

Medsafe consultation submission



Changes to warning statement for products containing sedating antihistamines

Name and designation	
Company/organisation name and address	
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 type="checkbox"/> No
(Reasons for requesting confidentiality must meet Official Information Act 1982 criteria)	
I would like my name to be removed from all documents prior to publication on the Medsafe website.	<input type="checkbox"/> Yes <input type="checkbox"/> No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	<input 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 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 type="checkbox"/> Health professional – <i>please indicate type of practice:</i>	
<input type="checkbox"/> Other - <i>please specify.</i>	

Please return this form to:

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

Or Post: Product Regulation
Medsafe
PO Box 5013
Wellington 6145

Medsafe is seeking comments on:

Whether the following statement should be added to the Label Statements Database for all sedating antihistamine products (unless other age restrictions apply):

For oral use: Do not use in children under 2 years old.

- Please provide your reasoning
- Is the statement acceptable or should it be reworded?

Whether the following statement in the Label Statements Database for sedating antihistamines is amended (when appropriate) to:

For the treatment of insomnia ~~or anxiety~~: Consult a doctor if sleeplessness (~~or anxiety~~) persists

- Please provide your reasoning
- Are the statements acceptable or should they be reworded?

Please include additional pages if necessary.

What is a suitable target date for implementation?

- Please provide justification

Please include additional pages if necessary.