The information in this guideline is being reviewed and updated by the TGA.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

# Guidelines on route of evaluation

## Australian regulatory guideline for over-the-counter medicines

Version 1.4, November 2012

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.
- 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>.

## Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.4 | Extract from Section 2 of ARGOM, V1.4 | OMA-OTCME | 09/11/2012 |

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# Route of evaluation

Medicines are evaluated by one of three regulatory units. OTC Medicines are evaluated by the OTC Medicines Section (OTC), complementary medicines by the Office of Complementary Medicines (OCM) and prescription and other specified medicines by the Drug Safety and Evaluation Branch (DSEB). The criteria for deciding which of these units evaluates a particular medicine are set out in Schedule 10 to the Therapeutic Goods Regulations.

In some circumstances it may be more appropriate for a particular medicine to be evaluated by a different unit to the one specified in Schedule 10. Here are some examples of where this may occur:

- Where a medicine is currently classified as a 'Prescription Only Medicine' (Schedule 4) but meets the criteria for classification in an OTC schedule and the sponsor intends to lodge an application for down-scheduling;
- Where a product contains a new active substance that is closely related to a substance already classified OTC (eg. an active metabolite of an existing 'Pharmacy Medicine' (Schedule 2) or 'Pharmacist Only Medicine' (Schedule 3) substance) and is likely to meet the criteria for classification as a non-prescription medicine in the Guidelines for the National Drugs and Poisons Schedule Committee.

The Regulations allow for the transfer of applications between the regulatory units. Once transferred, the applications are dealt with according to the requirements (eg. fees and data requirements) of the new area.

A decision to transfer an application to a different regulatory unit may be taken at the initiative of the TGA delegate (eg. OTC products containing oral nitrates for the treatment of heart disease are routinely transferred from OTC to DSEB to maintain consistency in evaluation with prescription medicines). In such cases, the sponsor will be advised before the transfer takes place and be given the opportunity to provide comment.

Where a sponsor wishes to have an application dealt with by an evaluation unit other than the one specified in Schedule 10 to the Regulations, they will need to provide a justification to the TGA to establish that this is appropriate. The justification can be provided separately in advance of an application or as part of the application itself.

If the justification is accepted, the application for that product will then be dealt with by the 'new' evaluation unit in the same way as other products regulated by that unit (eg. application and evaluation fees and data requirements will be those of the 'new' evaluation unit).

If the justification is refused, any subsequent application for that product will be dealt with according to Schedule 10 to the Regulations. Details of a procedure for appeals are included under 'Administrative details', below.

The information required in a justification will vary depending on the current and proposed route of evaluation.

- DSEB to OTC or OCM
- OTC to OCM or vice versa
- OTC or OCM to DSEB
- Administrative details

- Excipients
- Currently registered non-prescription transdermal patches
- Relationship to scheduling in the SUSDP

## DSEB to OTC or OCM

Products containing new active substances (ie. those that are not included in any medicine currently authorised for sale in Australia) are usually evaluated by the DSEB. Exceptions to this general rule are sunscreens (evaluated by OTC) and herbal substances (evaluated by OCM).

Where a justification for evaluation of a product or substance via the OTC or OCM route is proposed, the primary factors to be taken into account include:

- The safety of the active substance;
- The need for professional counselling before use;
- The nature of the ailments or symptoms to be treated (can they be easily recognised by the consumer, do they require medical diagnosis or management?)
- The abuse potential of the product or substance;
- The incidence of adverse effects and contraindications;
- The risk of masking serious disease;
- The risk/benefit profile of the product (eg. therapeutic index).

Other factors that may be taken into account include:

- Whether the product would be in a lower schedule if presented in a different form (eg. different pack size, different strength, different indications, different route of administration);
- Whether products containing the substance are available without prescription in other countries with comparable regulatory regimes to Australia;
- Whether the product contains a substance that has a closely related chemical structure and similar therapeutic action to other substances that are in a less restrictive schedule;
- Whether the substance appears to meet the criteria for listing.

## OTC to OCM or vice versa

In general, products containing active ingredients that would normally be evaluated as OTC (eg. paracetamol) in combination with active ingredients that would normally be evaluated as complementary (eg. herbal substances, vitamins, minerals) will be evaluated via the OTC route.

Where a sponsor wishes to propose a different route to that specified in Schedule 10 to the Regulations, a justification should be provided.

