

Medsafe consultation submission



Addition of warning statements on labels of OTC oral and topical diclofenac medicines

Name and designation	
Company/organisation name and address	Novartis Consumer Health Australasia 327 Police Rd. Mulgrave, VIC, Australia.
Contact phone number and email address	
I would like the comments I have provided to be kept confidential: <i>(Please give reasons and identify specific sections of response if applicable)</i> Inclusion of internal company studies. (Reasons for requesting confidentiality must meet <u>Official Information Act 1982</u> criteria)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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It would help in the analysis of stakeholder comments if you provide the information requested below.

I am, or I represent, an organisation that is based in:

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I am, or I represent, a: *(tick all that apply)*

- Importer Manufacturer Supplier Sponsor
 Government Researcher Professional body Industry organisation
 Consumer organisation Member of the public Institution (e.g. university, hospital)
 Regulatory affairs consultant Laboratory professional
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Please return this form to:

Email: askmedsafe@moh.govt.nz including 'Diclofenac warning statements' in the subject line

Or Post: Product Regulation
 Medsafe
 PO Box 5013
 Wellington 6145

Medsafe is seeking comments on:

Oral Diclofenac warning statements

Novartis Consumer Health supports the addition of cardiovascular warning statements on the labels of over-the-counter (OTC) oral diclofenac. However, Novartis Consumer Health requests that Medsafe considers a harmonised approach with the Therapeutic Goods Administration (TGA), both in terms of the exact wording of the warning statements and in terms of consistency across all OTC oral non-steroidal anti-inflammatory drugs (NSAIDs). Please see attached response document.

Topical Diclofenac warning statements

For OTC topical diclofenac, Novartis Consumer Health strongly opposes the addition of a cardiovascular warning. There is no safety signal, trial data or observational research data to suggest an increased cardiovascular risk with topical diclofenac. Novartis Consumer Health considers that the addition of label warning statements based on insufficient evidence as not justified. Please see attached response document.

12 December 2015 - target date for implementation:

Novartis Consumer Health proposes an alternative target implementation date of 1 July 2016. This is in line with the target implementation date in Australia.

Please see attached response document.