

Medsafe consultation submission



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

Name and designation	[REDACTED], Intern Pharmacist	
Company/organisation name and address	N/A	
Contact phone number and email address	[REDACTED]	
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 Official Information Act 1982 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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No
I would like my name not to be included within the list of submissions published on the Medsafe website.		<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

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:			
<input checked="" type="checkbox"/> New Zealand	<input type="checkbox"/> Australia	<input type="checkbox"/> Other (<i>please specify</i>):	
I am, or I represent, a: (<i>tick all that apply</i>)			
<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 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 checked="" type="checkbox"/> Health professional – <i>please indicate type of practice</i> : Pharmacist Intern			
<input type="checkbox"/> Other - <i>please specify</i> :			

Please return this form by:

Email: 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.

I agree with the proposed label changes and would like the advice to be extended to those that are prescription products. It's scary seeing a midwife script for a heap of Ibuprofen when the patient appears to be pregnant and the risks of NSAIDs in pregnancy are pretty clear.

To my mind I can't think of a case where an NSAID absolutely **has** to be used by a pregnant or attempting to get pregnant female, there are both safer OTC and prescription products which can be safely used (paracetamol for OTC, low strength opiates in combination with paracetamol for prescription – just as an example).

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

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

I agree and as stated above I would like the warnings to be extended to prescription NSAIDs as they have little place in the treatment of a pregnant woman. I am a new health professional so perhaps I am very much wrong in that regard – but if an argument can be made for alternative safer therapies then I believe it should apply as such.

Please include additional pages if necessary.

What is a suitable target date for implementation?

- Please provide justification

Early 2018 – This gives those that market these products time to change their packaging to make it compliant and gives time for pharmacists/doctors/other prescribers to be made aware of the changes.

Are there any other comments you would like to make?

Please include additional pages if necessary.