

20th June 2015

CONFIDENTIAL

Product Regulation
Medsafe
PO Box 5013
WELLINGTON

CONSULTATION RESPONSE

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

The New Zealand Self Medication Industry (NZSMI) is the representative trade organisation for the major "over the counter" (OTC) medicine sponsor companies within New Zealand.

We appreciate the opportunity to make comment on the consultation document and hope our comments are taken in a constructive manner to assist in developing the final document.

We are willing to support our comments verbally if required and meet with representatives of Medsafe if appropriate.

Yours faithfully


Tim Roper
Executive Director
New Zealand Self-Medication Industry

Ph/Fax +64 9 235 5260
M +64 21 992 113

Email tim.roper@nzsmi.org.nz
Web www.nzsmi.org.nz

Pencarrow, 203 Whiriwhiri Rd, RD2, Waiuku 2682, Auckland.
PO Box 6473, Auckland, New Zealand

Executive Summary

NZSMI welcomes the opportunity to comment on the proposed addition of warning statements on labels of OTC oral and topical diclofenac medicines.

NZSMI are broadly in agreement with most (but not all) recommendations made, as detailed below.

Harmonisation with Australia

In the interests of harmonisation with Australia, NZSMI encourage Medsafe to align the exact wording of the warning statements for oral medicines as detailed by the TGA in their final proposal of 11 June 2015 (<https://www.tga.gov.au/node/705497>).

Oral diclofenac warning statements

- Overall NZSMI supports the proposed amendments to labelling of OTC oral diclofenac medicines, including the addition of the cardiovascular warning statements.

Topical diclofenac warning statements

- NZSMI supports *in part* the proposed warning statements for OTC topical diclofenac medicines.
- NZSMI opposes the addition of the cardiovascular warning statements for OTC topical diclofenac medicines. A detailed explanation on why NZSMI believe this statement is not required is provided in Appendix 1.
- NZSMI supports the intent of the statement on duration of use, but suggests that the duration specified be carefully reviewed against the licenced details for all OTC topical diclofenac medicines.

Target date for implementation

- NZSMI strongly recommend that an implementation date of 1 July 2016 be adopted, in line with the implementation date specified by the TGA.