Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for over-the-counter medicines (ARGOM)

Version 1.4, November 2012

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The 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
V1.0	First Publication	ONPM	01/07/2003
V1.1	Transferred to new template Corrected hyperlinks	OPSS	04/05/2011
V1.2	Amended Chapter 5C	MAG – OTCME	02/06/2011
V1.3	1. Transfered to new template; 2. Removal of 'July 2003' from cover page and footer 3. Removal of Foreword; and 4. Replacement of the following chapters with appendices: (The appendices referred to below have been published as separate documents on the TGA website). · 4 Quality · 4A Manufacture · 4B Formulation · 4C Starting material specification · 4D Finished product specification · 4E Stability testing · 4F Microbioloigcal testing replaced with Appendix 2: Guidelines on Quality aspects of OTC applications. · 5 Presentation · 5A Product name · 5B Labelling · 5C Product Information · 5D Consumer Medicines Information	MAG – OTCME	12/10/2012

Version	Description of change	Author	Effective date
	· 5E Changes to Scheduling replaced with Appendix 3: Guidelines on presentation aspects of OTC applications. · 6A Efficacy and safety replaced with Appendix 1: Guidelines on safety and efficacy aspects of OTC applications. · 6B New substances replaced with Appendix 4: Guidelines on OTC application for new substances. · 9 MEC Guidelines replaced with Appendix 5: Guidelines on OTC applications for specific substances. Chapters amended to refer to the corresponding appendices.		
V1.4	10 Sunscreens replaced by Australian Regulatory Guidelines for Sunscreens (ARGS)	MAG – OTCME	09/11/2012

Contents

The current Australian Regulatory Guidelines for Over-the-counter Medicines (ARGOM) is currently being reviewed and updated by the TGA.

Selected chapters have been removed and replaced with references to the appendices. This document will remain as the guidance document until it can be fully replaced by the updated ARGOM, i.e. chapters such as Chapter 2, 3, 7, 8 and 11 will remain in effect until such time it is replaced.

1. Introduction

These guidelines describe the information to be supplied with applications for registration or variation of OTC medicines. These are medicines which are available without a prescription but not 'complementary medicines'. 'OTC medicine' and 'complementary medicines' are defined in the Therapeutic Goods Regulations 1990[1].

The object of the guidelines is to assist sponsors to submit applications which will be evaluated in the minimum possible time and be successful.

While the guidelines reflect the views of the TGA and its evaluation committees at the time of publication, there may be occasions where a departure from the guidelines is warranted. If you believe this to be the case, a justification for the departure should be submitted with the application. You may wish to contact staff of the OTC Medicines Section for advice in such instances.

The guidelines contain many references to legislation. However, these references, although accurate at the time of publication, are not intended to be comprehensive. It is the sponsor's responsibility to ensure that current regulatory requirements are fully met.

It is possible for some products containing 'new' substances (ie. those not contained in a product currently included in the Australian Register of Therapeutic Goods for supply in Australia) to be evaluated as OTC medicines. Provisional approval of a substance which is not, as yet, included in a product is also possible. Details of provisions for the approval of substances, as opposed to products, are given in Chapter 6B.

Except where otherwise indicated, these guidelines apply to products rather than substances.

The guidelines are available on the TGA website or in hard copy from the TGA Publications Office. Each chapter is separately numbered to facilitate future additions and amendments.

The TGA would welcome comments or suggestions and these should be directed to:

The Director
Non-prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

[1] http://www.tga.gov.au/industry/legislation.htm

2. Overview

This Chapter gives an overview of the legislative and procedural framework within which OTC medicines are regulated. It also defines the terms used in these guidelines. Information on substances which are not, as yet, included in a product is contained in Chapter 6B.

Therapeutic goods

The *Therapeutic Goods Act 1989* (the Act) came into operation in February 1991. Its object is:

> *to promote the development of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia, whether the goods are produced in Australia or elsewhere.*

'Therapeutic goods' are defined in the Act. All therapeutic goods (other than those which are exempt) must be registered or listed in the Australian Register of Therapeutic Goods (ARTG) before they can be imported, exported, manufactured or supplied in Australia.

Therapeutic goods are divided into 'medicines' and 'medical devices'. Some 'medicines' are limited to prescription-only while others are available without a prescription. Non-prescription medicines may be 'complementary medicines' or 'OTC medicines' and may be 'listed' or 'registered' in the ARTG.

These guidelines are solely concerned with OTC medicines. Some OTC medicines (eg. sunscreens) are normally 'listable' but the majority are 'registrable'. Information on registration and listing is available on the TGA website[2].

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

[2] http://www.tga.gov.au/archive/medicines-information-kit-1999.htm

meet the criteria for classification as a non-prescription medicine in the *Guidelines for the National Drugs and Poisons Schedule Committee*[3].

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

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).

[3] http://www.tga.gov.au/ndpsc/ndpscg.htm [note: this web page is no longer available]

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*)[4] 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.

[4] http://www.tga.gov.au/industry/medicines-forms-justification-evaluation.htm

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 (PDF to PMI);
- Quality Control changes – finished product specifications (QFX to QFR) which do not result in a new transdermal system;
- Quality control changes – starting material specifications (QSX to QSS) which do not result in a new transdermal system;
- Manufacturing changes – finished product (MMA to MPR).

The codes quoted above are from the Changes table (Chapter 11).

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.