## OTC or OCM to DSEB

In some circumstances, sponsors may prefer to have an application evaluated by the DSEB rather than OTC or OCM (eg. where a product range includes strengths that are 'prescription' as well as OTC). A justification should be submitted but minimal supporting data will be required in such cases.

## Administrative details

A form (Justification for a particular route of evaluation) is provided to assist sponsors in submitting the required information. The justification request should be submitted to the evaluation unit specified in Schedule 10 to the Regulations (eg. a 'Prescription Only Medicine' (Schedule 4) justification request should be submitted to the DSEB with a copy sent to the proposed evaluation unit. There is no fee for this.

A decision will be made by the TGA within 20 working days (four weeks) of receipt of the justification request. The decision will be made by the relinquishing area following discussion with the proposed receiving area. The sponsor will be advised of the decision by the relinquishing area. If the initial decision is to refuse the justification request, the reasons for refusal will be given.

Following the initial decision, if the sponsor and the TGA cannot come to a mutually acceptable position, the sponsor may request the TGA National Manager to undertake an independent internal review. This review will be completed within 20 working days of the receipt of the request and may involve consultation with the chairs of the relevant evaluation committees.

## Excipients

Excipients are usually evaluated via the same route as the products in which they are to be used (eg. a new excipient that is to be used in complementary medicines will be evaluated by the OCM).

In general, the evaluation criteria for new excipients are common across all areas of the TGA. Information on data requirements is available from the relevant evaluation area.

## Currently registered non-prescription transdermal patches

Under Schedule 10 to the Regulations, transdermal systems are routinely evaluated by the DSEB even if they are non-prescription products.

Notwithstanding this, evaluation of a particular application via the OTC or OCM route will be accepted when it involves a change or changes that do not result in a new delivery system or influence the characteristics of the currently approved delivery system. Changes in formulation, membrane or other specific factor(s) that control release of the active frequently result in what could be considered a new delivery system.

Acceptable changes (ie. to be considered by the OTC or OCM route), therefore include applications involving clinical data, toxicological data, and only those pharmaceutical chemistry changes that do not create a new transdermal system or influence the characteristics of the currently approved system.

Examples of changes that will be accepted for evaluation via the OTC or OCM route are:

- Labelling changes
- Sponsor changes
- Consumer Medicine Information
- Product Information
- Packaging changes, other than immediate packaging
- Product detail changes not involving a change to the delivery system.

Changes other than those specified will require a justification if an alternative evaluation area is desired. For example:

- Product detail changes involving the delivery system;
- Quality Control changes – finished product specifications which do not result in a new transdermal system;
- Quality control changes – starting material specifications which do not result in a new transdermal system;
- Manufacturing changes – finished product.

## Relationship to scheduling in the SUSDP

Where a product that contains a new active substance is approved for registration and it appears that the substance meets the criteria for inclusion in a schedule of the SUSDP, the matter will be referred to the National Drugs and Poisons Schedule Committee (NDPSC) for consideration as to the most appropriate schedule for the substance. The sponsor may wish to make a submission to the NDPSC at that time.

Where a product is already included in Schedule 4, 8 or 9 of the SUSDP and the TGA has accepted a justification for evaluation via the non-prescription route, the sponsor should submit an application to the NDPSC for 'switching' the substance to a lower schedule. Depending on timeframes, the sponsor should consider submitting these applications concurrently.

In both the above instances, the NDPSC will generally consider the application for scheduling or 'switching' schedules after advice of the TGA's decision on registration of the product has been received. The TGA's evaluation report will be made available to the NDPSC to assist in its assessment.

In cases where it is clear that the 'new' substance does not meet the criteria for inclusion in any schedule of the SUSDP, the matter will not be referred to the NDPSC.

It must be recognised that the decision on which schedule a substance is allocated is the sole responsibility of the NDPSC. It should not be expected that because a substance or product has been evaluated via the non-prescription route that the NDPSC will necessarily allocate a non-prescription schedule to that substance, or that it will accept a recommendation to include a substance in a particular schedule.

In circumstances where a product is evaluated via a non-prescription route and then the NDPSC allocates or confirms a 'Prescription Only Medicine' (Schedule 4) classification, the evaluation will not be repeated via the DSEB.

**Therapeutic Goods Administration**

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
**www.tga.gov.au**

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