

Medsafe consultation submission

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

Name and designation	, Professional Services Pharmacist			
Company/organisation name and address	The Pharmacy Guild of New Zealand (the Guild)			
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. Reasons for requesting confidentiality must meet Official Information Act 1982 criteria</i>)			⊠No	
I would like my name to be removed from all documents prior to publication on the Medsafe website.			⊠ No	
I would like my name not to be included within the list of submissions published on the Medsafe website.			⊠ 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:							
⊠ New Zealand	Australia	□ Other (<i>please spe</i>	cify):				
I am, or I represent, a: (tick all that apply)							
□ Importer	Manufacturer	🗆 Supplie	∍r	□ Sponsor			
Government	□ Researcher	⊠ Profess	sional body	\Box Industry organisation			
□ Consumer organisation	□ Member of th	e public 🛛 🗆 Instituti	on (e.g. unive	ersity, hospital)			
□ Regulatory affairs consulta	nt 🛛 Laboratory pi	ofessional					
☐ Health professional – please indicate type of practice: Pharmacist							
□ 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.

The Guild supports the proposal to change the warning statements regarding the use of NSAIDS in pregnancy. We believe there is a need to include this wording on the packaging as this would aid the consumer to make an informed choice at the time of purchase.

We feel the wording of the warning statement needs to reflect all health professionals that provide care for pregnant women (eg, midwives and pharmacists) not just doctors. We could like to suggest the following alternative warning statement.

"Do not use [product name] if trying to become pregnant or during the first 6 months of pregnancy except on advice from your doctor, midwife or pharmacist "

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

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

Yes, we agree with the proposed list of medicines the warning statement should apply to.

	What is a s	uitable target	date for i	implementation?
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- Please provide justification

Implementation needs to allow sufficient time for current stock to move though the supply chain. We feel 12 months is sufficient time for implementation.

Are there any other comments you would like to make?

This proposal highlights the potential risks of taking NSAIDS during pregnancy. NSAIDS also pose significant risks for other population groups (eg, people with kidney disease, asthma and those taking medicines such as lithium, ace inhibitors and diuretics). It therefore concerns us that some NSAIDS can be purchased as unsupervised general sales medicines from retail outlets without verbal advice or counselling from a health care professional.

Medicines are not ordinary items of commerce and in the interest of public safety we believe Medsafe should review the general sale classification of NSAIDS.

Thank you for considering our response.