3. The application

This chapter describes the information required to support an application to register an OTC medicine. In general, that information should consist of an application form (accompanied by the prescribed fee) together with a submission containing information and data to support the product's registration. Submissions should be page numbered and include an index. Applications prepared in the European or ICH format are preferred.

The application form

The application form is called the *New medicine registration application form* (OTC)[5]. Instructions on how to complete the form are printed opposite the corresponding item in the form. The instructions on the form are additional to the requirements in these guidelines. Contact the OTC Medicines Section if you are unsure as to how to complete any particular item in the form.

Fees

Application and evaluation fees are payable for most applications. Full details of the current fees are contained in Schedule 9 to the Regulations. A summary of fees and charges is available on the TGA website[6]. To avoid delay, you should pay the full application and evaluation fees at the time of submitting your application.

[5] http://www.tga.gov.au/industry/otc-forms.htm
[6] http://www.tga.gov.au/about/fees.htm

In some circumstances, a waiver or reduction of the evaluation fee (but not the application fee) may be possible under the provisions of Regulation 45 of the Therapeutic Goods Regulations (eg. where the TGA has already evaluated relevant data on a related product and the evaluation can be abridged).

If you believe you are eligible for a waiver or reduction of the evaluation fee, include a request with your application. If approved, a refund will be issued by the Business Management Unit (BMU).

The BMU will acknowledge receipt of your application within a few days of its arrival in the TGA. The acknowledgment letter will quote a TGA Identification Number (TGAIN) which uniquely identifies your application. This number should be quoted in any correspondence or enquires concerning the application.

The submission

In general, a submission for registration of an OTC medicine should include the following components:

- Specifications and stability data as specified in Chapter 4, Quality;
- Copies of all labelling including package inserts;
- A copy of the Product Information (PI) and Consumer Medicine Information (CMI) documents where relevant (refer Chapter 5, Presentation);
- Efficacy and safety information where relevant (refer Chapters 6A, Efficacy and safety and 6B, New substances)

The evaluation process

Instructions for lodging applications are given on the application form. On receipt at the TGA, applications are screened to ensure that they comply with the following criteria:

- correct fees paid;
- form filled correctly;
- all necessary data present (including stability and validation data as detailed in Chapter 4E, Quality – Stability testing);
- all necessary attachments present (eg. labels, PI and CMI documents, where relevant);
- Information on the GMP status of manufacturer(s) provided (usually in the form of a clearance letter from the TGA's Manufacturer Assessment Section).

If any of these factors are absent, the application may be returned to the sponsor on the basis that "*An application is not effective unless: the applicant has delivered ... such information ... as will allow the determination of the application*" (Section 23 of the Act). In such cases the application fee is not eligible for refund but the evaluation fee may be refunded on the basis that evaluation had not commenced.

The sponsor may also be contacted at this stage (before evaluation commences) if, in the opinion of a senior evaluator, the application is unlikely to be approved. In such cases the sponsor will be given the option of withdrawing the application (with loss of the application fee but not the evaluation fee) or requesting that the application proceed regardless.

Applications which are returned at this screening stage or subsequently withdrawn can be corrected and resubmitted (as a new application with the appropriate fees) at any time. The TGA is willing to provide some general guidance as to what would be required for a future application but for detailed or technical assistance, it is recommended that the services of an appropriately qualified and experienced regulatory affairs consultant be sought (see Consultants).

Where a product is required to be sterile (eg. eye drops), the sterility and preservative efficacy aspects of the product will be evaluated concurrently by the TGA's Microbiology Section. The microbiology evaluator may contact the sponsor directly if there are any issues relating to this part of the evaluation.

Where a product contains ingredients of animal origin the sponsor must comply with the requirements specified under Ingredients of human or animal origin in Chapter 4B.

Applications for new products may be referred to the Medicines Evaluation Committee (MEC) for assessment and recommendation. However, the delegate may choose to make a decision on the basis of information already to hand without advice from the committee. For example:

- where the new product is a 'clone' (ie. identical in all respects except for the name) of an existing evaluated product (with the consent of the sponsor of the 'parent' product);
- where the new product is similar to products which have been evaluated in the past (eg. a new brand of paracetamol tablet) and bioequivalence data are not required;
- where all issues have been dealt with by the MEC in the past and the Delegate does not require further advice from the committee.

Applications which are precedential or which contain issues that have not been fully addressed in the past will usually be referred to the MEC.

The MEC comprises members with expertise and experience in medicine, paediatric medicine, clinical pharmacology, pharmacy, toxicology, microbiology, regulatory affairs, pharmaceutical chemistry, manufacturing and forensic pharmacy. Its secretariat is provided by the OTC Medicines Section and meetings are held on a two monthly basis. Further details of the composition and terms of reference of the MEC can be found on the TGA website[7].

An evaluation report is prepared by a TGA evaluator for submission to the MEC. The purpose of the evaluation report is to provide an objective regulatory and scientific assessment and summary of the application to assist the committee in reaching a conclusion about the suitability of the product for registration.

Applications for variation of existing products are generally not referred to the MEC unless the advice of the committee is specifically required. Circumstances where this may occur include:

- new indications, directions for use or claims for an existing product;
- a chemistry, quality control or labelling issue which is precedential; or
- where the delegate requires technical or policy advice from the committee.

