Medsafe consultation submission

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

Name and designation	[redacted]
Company/organisation name and address	Actavis New Zealand Limited [redacted]
Contact phone number and email address	[redacted]

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)* (Reasons for requesting confidentiality must meet Official Information Act 1982 criteria)	☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication on the Medsafe website.	☒ Yes ☐ No
I would like for my name not to be included within the list of submissions published on the Medsafe website.	☒ Yes ☐ 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 (*please specify*):

I am, or I represent, a: *(tick all that apply)*

☒ Importer	☐ Manufacturer	☐ Supplier	☒ Sponsor
☐ Government	☐ Researcher	☐ Professional body	☐ Industry organisation
☐ Consumer organisation	☐ Member of the public	☐ Institution (e.g. university, hospital)	
☐ Regulatory affairs consultant	☐ Laboratory professional		

☐ Health professional – *please indicate type of practice*:

☐ Other - *please specify*:

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?

Loratadine is subject to the Pharmac sole supply tender system whereby a consumer/patient may obtain an OTC pack presentation either dispensed on prescription or purchased as an over-the-counter medicine. Bearing this in mind, we believe the proposed warning statement is appropriate if the following points are addressed:

- Has the proposed warning statement undergone end user testing to establish the end user understands the statement?

- The proposed warning statement must be aligned/harmonised with other overseas markets to remove any potential barrier that could prevent sponsors from sourcing overseas packs. This also extends to ensuring that words of a similar meaning to the statement are permitted as per Medsafe's Label Statements Database.

- At the dispensary level, if loratadine is dispensed in the original packaging, there is no potential for patient confusion arising from information or advice provided with the dispensed medicine versus the warning statement appearing on the medicine packaging.

We have no specific comments regarding desloratadine.

1 March 2017 - target date for implementation:

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

We estimate it could take up to 12 months to introduce labelling which complies with the proposed warning statement. This timeframe is dictated by supply chain leadtimes and seasonal demand for the product which has higher turnover in allergy season.

The transition to the proposed warning statement on pack labelling may also occur within different timeframes for the tender pack supplied for dispensing purposes versus OTC packs.

The target date for implementation should take into account any impact on data sheets/CMI where changes may be necessary to ensure consistency across labelling and information for prescribers/consumers.

Please include additional pages if necessary.