

Medsafe consultation submission

Addition of warning statements on labels of topical miconazole-containing medicines			
Name and designation			
Company/organisation name and address	Mylan New Zealand Limited PO Box 11183, Ellerslie Auckland 1542		
Contact phone number and email address			
I would like the comments I have provided to be kept confidential: (Please give reasons and identify specific sections of response if applicable)			entify
(Reasons for requesting confide	ntiality must meet Official Informatio	<u>1 Act 1982</u> criteria)	
I would like my name to be removed from all documents prior to publication on the Medsafe website.			ebsite.
I would like for my name not to be included within the list of submissions published on the Medsafe website.			safe
It would help in the analysis of stakeholder comments if you provide the information requested below.			
I am, or I represent, an o	rganisation that is based in		
l am, or l represent, a: (tick all that apply)			
		Supplier	⊠ Sponsor
Government	Researcher	☐ Professional body	☐ Industry organisation
☐ Consumer organisation	☐ Member of the public	☐ Institution (e.g. university, hospital)	
Regulatory affairs consultan	t		
☐ Health professional – please indicate type of practice:			
☐ Other - please specify:			

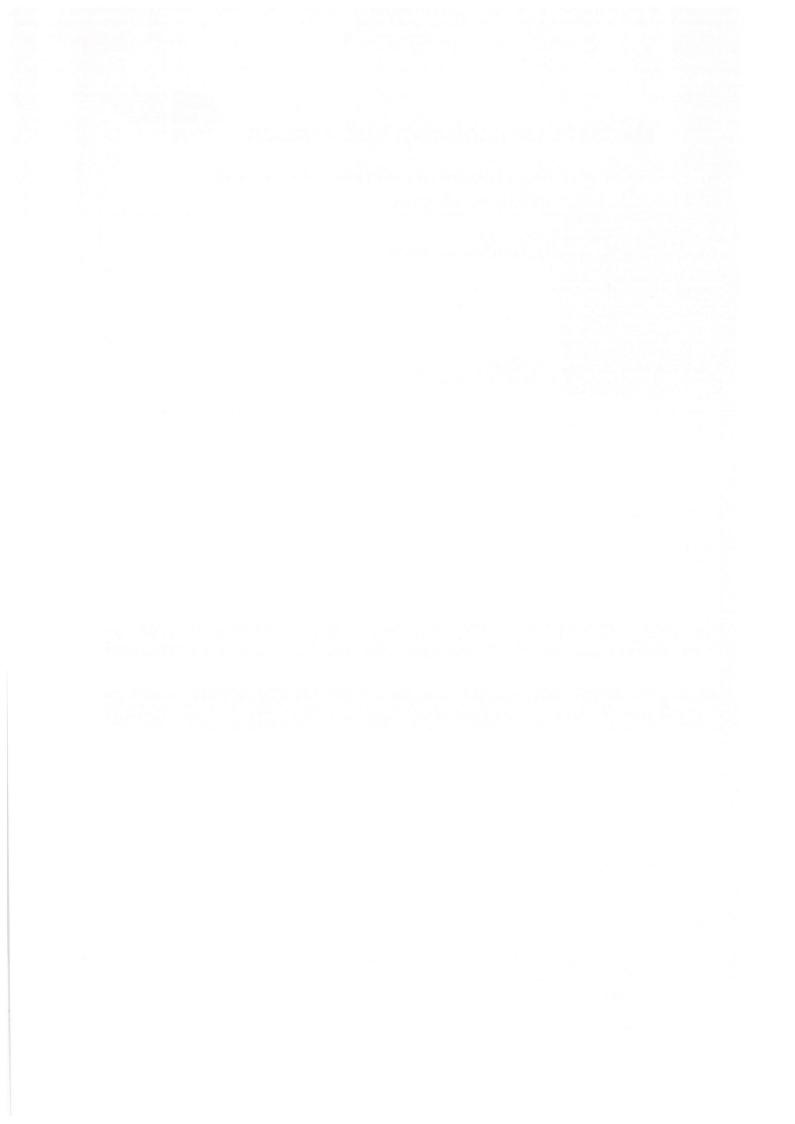
Please return this form to:

Email: medsafeapplications@moh.govt.nz including 'Miconazole warning statements' in the subject line

Or Post:

Product Regulation

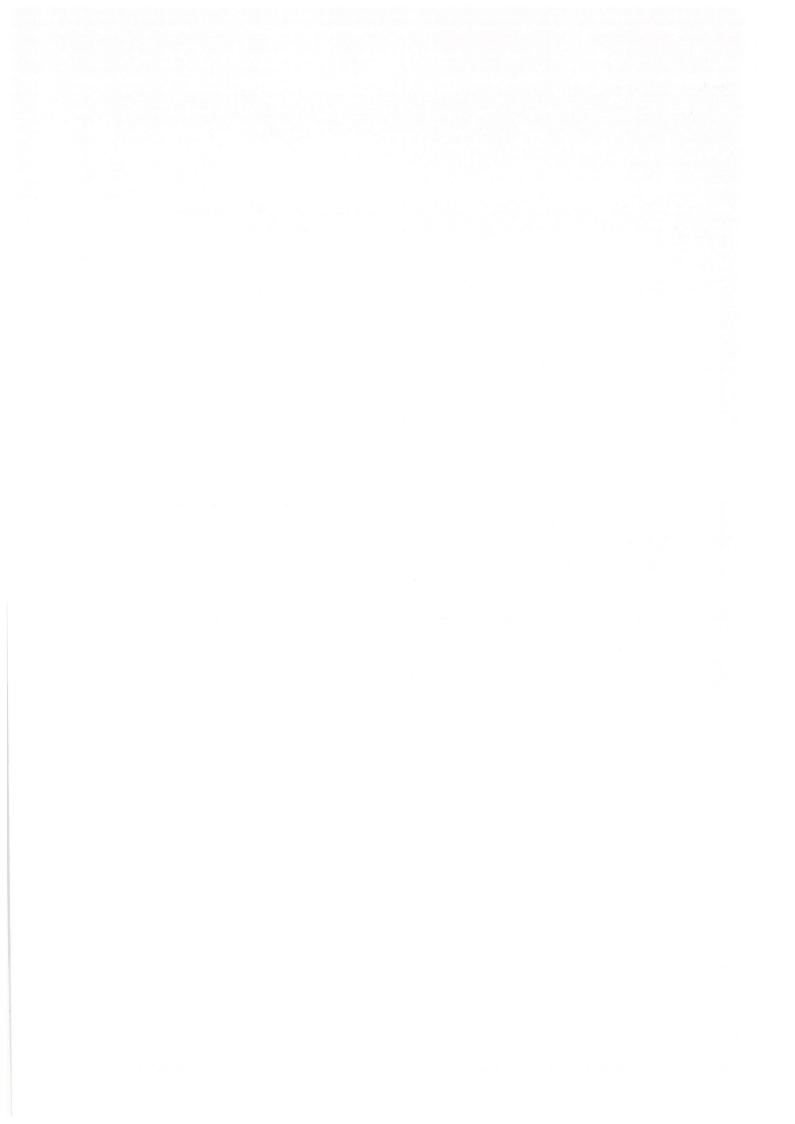
Medsafe PO Box 5013 Wellington 6145



Medsafe is seeking comments on:			
Whether a warning statement about the interaction between warfarin and miconazole is required for all topical miconazole containing medicines available without prescription.			
- If a warning is not required for all products please provide your reasoning			
Mylan New Zealand supports Medsafe's proposal for a warning regarding the potential for interaction with warfarin to be included on the labels of all topical miconazole-containing products.			
Which of the proposed warning statements about the interaction between warfarin and miconazole is preferred?			
 Please provide your reasoning, this will help Medsafe when considering future warning statements 			
Patients taking warfarin - talk to a healthcare professional before using [this product].			
Use of positive statements to give direction is preferred. Moreover, this statement is also congruent with the CMI for miconazole topical cream "Tell your doctor or pharmacist if you are taking anticoagulants, medicines used to prevent blood clots such as warfarin".			

Please include additional pages if necessary.

Medsafe consultation: Miconazole warning statements



Whether the statements required in Australia for intravaginal miconazole products should be included in the Label Statements Database. - Please provide your reasoning - Are the statements acceptable or should they be reworded? Mylan New Zealand considers these to be unnecessary. Miconazole for vaginal use is classified as a restricted medicine and requires consultation with a pharmacist for sale. Pharmacists are adequately trained to identify 'red flags' that may require referral to a doctor and provide information to patients as to when they should seek further medical advice. It should also be highlighted that the Label Statement Database do not include such statements for topical clotrimazole products, which is similarly indicated for vaginal candidiasis. What is a suitable target date for implementation: - Please provide justification A transition period of 18 months, following the change to the Label Statements Database, is proposed to allow sufficient time for sponsors to adequately manage stock. This is in line with similar labelling consultation outcomes published by Medsafe.