Where the product is to be referred to the MEC, the sponsor will be sent a copy of the TGA's evaluation report at least ten days before the cut-off date for the meeting at which

[7] http://www.tga.gov.au/archive/committees-mec.htm

the application is to be considered. Comments from the sponsor will be given to the MEC. In general, comments must be limited to three pages and should only address substantial issues raised in the evaluation report. Minor and administrative issues can be dealt with separately by the evaluator. Additional data will not be accepted at this stage.

Where an application is recommended by the MEC for rejection, the committee will usually offer the sponsor the opportunity to appear before a future meeting in support of the application. If the sponsor chooses to accept this invitation, the following considerations will apply:

- The sponsor should contact the OTC Medicines Section as soon as possible to arrange a suitable meeting;
- The sponsor is allocated half an hour (usually towards the end of the meeting) to present their case;
- New data that require evaluation are not usually accepted at this stage;
- Presentation aids (eg. PowerPoint, overhead projector) will be available on request;
- The committee may ask questions at the end of the presentation.

This procedure has been accepted as a long-standing custom of the MEC. It is not a formal appeal and does not affect the sponsor's appeal rights under Section 60 of the *Therapeutic Goods Act 1989*. Refer also to Chapter 7, Review of decisions.

'Clone' applications

The term 'clone' is used in relation to OTC medicines that are identical in all respects to an existing evaluated medicine, apart from the product name and identifying details on the product label.

Where a product is accepted as a 'clone', no supporting data are required (apart from the proposed labelling, PI and CMI) and the evaluation fee will be reduced to the amount of the variation evaluation fee.

If the application is approved, the 'clone' will be registered in its own right in the ARTG. From the time of registration onwards, the 'clone' will bear no legal relationship to the 'parent' product. The sponsor of the 'clone' will be fully responsible for that product.

In general, 'clone' applications must comply with the following requirements:

- The application should be accompanied by a letter from the sponsor of the 'parent' product authorising the TGA to access information on the 'parent' to support the 'clone' application.
- The 'parent' product must have been fully evaluated (ie. not a grandfathered product).
- The sponsor must provide an assurance that all quality aspects of the proposed 'clone' product are identical to the 'parent' product, and that the sponsor will ensure that the 'clone' product will comply with all applicable regulatory requirements.
- The application should be accompanied by copies of all labels, PI and CMI (where applicable) of the 'parent' product and the 'clone'.

The TGA will closely compare the labels, PI and CMI of the 'parent' and 'clone' products. If there are changes beyond the product name and identifying details, the label, PI and CMI will be fully evaluated without regard to the 'parent'. In such cases, the full new product evaluation fee will apply.

Confidentiality

Applications are treated on a commercial-in-confidence basis. Details of an application will only be discussed with the sponsor or the sponsor's appointed agent. All TGA committees operate under a strict code of confidentiality. Members of committees must declare any conflict of interest in matters to be considered at a meeting and are excluded from taking part in any final determination of those matters.

The delegate's decision

The Act is written in terms of two parties – 'the sponsor' and 'the Secretary'. In practice, where the Act specifies that decisions are to be made by 'the Secretary', those decisions are usually made by an officer of the TGA to whom the Secretary's authority has been formally delegated. Delegations of this nature are generally restricted to senior officers.

When an evaluation has been completed, the delegate makes a decision on whether the product is suitable for entry in the ARTG on the basis of the application and accompanying data, advice from evaluation committees, other relevant sources and his or her own professional judgement. Decisions made under the Act may be appealed – information on appeal rights is given in Chapter 7, Review of decisions.

Entry in the 'Register'

If your application for registration of a product is approved it will be entered in the Australian Register of Therapeutic Goods (ARTG). You will be sent a letter asking you to check the accuracy of all details of the ARTG entry using your on-line access to the SIME ARTG and confirm it is correct (or advise any amendment required). A certificate of registration will be issued following receipt of your confirmation that all details are correct. The registration of the goods will commence on the day specified for the purpose in the certificate of registration. The goods may not be supplied before this date.

The Certificate of Registration will include a number of conditions of registration. Read the conditions carefully as they must be complied with in order to retain your product in the register.

How long will it take?

The target times for the various types of applications are set out in the table below.

Application type	Target time (working days)
New applications Variations referred to the MEC 'Clone' applications	71
Variation processed through TGA only	32
Variation – notification only	20

These targets are set by agreement between the TGA and industry representative bodies and are exclusive of 'company response time' (ie. time taken for the sponsor to respond to issues raised during the evaluation).

The TGA's goal is to finalise all applications within the target time. To help achieve these goals, the following procedures are followed:

- applications not meeting acceptance criteria (see above) are returned to the sponsor without evaluation;
- where possible, applications are assessed by the evaluator and evaluation committee only once;
- in general, applications are dealt with on the basis of the submitted information – deficiencies can be corrected by the sponsor in a new application rather than by a process of iterative submissions.

Changes to existing products

Specific information on the requirements for changes to existing products is given in Chapter 11, Changes to OTC medicines.

Consultants

Sponsors who are not experienced in preparing registration applications may find it to their advantage to engage the services of an appropriately qualified and experienced regulatory affairs consultant.

Information on how to locate consultants is available on the TGA website[8].

[8] http://www.tga.gov.au/industry/basics-regulatory-affairs-consultants.htm

4. Quality - refer to Appendix 2

4A. Manufacture

4B. Formulation

4C. Starting material specifications,

4D. Finished product specifications,

4E. Stability testing,

4F. Microbiological testing

Chapters 4 to 4F have been updated. Refer to Australian Regulatory Guidelines for Over-the counter Medicines: Appendix 2 Guideline on quality aspects of OTC applications <http://www.tga.gov.au/industry/otc-argom-app2.htm>.

