Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Proposed advisory statements for medicines - fexofenadine and loperamide

About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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.

Contents

Proposed advisory statements for medicines – fexofenadine and loperamide

Invitation to comment

The TGA is seeking comments from interested parties on the proposed advisory statements for fexofenadine and loperamide for inclusion in the RASML document when it is next updated.

The proposed advisory statements for fexofenadine and loperamide would be required on the 'label' of non prescription products containing these two ingredients. Advisory statements on the label of medicines assist in the quality use of medicines by consumers.

Through the consultation process, the TGA is requesting feedback that will help ensure that the proposed advisory statements are considered appropriate and supports the quality use of medicines for non-prescription products containing fexofenadine or loperamide.

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

Timetable

Document released for consultation on 4th May 2012.

Interested parties should respond by close of business 4th June 2012.

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

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 coversheet. Submissions must include full personal or organizational contact details (including address, telephone number and email).

Electronic submissions are preferred and should be emailed to otc.medicines@tga.gov.au. Please include 'Proposed advisory statement – fexofenadine and loperamide' 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. Recommendations made by the TGA following consideration of submissions from interested parties will be published on the TGA website.

The proposed advisory statements will then be included in the next update of the RASML document.

Confidentiality

All submissions will be placed on the TGA's 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 TGA 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.

The RASML Edition 1 including update 4 (dated September 2008) remains the current version which sponsors should continue to refer to.

Background

In order that medicines are used safely and effectively, consumers rely on accessing information about their medicines from their health practitioner, pharmacist and medicine 'label'. Generally for non prescription medicines, also known as over-the-counter (OTC) medicines, the label of the product contains information on appropriate directions for use. In addition advisory statements may also be included on the labels of these OTC products to facilitate the quality use of medicines by consumers.

The Standard Uniform Scheduling of Medicines and Poisons (SUSMP) sets out the level of control of the availability of medicines and poisons in Australia. The following classification relates to medicines.

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

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

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

The decision to change the scheduling of fexofenadine and loperamide in the SUMSP, hence reducing the level of control by making the medicine more widely available for self selection by consumers; means that there is a need to ensure that appropriate advisory statements are included on the labelling of these medicines to enable consumers to self select and use these medicines safely and effectively.

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

Fexofenadine

In June 2011, a change was made to the scheduling of medicines containing fexofenadine in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The scheduling delegate confirmed a decision to exempt fexofenadine from scheduling when intended for short-term symptomatic relief of seasonal allergic rhinitis in adults and children 12 years of age and over, when sold in small packs of 10 dosage units or less (i.e. not more than 5 days' supply at the current maximum recommended dose) with a maximum daily dose of 120mg. The decision to exempt fexofenadine from scheduling means that fexofenadine will be available to consumers from pharmacies as well as retail outlets other than a pharmacy (i.e. supermarkets. local corner stores, petrol station or newsagencies).

Note: In September 2011 the delegate decided to editorially amend the Schedule 2 and 4 fexofenadine entries in the Standard Uniform Scheduling of Medicines and Poisons (SUSMP) to specifically stipulate a limit of 5 days' supply in the exemption

In making the decision to "down schedule" fexofenadine from Schedule 2 (Pharmacy medicine) to unscheduled, hence increasing the access to consumers, the scheduling delegate affirmed the recommendation made by the Advisory Committee on Medicines Scheduling (ACMS) that the requested exemption from scheduling was acceptable. The delegate also decided to recommend to the appropriate areas of the TGA for consideration of a requirement for a labelling warning statement in the *Required Advisory Statements for Medicine Labels* (RASML) for exempt preparations of fexofenadine to the following effect:

> "This product should not be used when pregnant or breastfeeding except when advised by your doctor or pharmacist. Do not use with other antihistamines"

Proposed advisory statement

Following advice from the Advisory Committee on Non prescription Medicines (ACNM), the TGA proposes the following advisory statement for fexofenadine when supplied as a non-prescription medicine [i.e. an over-the-counter (OTC) medicine];

- Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist (statement no. xx in proposed update 6 of RASML)

