i>			
<input type="checkbox"/> Other - <i>please specify:</i>			

**Please return this form by:**

**Email:** [medsafeapplications@moh.govt.nz](mailto:medsafeapplications@moh.govt.nz) including 'NSAIDs warning statements' in the subject line

**Or Post:** Product Regulation  
Medsafe  
PO Box 5013  
Wellington 6145

**Medsafe is seeking comments on:**

*Whether you support the proposed changes to warning statements regarding use in pregnancy.*

- Is there a need to include this wording on the packaging?

- Is the wording acceptable? If you do not support the wording of the statements please make suggestions for alternatives acceptable to you.

Please see attached submission letter.

*Do you agree with the proposed list of medicines this statements should apply to?*

- If you do not support this, please provide your reasoning.

Please see attached submission letter.

Please include additional pages if necessary.

*What is a suitable target date for implementation?*

- Please provide justification

*Are there any other comments you would like to make?*

Please see attached submission letter for comment regarding NSAIDs in children and the risk of acute kidney disease.



15 September 2017

Our Ref: MT17-295

Product Regulation  
Medsafe  
PO Box 5013  
WELLINGTON 6140

Email: [medsafeapplications@moh.govt.nz](mailto: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**

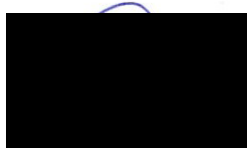
The College supports the change to the warning statement as proposed. Members commented that this change was well overdue.

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 guidance<sup>1</sup> 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.<sup>2</sup>

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”.<sup>3</sup> 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](mailto:policy@rnzcgp.org.nz).

Yours sincerely,



Manager – Strategic Policy

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<sup>1</sup> <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

<sup>2</sup> 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

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