5. Presentation - refer to Appendix 3

5A. Poduct name

5B. Labelling

5C. Product Information (PI)

5D. Consumer Medicine Information (CMI)

5E. Changes to scheduling

Chapters 5 to 5E have been updated. Refer to Australian Regulatory Guidelines for Over-the counter Medicines: Appendix 3 Guidelines on presentation aspects of OTC applications <http://www.tga.gov.au/industry/otc-argom-app3.htm>.

6A. Efficacy and safety - refer to Appendix 1

Chapter 6A has been updated. Refer to Australian Regulatory Guidelines for Over-the counter Medicines: Appendix 1 Guidelines on safety and efficacy aspects of OTC applications <http://www.tga.gov.au/industry/otc-argom-app1.htm>.

6B. New substances - refer to Appendix 4

Chapter 6B has been updated. Refer to Australian Regulatory Guidelines for Over-the counter Medicines: Appendix 4 Guidelines on OTC applications for new substances. <http://www.tga.gov.au/industry/otc-argom-app4.htm>.

7. Review of decisions

The Medicines Evaluation Committee - 'opportunity to be heard'

Where an application is under evaluation by the MEC and it appears that rejection is to be recommended, the committee has established a procedure whereby the sponsor is invited to appear at a committee meeting and present a submission in support of the application.

This is not a formal appeal mechanism but is simply a means of ensuring that you have an opportunity to personally present a case to the committee. It has no bearing on any subsequent right of appeal to the Minister or Administrative Appeals Tribunal if the application is rejected.

If your application is formally rejected by the TGA you will be sent a letter from the Delegate of the Secretary informing you of the decision and setting out the reasons for the rejection. If you wish to have this decision reviewed, a number of procedures are available (section 60 of the Act refers).

Reconsideration by the Minister

In the first instance you may write to the Minister, within 90 (calendar) days of receiving the rejection letter, requesting a reconsideration of the decision to reject the application. Directions on how to proceed will be given in the rejection letter. The decision is generally reviewed by a delegate of the Minister, usually a senior officer of the TGA other than the officer who made the initial decision.

After the decision has been reviewed, you will be given a statement of the outcome and, if the decision is confirmed, advice on further options available to you. The delegate of the Minister may confirm the initial decision or revoke it and substitute another decision in its

place. If you do not receive notice of the review of the decision within 60 (calendar) days of your request it is taken that the initial decision is confirmed.

The Administrative Appeals Tribunal

If you are dissatisfied with the results of the reconsideration you may then make an appeal to the Administrative Appeals Tribunal for a review of the decision.

8. Post marketing surveillance

Products which are already being marketed are subject to a number of levels of surveillance by the TGA.

The sampling program

The TGA Laboratories undertake a continuous sampling program in all states of Australia. Products are purchased in the marketplace, or obtained from manufacturers or sponsors, and subjected to analysis and regulatory scrutiny. Products not meeting the required standards may be subject to corrective action, recall or removal from the register.

Good Manufacturing Practice (GMP) audits

Manufacturers of therapeutic goods in Australia are subject to regular inspections by the TGA's Manufacturer Assessment Section. Details of requirements for manufacture are specified in the *Australian Code of Good Manufacturing Practice for Medicinal Products*[9].

The evaluation committees may request that particular problems encountered during the evaluation process be followed up with the manufacturer during subsequent GMP audits.

See also Post-registration requirements in Chapter 4E, Stability testing.

'Grandfathered' products

Those products entered in the ARTG under the 'grandfather' provisions of the Act may be subject to future evaluation to determine whether they should remain on the Register. If you are the sponsor of such a product, you should ensure that you hold evidence to substantiate the quality, safety and efficacy of the product. You should also ensure that an ongoing stability testing program is in place for each product under your control.

[9] http://www.tga.gov.au/industry/manuf-medicines-cgmp.htm

The Surveillance Unit

The Surveillance Unit investigates breaches of the legislation and coordinates prosecutions.

Problem reporting and recall

Recalls of therapeutic goods are coordinated by the TGA's Recalls Section. Information can be obtained from the TGA website[10].

9. MEC guidelines - refer to Appendix 5

Chapter 9 has been updated. Refer to Australian Regulatory Guidelines for Over-the counter Medicines - Appendix 5 Guidelines on OTC applications for specific substances <http://www.tga.gov.au/industry/otc-argom-app5.htm>.

10. Sunscreens - refer to Australian Regulatory Guidelines for Sunscreens

Chapter 10 has been replaced by the Australian Regulatory Guidelines for Sunscreens <http://www.tga.gov.au/industry/sunscreens-args.htm>.

11. Changes to OTC medicines

Is notification or prior approval required?

Following the inclusion of your product as a registered OTC medicine in the Australian Register of Therapeutic Goods (ARTG), you may wish to change certain details held by the TGA. Influences such as product stability, manufacturer changes and developing marketing strategies may dictate changes to product details which were approved at the time of the product's inclusion in the ARTG.

It is a condition of registration of your goods that you notify the TGA of any changes in information that may have been relevant to a decision to register the goods.

[10] http://www.tga.gov.au/safety/problem.htm

The Changes table in this Chapter sets out the steps that you must take **before** proceeding with a change. Note that the *Therapeutic Goods Act 1989* provides for penalties where a change is implemented without the approval of the TGA (see subsection 22(3) of the Act).

