Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Cetirizine: proposed advisory statements for medicines

Version 1.0, April 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Version history

Version	Description of change	Author	Effective date
V1.0	Original Publication	OTC Medicines Section/Office of Medicines Authorisation	05/04/2013

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Invitation to comment

The TGA is seeking comments from interested parties on advisory statements for cetirizine, when included in non-prescription medicines for oral use, which are proposed for inclusion in the Required Advisory Statements for Medicine Labels (RASML) when it is next updated.

Timetable

Document released for consultation on **5 April 2013.**

Interested parties should respond by close of business **3 May 2013.**

Feedback will be released following consideration of submissions. (see 'What will happen').

About the consultation

The proposed advisory statements would be required on the 'labels' of non prescription medicines containing cetirizine for oral use.

Advisory statements on the label of medicines assist in the quality use of medicines by consumers (see 'Background'). Through the consultation process, the TGA is requesting comment that will help ensure that the proposed advisory statements are appropriate and support the quality use of medicines for non-prescription products containing cetirizine for oral use.

This consultation will contribute to the update of the RASML.

Note: 'Label' means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods.

Content of submissions

Submissions may address any, or all, of the proposed advisory statements and other identified issues. In addition, submissions might include:

- Whether or not you support the wording of the advisory statement. If you do not support the wording of the statement you may make suggestions for an alternative acceptable to you.
- An assessment of how the proposed change will impact on you. That is, what do you see as the likely benefits or costs to you (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

How to respond

All submissions should be accompanied by a TGA submission cover sheet. Submissions must include full personal or organizational contact details (including address, telephone number and email).

Electronic submissions are preferred and should be emailed to rasml@tga.gov.au. Please include 'Cetirizine – proposed advisory statements' in the subject line of the email.

Alternatively, hard copy submissions may be mailed to:

OTC Medicines Evaluation
Office of Medicines Authorisation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

What will happen

Submissions will be reviewed by the TGA and feedback on submissions will be provided through the TGA's Internet site.

It is proposed that the advisory statements will then be included in the next update of the RASML.

Confidentiality

All submissions will be placed on the TGA website unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked 'IN CONFIDENCE'. Reasons for a claim to confidentiality must be included in the space provided on the submission coversheet.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's website.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Enquiries

Enquiries should be directed via email to rasml@tga.gov.au or by telephone to **1800 020 653.**

Background

The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) sets out the level of control on the availability of medicines and poisons in Australia. The majority of medicines that are included in the SUSMP fall under one of the following classifications.

Schedule 2 – Pharmacy Medicine (available from a pharmacy without a prescription)

Schedule 3 – Pharmacist Only Medicine (available from a pharmacist without a prescription)

Schedule 4 – Prescription Only Medicine (available from a pharmacist with a prescription)

Medicines that are not included in the SUSMP are freely available from both pharmacies and other retail outlets, and are referred to as 'unscheduled' or 'general sales' medicines. Medicines that are unscheduled or included in Schedule 2 or Schedule 3 of the SUSMP are collectively referred to as 'non-prescription' or 'over-the-counter' (OTC) medicines.

Consumers rely on information from their health practitioner, pharmacist and medicine 'label' in order to use medicines safely and effectively. In the case of non prescription medicines, the label of the medicine contains information and directions for appropriate use, as well as any advisory statements (warnings) that are needed for safe and effective use of the medicines.

The need for new advisory statements can arise under a number of circumstances. One of these circumstances is when a medicine undergoes a change in scheduling, hence reducing the level of control and making it more widely available to consumers for self-selection.

Under these circumstances there may be a need to ensure that appropriate advisory statements are included on the labelling of these medicines to ensure consumers are able to self-select (where applicable) and use these medicines safely and effectively.

Cetirizine

In October 2012, the TGA scheduling delegate decided to amend the entry for cetirizine in Schedule 2 of the SUSMP from "*Cetirizine for oral use*" to *"Cetirizine in preparations for oral use,* ***except*** *in divided preparations for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over when (a) in a primary pack containing not more than 5 day's supply; and (b) labelled with a recommended daily dose not exceeding 10 mg of cetirizine"*, with an implementation date of 1 January 2013.

The consequence of this change is that packs containing five 10 mg tablets of cetirizine for the treatment of seasonal allergic rhinitis in adults and children 12 years of age and over are now 'unscheduled' medicines. This is a 'down scheduling' for cetirizine tablets, when supplied for this indication, in this pack size.

In making the decision, the scheduling delegate recommended that the appropriate areas of TGA consider any requirements for label warning statements, including in relation to sedation, in the RASML.

The Advisory Committee on Non-prescription Medicines (ACNM) advised, at its meeting on 6 December 2013, that the RASML should require the same advisory statements for unscheduled cetirizine products as those currently required for schedule 2 cetirizine products (under 'Antihistamines').

In addition, the ACNM noted that cetirizine is in pregnancy category B2. The Australian Regulatory Guidelines for OTC Medicines (ARGOM) states, in Appendix 3, that the label of

OTC products that contain active ingredient(s) in category 'B' (including 'B1', 'B2, 'B3') should include a statement advising consumers who are pregnant to check with their doctor or pharmacist before taking or using the medicine. The ACNM also noted that cetirizine may be found in breast milk. Therefore, the ACNM advised that both unscheduled and scheduled cetirizine products should include the pregnancy and breastfeeding warning that has recently been required for fexofenadine, loratadine and desloratadine (for the same reasons).

Proposal

The OTC Medicines Evaluation Section of the TGA proposes that the RASML should include the following new separate entry for cetirizine **(See Table 1).**

Table 1. Proposed advisory statements for cetirizine

Which Meet The Following Conditions ...	Required Statements
When included in non-prescription medicines for oral administration	*This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol.* or *This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.*
	If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.

Therapeutic Goods Administration

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Reference/Publication #