Medsafe consultation submission

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

Name and designation	[redacted]
Company/organisation name and address	Bayer 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
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I am, or I represent, an organisation that is based in:

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

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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

Please include additional pages if necessary.

Medsafe is seeking comments on:

Change to the warning statement for OTC loratadine and desloratadine:

- Is the proposed warning statement appropriate?

We believe the proposed warning statement is *not appropriate*. Furthermore, we submit that the appropriate action for New Zealand on this matter would be ***to remove any warning regarding drowsiness***, as neither the current warning nor the proposed warning materially contributes to the safe use of loratadine or desloratadine. Substantial clinical evidence for this approach has already been provided to Medsafe and MARC. Therefore, only a summary of reasons for removal of any warning statement is provided below:-

- The proposed statement is not consistent with international precedent on this topic. Australia, the United Kingdom and Canada do not require a warning on the labelling for loratadine or desloratadine. Furthermore, the United States does not require a warning on the outer labelling for desloratadine, and a warning is only required for loratadine *if overdose occurs*.

- There is no evidence that the absence of a drowsiness warning on the labelling of the products in the countries above is contributing to safety issues for these active ingredients in these countries.

- The proposed statement refers to an effect that is unknown until after the consumer has purchased the product. The warning is of no assistance to the consumer in making the purchase decision.

- Clinical evidence clearly demonstrates that the incidence of drowsiness is the same as that of placebo, and that allergies themselves can cause drowsiness. Drowsiness experienced is not necessarily attributable to the products, and a warning regarding drowsiness is inappropriate.

- Removal of any warning statement regarding drowsiness would allow labels to be harmonised with other jurisdictions (primarily Australia), contributing to the provision of a wide range of cost-effective products in New Zealand.

- In the past, drowsiness has generally been linked with impaired ability to drive or operate machinery, both in New Zealand (refer to the label statements database – sedating antihistamines, levocabastine) and internationally (see TGA Medicines Advisory Statement Specification 2016, United Kingdom warnings). Driving and operating machinery have long been recognised as the primary risk factors if drowsiness occurs.

  In the minutes of the 166th MARC meeting, it is acknowledged that the risk of impaired driving is so low the reference to driving and operating machinery in the warning can be removed. However, since the risk of drowsiness is traditionally associated with the risk of impaired driving or operating machinery, we question the usefulness of retaining any form of warning if it does not apply to driving or operating machinery.

- The proposed statement refers to a very rare side effect. It is unusual for OTC medicine labelling to have a warning about a rare side effect unless the side effect is very serious. Therefore, it appears that the proposed warning is out-of-line with the types of warnings usually applied to OTC medicines (i.e. either common or very serious). Application of such a warning constitutes a precedent not appropriate for all OTC medicines.

Please include additional pages if necessary.

- The proposed statement is, in effect, broader than the current warning statement as the advice that the consumer is unlikely to be affected has been removed, and ability to drive or operate machinery has been broadened to all activities that require full attention. There is no evidence that drowsiness is causing safety concerns for these products in New Zealand, and broadening the current warning appears unwarranted.

- Due to current road and work safety programmes, New Zealanders are well aware that they should not drive or do other tasks that require concentration if they are drowsy or sleepy. As drowsiness can also be caused by allergies (and as such is more general than just for these products if the consumer is suffering allergies) these general health and safety messages are a more appropriate vehicle for offering such advice to consumers.

- The proposed statement is very long, and we question how well it imparts information to the consumer. We believe the wording of the statement is potentially confusing, as the two parts of the warning deliver conflicting information. Furthermore, in reality it is very difficult for the consumer to follow the instructions "You should make sure you are not affected before doing activities that require full attention." as they have to self-assess the timeframe and degree to which they consider 'not affected' applies, and this will certainly be highly variable within the patient population.

For the reasons above, we respectfully request that Medsafe consider removal of any warning relating to drowsiness for these products.

1 March 2017 - target date for implementation:

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

As discussed above, we propose that the current requirement for a warning regarding drowsiness should be removed altogether, with the proviso that the current warning can be temporarily retained if desired by the sponsor as it is more restrictive. In this case, the implementation could be brought forward to 1 January 2017, with a final date for removal of the warning of 1 January 2020 – this would allow sufficient time for label changeover and stock to be sold through the market.

Please include additional pages if necessary.