About this document

While this document gives summary information about the legislation, you are strongly advised to refer to the legislation itself for complete information on the implications for your product. This document refers only to registered OTC medicines. It does not apply to listed medicines, complementary medicines or medicines of the type evaluated by the Drug Safety and Evaluation Branch.

Which form do I fill in?

Applications for variation of an existing product should be made on the *Registered medicine variation form (OTC)*[11]. Applications for registration of a new product should be made on the *New medicine registration application form (OTC)*[12]. These forms are available on the OTC medicines page[13] of the TGA website.

How much will it cost?

All applications directed to the Non-Prescription Medicines Branch, whether requiring notification or prior approval, will attract an application fee. For applications which require approval, a separate evaluation fee is payable. Information on current fees is available on the TGA website[14] or from the TGA Publications Office - Freecall 1800 020 653.

The Therapeutic Goods Regulations provide for the waiver or reduction of evaluation fees under certain circumstances. If the change to your product is such that you feel you are eligible for a waiver or reduction of the evaluation fee you should pay the full fee at the time of application and include a request for waiver/reduction with the application. Reductions or waivers are ***not*** granted as a matter of course. Each application is judged on its own merits. If approved, the appropriate amount will be refunded by the Business Management Unit. Processing delays may result if the correct fees are not paid at the time of application.

Refer to Regulation 45 of the Therapeutic Goods Regulations for the criteria applying to the waiver and/or reduction of fees.

[11] http://www.tga.gov.au/docs/html/regmedfm.htm [note: this web page is no longer available]
[12] http://www.tga.gov.au/docs/html/regist.htm [note: this web page is no longer available]
[13] http://www.tga.gov.au/industry/otc.htm
[14] http://www.tga.gov.au/about/fees.htm

Does the change make the goods 'separate and distinct'?

Some changes may render the changed goods *separate and distinct* from the present goods. Section 16 of the Act lists those criteria which make goods *separate and distinct*. Where the *Therapeutic Goods (Groups) Order* (the 'Groups Order') applies, the 'new' goods, although technically *separate and distinct* from the present goods, may be 'grouped' in the same register entry as the existing goods. If the 'new' goods are *separate and distinct* and the Groups Order does **not** apply, you will need to submit a new application for registration of the goods.

See Groups Order (below) for a summary of the provisions of the Therapeutic Goods (Groups) Order.

What else do I need to send?

For applications that require approval, and for some applications that require notification, you will need to submit further documentation with the variation form. Some supporting documentation requirements are self-evident. If you wish to change details of the label, for example, you will need to send a copy of the present label and a draft copy of the new label, highlighting the changes (note that finished artwork is not necessary at this stage).

In other cases, what is required as supporting documentation may not be so evident. If you have consulted the various references and are still unsure, contact the staff of the OTC Medicines Section.

In some instances, certain assurances about the change will also need to be made before the application can proceed. Where these are required, details are given in the Changes table. Note that it is your responsibility to ensure that the required assurances are given in your application. If they are not given, the change may require prior approval, rather than notification.

Other aspects of the product (that are not being changed)

Generally, only the requested change will be reviewed at the time of application. However, some changes naturally impact on other aspects of the product which may require further clarification. If a problem is detected which is unrelated to the requested change it may be followed up as a separate issue but will not generally hold up processing of the application.

Obviously, some flexibility will be necessary, as it may be in the interests of both the TGA and the sponsor to have all outstanding issues resolved before the change is implemented.

Sponsors should be aware that sometimes a proposed change might involve additional consequential changes (eg. removal of a colouring agent may also require change to visual identification). In such cases each of the relevant changes should be specified in the application.

The same changes for many products?

If you wish to implement an identical change across a range of similar products, only one application form may need to be completed in certain cases. An example is the notification of a change of the same principal manufacturer (licensed) for a range of registered products.

What if the proposed change is not in the Changes table?

If you cannot find a description of your proposed change in the Changes table, contact the staff of the OTC Medicines Section. The absence of your proposed change does not imply that you may proceed with the change without notifying us or seeking prior approval of the change.

Acknowledgment of application

You will be sent an acknowledgment by the Business Management Unit (BMU) in response to all submissions for changes which require either notification or prior approval. For changes requiring notification, you need not wait until you receive the acknowledgment of your notification before implementing the change.

For changes that require prior approval, a letter of approval, signed by the delegate of the Secretary, is sent. It is important that you do not proceed with this type of change until you receive the approval letter. Should your application be refused, a rejection letter containing details of procedures for review of the decision will be sent.

Groups Order - summary

The 'Groups Order' specifies the circumstances in which 'separate and distinct' therapeutic goods can be 'grouped' in the same ARTG entry (ie. under the same AUST R number).

Section 16 of the *Therapeutic Goods Act 1989* sets out the criteria which make goods 'separate and distinct'. These are:

- a different name; or
- different indications; or
- different directions for use; or
- a different type of container; or
- a different dosage form; or
- a different formulation or composition.

When the Groups Order does not apply, the changed goods must have a separate ARTG entry and bear a separate AUST R number. If this is the case, you should apply for registration of the changed goods as if it were an entirely new product.

The provisions of the Groups Order (as applied to non-prescription drug products) may be summarised as follows:

Name change

Goods may be grouped when the only difference between the new goods and the existing goods is the proprietary name and when the new goods are to replace the existing goods in use.

