

Medsafe consultation submission



Change to warning statements on labels of OTC loratadine and desloratadine medicines

Name and designation	Scott Milne – Executive Director	
Company/organisation name and address	New Zealand Self Medication Industry Association	
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>		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes <input checked="" 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:			
<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>)			
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<input type="checkbox"/> Consumer organisation	<input type="checkbox"/> Member of the public	<input type="checkbox"/> Institution (e.g. university, hospital)	
<input checked="" type="checkbox"/> Regulatory affairs consultant	<input type="checkbox"/> Laboratory professional		
<input checked="" type="checkbox"/> Health professional – <i>please indicate type of practice</i> : Pharmacy			
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Please return this form to:

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

Or Post: Product Regulation
 Medsafe
 PO Box 5013
 Wellington 6145

Medsafe is seeking comments on:

Change to the warning statement for OTC loratadine and desloratadine:

- Is the proposed warning statement appropriate?

The New Zealand Self Medication Industry Inc. (SMI) is the peak body representing manufacturers and sponsors in the non-prescription medicines industry in New Zealand.

Our purpose is to represent the best interests of our members through negotiation, debate and co-operation with a wide range of stakeholders in New Zealand and around the world. We also gather the most current information and intelligence from diverse sources and disseminate it to our members to alert them to potential issues that may affect their product or its market.

SMI believes the proposed labelling requirement is superfluous, likely to cause confusion, unhelpful and not in the best interests of consumer education and safety. We propose that no warning label is necessary on non-sedating antihistamines, proven not to cause drowsiness or sedation.

Our suggested proposal would align us with the majority of similar international markets (Australia, UK, Canada) that do not require warning labels.

Label harmonisation with Australian manufacturers and distributors is sensible and beneficial to both markets.

It is unhelpful that the proposed label refers to very rare side effects, which is a highly unusual departure from normal warning label protocols. We suggest this will cause confusion amongst the public and does not augment any safety initiative.

There is clear clinical evidence over a wide range of non-sedating antihistamines that drowsiness reactions are at the same level as a placebo effect and warnings regarding drowsiness are therefore not helpful and are unlikely to improve patient safety.

The addition of a warning label that targets a highly unlikely event diminishes the overall value of warning labels in the eyes of the consumer.

We respectfully request that patient safety and improved patient education is better served by removing any drowsiness reference on non-sedating antihistamines such as Loratadine and Desloratadine.

Please include additional pages if necessary.

1 March 2017 - target date for implementation:

- Is the target date for implementation in New Zealand reasonable?

We suggest that manufacturers be given the opportunity to run out existing labelled stock but new product that shows no warning label be acceptable after 1 March 2017 as suggested.

We thank you for the opportunity to submit on behalf of the industry.

Please include additional pages if necessary.