Loperamide

In September 2011, a change was made to the scheduling of medicines containing loperamide in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The scheduling delegate confirmed a decision to exempt loperamide from scheduling when in divided oral preparations containing 2mg or less of loperamide per dosage unit, in a primary pack containing 8 dosage units or less. The decision to exempt loperamide from scheduling means that loperamide will be available to consumers from pharmacies as well as retail stores other than a pharmacy (i.e. supermarkets. local corner stores, petrol station or newsagencies)

In making the decision to "down schedule" loperamide from Schedule 2 (Pharmacy medicine) to unscheduled, the scheduling delegate confirmed the recommendations made by the ACMS that the requested exemption from scheduling was acceptable. The delegate also agreed to communicate the evaluator's labelling recommendations to the appropriate areas of the TGA for consideration.

Current requirement

In the current RASML document dated September 2008, Loperamide when included in a Schedule to the Standard Uniform Scheduling of Medicines and Poisons (SUSMP) requires

- Do not give to children under 12 years of age (statement no.)
- Do not use beyond 48 hours or in pregnancy or lactation except on doctor's advice (statement no. 17)

Proposed advisory statements

The TGA has proposed, in response to stakeholder submission to the public consultation on RASML updates 5 & 6, that the RASML requires the labels of Schedule 2 loperamide products to include warnings consistent with the following.

- Do not give to children under 12 years of age (statement no. 6)
- If the condition persists after two days of treatment, seek medical advice as soon as possible (statement no. 180 in proposed update 5 of RASML)
- Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist (statement no. xx in proposed update 6 of RASML)

Following advice from the ACNM, the TGA proposes the following advisory statements for loperamide when supplied as a non-prescription medicine [i.e. an over-the-counter (OTC) medicine]:

- Do not give to children under 12 years of age. (statement no. 6 in RASML September 2008)
- If [the condition] persists after two days of treatment, seek medical advice as soon as possible. (statement no. 180 in proposed update 5 of RASML)
- Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist. (statement no. xx in proposed update 6 of RASML)
- If you get an allergic reaction stop taking and see your doctor immediately. (statement no. 159 in RASML September 2008)
- Drink plenty of water (statement no. 184 in proposed update 5 of RASML)
- See your doctor or pharmacist before taking [this product/product name] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing medical condition affecting the bowel.
- Do not take if you suffer a medical condition where constipation should be avoided.

Summary of proposed changes

Substance	Change type
Fexofenadine	New entry
Loperamide	Amendment to existing entry

Details of the proposed changes are shown in the tables below. These tables show:

- the existing entry# which requires amendment or inclusion of additional information showing proposed amendment in red and underlined and the deletions, if any, in black ~~strikethrough~~); or
- the proposed new entry (inserted details in red and underlined);

#As per RASML Edition 1 including update 4 (dated September 2008)

Section 1 – Medicines to which advisory statements apply

1. Amendment to existing entry

Medicines Containing ...	Which Meet The Following Conditions ...	Required Statement(s)
Loperamide	(a) When included in ~~SUSDP~~ SUSMP Schedule 2; or (b) When excluded from the Schedules to the SUSMP.	(6, ~~17~~ 159, 180#, 184#, xx^, A, B)

#Statement as proposed for update for RASML 5

^Statement as proposed in response to submissions to the consultation for update 6, therefore no number has been allocated.

2. New entry

Medicines Containing	Which Meet The Following Conditions .	Required Statement(s)
Fexofenadine	(a) When included in SUSMP Schedule 2; or (b) When excluded from the Schedules to the SUSMP.	xx^,

^Statement as proposed in response to submissions to the consultation for update 6, therefore no number has been allocated.

Section 2 – Advisory statements

1. Added new advisory statements

No	Statement Text
180#	If the [condition] persists after two days of treatment, seek medical advice as soon as possible.
184#	Drink plenty of water

No	Statement Text
xx^	If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
A*	See your doctor or pharmacist before taking [this product/product name] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing affecting the bowel
B*	Do not take if you suffer a medical condition where constipation should be avoided

#Statement as proposed for update for RASML 5.

^Statement as proposed in response to submissions to the consultation for update 6, therefore no number has been allocated.

*A number will be allocated in the RASML document at the time of updating to ensure consistency with the numbering system.

Therapeutic Goods Administration

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