Change in the amount of an excipient

Goods may be grouped when the formulation of the new goods is to be changed by increasing or decreasing the amount of an excipient (but not adding or deleting an excipient) and when the new goods are to replace the existing goods in use.

Removal or addition of a fragrance, flavour, printing ink or colour

Goods may be grouped when the formulation is changed by the addition or removal of a fragrance, flavour, printing ink or colouring agent and when the new goods are to be registered in place of the existing goods.

Revised indications and/or directions for use

Goods may be grouped when only the indications and/or directions for use are changed and the new goods are to be registered in place of the existing goods.

Changes table codes

The following codes should be read in conjunction with the Changes table (below). Assurances should be made in writing, signed and dated by an authorised person, and should accompany the variation form. Note that the exact wording, as given here, should be used. Failure to make the relevant assurances that are required for notifiable changes may render the change approvable.

Status codes

NEW New application for registration required.

A Prior approval required before proceeding with the change.

N Notification to the Non-Prescription Medicines Branch before proceeding with the change, *provided that* the required supporting documentation has been supplied.

O No prior approval or notification required. Changes with status 'O' have been included for completeness and do not imply that this information is required for evaluation of an equivalent new product.

ASK Contact OTC Medicines Section

Documentation and assurance codes

E Evidence to support the change where an ARTG entry is to be corrected.

G GMP pre-clearance certificate

L A copy of the current label of the goods plus a draft copy of the new label, with the relevant *changes highlighted*, have been supplied.

T The submission is accompanied by written requests to effect the change from both the existing and the proposed sponsors.

PI A copy of the current Product Information (PI) of the goods plus a draft copy of the new PI, *with the relevant changes highlighted*, have been supplied.

P The SUSDP schedule (or 'N' for unscheduled goods) for the new pack size(s) is/are stated in the application form.

1. The 'new' goods are intended to replace the existing goods in use.

2. The only difference between the 'new' goods and the existing goods is the name.

3. The only differences between the 'new' goods and the existing goods are related to the indications for use and/or the directions for use.

4. No additional indications have been introduced or directions for use altered (other than change to wording).

5. No aspects of the labelling, PI, CMI, pharmaceutical data or other product details have been changed or are to be changed, other than changes nominated in this application and those made in conformity with the 'Changes table'.

6. The labelling for the new pack size is unchanged, other than to indicate the new pack size number/volume.

7. The only changes made are those which bring the label into compliance with requirements of the Labelling Order[15], or Schedule 2 to the Therapeutic Goods Regulations.

8. The change is in compliance with a requirement introduced in the most recent version or amendment of the *Standard for the Uniform Scheduling of Drugs and Poisons*.

9. The nominated manufacturer is licensed to manufacture goods of this type.

10. The container type (as defined in *TGA Approved Terminology for Drugs*) is unchanged and container material is unchanged.

[15] http://www.tga.gov.au/industry/legislation-tgo.htm

11. A stability testing protocol has been approved for this product and a copy of the approval letter is attached.

12. a. Neither the existing nor the new material is a modified starch; and
    b. The changeover has been validated; and
    c. At least 6 month's stability data have been generated at the maximum recommended storage temperature on product manufactured using the new type of starch, or 3 month's data at a temperature at least 10°C higher than the maximum recommended storage temperature; and
    d. Stability testing will continue for the full term of the product's shelf life and any batches not meeting specifications will be withdrawn from the market immediately and the Non-Prescription Medicines Branch notified immediately.

13. a. The changeover has been validated and the sponsor is satisfied that the change will not adversely affect the stability of the product; and
    b. Stability testing will continue for the full term of the product's shelf life and the TGA advised immediately of any batches not meeting specifications.

14. No new text or graphics have been introduced.

15. The change of material is one of the following:
    a. Polystyrene to PVC, polyethylene, polypropylene or glass;
    b. PVC to polyethylene, polypropylene or glass;
    c. Polyethylene to glass or polypropylene of density 0.89;
    d. From one density of polyethylene to a higher density; or
    e. Any change between glass, polyethylene of density 0.95, and polypropylene of density 0.89.

16. The new container/closure system has demonstrated equal or better moisture protection in the USP test for Containers Permeation (water vapour transmission) to that of the existing container/closure system.

17. The information on the container label is not less than the information on the primary pack.

18. The change to the plastic component is one of the following:
    a. PVC to PVC/PVDC or to PVC/PCTFE;
    b. PVC/PVDC to PVC/PCTFE.

    or the change to the plastic component is to a material with demonstrated lower or equivalent water permeability than the existing material (see for example USP monograph '*<671> Containers Permeation*').

19. Manufacturing method and specifications, other than visual identification, have not been changed.

20. Two production batches have been tested according to the approved stability protocol and all results fall within the acceptance criteria, as specified in the approved stability protocol.

21. The changes are in accordance with s.9D(1) of the *Therapeutic Goods Act 1989*.

Changes table

Label changes (including package insert)

Label changes (including package insert)		Status	A/D*
GPN	Proprietary name (if grouping applies)	A	1, 2, L
PIN	Proprietary name (if grouping doesn't apply)	NEW	-
GIN	New therapeutic indications (if grouping applies)	A	1, 3, L
PTI	New therapeutic indications (if grouping doesn't apply)	NEW	-
LIW	Therapeutic indications or directions for use – change of wording without altering meaning	A	4, L
LIS	Therapeutic indications – removal of sub-set of indications from label	N	5, L
LIR	Therapeutic indications – addition of registered indications to label	A	5, L
GDU	Directions for use – eg. dosage instructions (if grouping applies) (See also LIW)	A	1, 3, L
LDU	Directions for use (if grouping doesn't apply)	NEW	-
PSC	Recommended storage conditions – more restrictive	N	5
PST	Recommended storage conditions – less restrictive	A	-
LSR	Addition of more restrictive safety-related statements	N	5, L
LSF	Changes on label (signal headings, warning statements) in compliance with new SUSDP requirements, where the change in scheduling is from 'Prescription Only Medicine' (Schedule 4) to a lower schedule	A	-
LSU	Changes on label (signal headings, warning statements) in compliance with new SUSDP requirements, other than LSF	N	5, 8, L
LLO	Changes to bring a label into compliance with the Labelling Order – other than changes to the proprietary name, indications or directions for use	N	5, 7, L

Label changes (including package insert)		Status	A/D*
LLR	Addition of a required representation to a label (Part 2 of Schedule 2 to the Therapeutic Goods Regulations)	N	5, 7, L
LCF	Colour, font, type size only (no change in label copy)	N	5, L
LGR	Introduction of new graphics/icons (other than as specified in change SSP)	A	-
LFO	Reformatting of pre-existing text (ie. moving of blocks of text and not rewording – see LIW, LRT)	N	5, L
LRT	Rewording of pre-existing text without altering meaning (other than indications or directions for use – see LIW)	A	-
LDT	Deletion or addition of text to the label (eg. addition or removal of claims such as clinically proven, fast/rapid action; general claims regarding the product, its nature, mechanism of action, qualifying statements, etc)	A	-
LOC	Other changes	Ask	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Sponsor changes

Sponsor changes		Status	A/D*
SSP	Sponsor name/logo(same sponsor of goods) and/or change to manufacturer/supplier details on label	N	5, L
SAD	Sponsor address	Write to OTC	-
STR	Transfer goods to another sponsor	N	5, T, L

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Product detail changes

Product detail changes		Status	A/D*
GPN	Proprietary name (if grouping applies)	A	1, 2, L
PIN	Proprietary name (if grouping doesn't apply)	NEW	-
PSZ	Pack size – other than liquids/semi-solids (see PLS) or metered dose aerosols (see PMZ) (see also KBT, KGL, KBL and KOT)	N	5, 6, 10, L, P
PLS	Pack size – liquids/semi-solids	N	5, 6, 10, 13, L, P
PMZ	Pack size – metered dose aerosols	A	-
GIN	New therapeutic indications (if grouping applies)	A	1, 3, L
PTI	New therapeutic indications (if grouping doesn't apply)	NEW	-
PDF	Dosage form (as defined in *TGA Standard Terminology*[16])	NEW	-
PVI	Visual identification	N	5, 13, 19
PSL	Shelf life – increase (other than in change PSP)	A	-
PSR	Shelf life – decrease	N	5
PSP	Shelf life – increase (in accordance with an approved stability testing protocol for that product)	N	5, 11, 20
PPR	Approval of a stability testing protocol for a specific product	A	-
PSC	Recommended storage conditions – more restrictive	N	5
PST	Recommended storage conditions – less restrictive	A	-
PMI	Sterility status/technique	A	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

[16] http://www.tga.gov.au/industry/medicines-approved-terminology.htm

Formulation changes - active ingredients

Formulation changes - active ingredients		Status	A/D*
AAI	Addition of active ingredient	NEW	-
AAD	Deletion of active ingredient	NEW	-
AAA	Amount of an active ingredient (see also Actives/excipients – variations in weight per batch in Chapter 4B, Formulation)		
NEW	-		
AOV	Overage – decrease	N	5
AOA	Overage – increase	A	-
GPA	Change to amount of an excipient ingredient within a proprietary ingredient which contains an active substance (eg. a direct-compression paracetamol mix) (if grouping applies)	A	1
API	Change to a proprietary ingredient which contains an active ingredient, other than as above in change GPA	NEW	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Formulation changes - excipient ingredients

Formulation changes - excipient ingredients		Status	A/D*
GPI	Removal and/or addition of a fragrance, flavour, printing ink or colouring agent (if grouping applies), other than change ERT	A	1, 13
ERE	Removal or addition of a fragrance, flavour, printing ink or colouring agent (if grouping doesn't apply)	NEW	-
ERT	Removal of fragrance, flavour, printing ink and/or colouring agent(s) if the total agent(s) are present at not more than 2% w/w or w/v (if grouping applies) Note: This change may result in consequential changes (eg. deletion from the label of declared ingredients that are no longer relevant; change to visual identification and finished product specifications) which should also be addressed in accordance with the 'Changes Table'.	N	5

Formulation changes - excipient ingredients		Status	A/D*
EAD	Addition of excipient other than those above in change GPI	NEW	-
EDE	Deletion of excipient other than those above in change GPI	NEW	-
GEX	Amount of excipient (if grouping applies)	A	1
EAM	Amount of excipient (if grouping doesn't apply – see also Actives/ excipients – variations in weight per batch in Chapter 4B, Formulation)	NEW	-
EST	Type of starch	N	5, 12
EWI	Change to ingredients within a proprietary ingredient which is a flavour, fragrance, printing ink or colour (proprietary ingredient has same name)	N	5, 13
EWA	Change to ingredients within a proprietary ingredient which is an excipient (other than above in change EWI)	A	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Quality control changes – finished product specifications

Quality control changes – finished product specifications		Status	A/D*
QFX	Specification ranges – more restrictive	O	-
QFE	Specification ranges – less restrictive	A	-
QFT	Addition of an extra test	O	-
QFU	Deletion of an existing test	A	-
QFA	Analytical method – to comply with amendments to a standard (eg. the BP or a Therapeutic Goods Order)	O	-
QFB	Analytical method – which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity)	O	-
QFC	Analytical method – other than as specified above in change QFB	A	-

Quality control changes – finished product specifications		Status	A/D*
QFS	Expiry specification ranges following changes to the BP or the General standard for tablets pills and capsules or changes to the USP where a USP monograph has been approved by the TGA in relation to the product	O	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Quality control changes - starting material specifications

Quality control changes - starting material specifications		Status	A/D*
QSX	Range – more restrictive	O	-
QSE	Range – less restrictive	A	-
QST	Addition of an extra test	O	-
QSU	Deletion of an existing test	A	-
QSA	Analytical method – to comply with amendments to a standard (i.e. the BP, EP, USP or a Therapeutic Goods Order)	O	-
QSB	Analytical method – which has been demonstrated to maintain or improve analytical performance (accuracy, precision and/or specificity)	O	-
QSC	Analytical method – other than as specified above in change QSB	A	-
QSM	Manufacturer of starting material (specifications unchanged)	O	-
QSS	Supplier of starting material	O	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Packaging changes

Packaging changes		Status	A/D*
KCT	Container type (as defined in TGA Standard Terminology7)	NEW	-

Packaging changes		Status	A/D*
KBT	Container material – if the container is a bottle, the goods are a solid dosage form (eg. tablet) and the change is of a type listed in assurance 15	N	5, 10, 13, 15 & 16
KGL	Container material – clear to coloured glass	O	-
KBL	Container material – if the container is a blister pack, the goods are a solid dosage form (eg. tablet) and the change is of a type listed in assurance 18	N	5, 10, 13 & 18
KOT	Container material – other than in changes KBT, KGL or KBL	A	-
KCL	Closure	N	5, 13
KSL	Tamper evident seal – addition (including label notice to alert consumers to presence of seal)	O	-
KSX	Tamper evident seal – removal (including removal of label notice re seal)	O	-
KWA	Inert wadding material – addition, substitution or removal where stability is not affected by the action	O	-
KDA	Desiccant – inclusion in container	A	-
KDX	Desiccant – removal from container	A	-
KPP	Specifications of primary pack (other than labelling)	O	-
KSP	Introduction of a measuring device (eg. spoon, cylinder) or applicator (eg. finger cot)	N	5
KMD	Changes to existing measuring device (eg. spoon, cylinder) or applicator supplied with the goods or removal of a measuring device or applicator, where other means of accurately measuring or applying the dose are readily available	N	5
KPA	Introduction of a primary pack (no new text or graphics)	N	5, 14
KPI	Introduction of a package insert	A	-
KRI	Removal of a package insert	A	-

Packaging changes		Status	A/D*
	Changes to package insert (see 'Label changes' section)		
KPX	Removal of a primary pack	N	5, 17
KRP	Introduction of a refill pack	A	-
KRR	Removal of refill pack	N	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Manufacturing changes – finished product

Manufacturing changes – finished product		Status	A/D*
MMA	TGA licensed Australian manufacturer (includes site of manufacture)	N	5, 9
MOS	Overseas manufacturer (includes site of manufacture), if GMP pre-clearance certificate provided	N	5, G
MOP	Overseas manufacturer (includes site of manufacture), if GMP pre-clearance not provided	A	-
MPR	Manufacturing process (other than MBS)	N	13
MBS	Batch size for pressurised inhalation (nasal and oral respiratory) products	A	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Consumer Medicine Information (CMI)

Consumer Medicine Information (CMI)		Status	A/D*
CPI	Introduction of a CMI for a 'Pharmacist Only Medicine' (Schedule 3) product registered after 4 July 1995 where the CMI complies with Schedule 13 to the Therapeutic Goods Regulations and is not to be included as a package insert. Note: Change KPI applies where the CMI is to be included as a package insert.	O	-

Consumer Medicine Information (CMI)		Status	A/D*
CPO	Changes to an existing CMI, where the changes are consistent with all previously approved product details and the CMI is not to be included as a package insert. Note: Refer to the 'Label changes' section for guidance on changes to a CMI where the CMI is to be included as a package insert (package inserts are treated as part of the label).	O	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Product Information (PI)

Product Information (PI)		Status	A/D*
DPI	Introduction of a PI for an existing product	A	-
DRS	Addition of more restrictive safety-related statements	N	5, PI
DOT	Changes other than the addition of more restrictive safety-related statements	A	-

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Other

Other		Status	A/D*
CTA	Correction of ARTG record in accordance with section 9D(1) of the Therapeutic Goods Act 1989	N	E, 5, 21

*A/D = assurances to be given and supporting documentation required for the given status to apply. Refer to Changes table codes for an explanation of all codes used.

Appendices

- Appendix 1: Guideline on efficacy and safety aspects of OTC applications
- Appendix 2: Guideline on quality aspects of OTC applications
- Appendix 3: Guideline on presentation aspects of OTC applications
- Appendix 4: Guideline on OTC applications for new substances
- Appendix 5: Guideline on OTC applications for specific substances

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Reference/Publication #