Australian Government
Department of Health
Therapeutic Goods Administration

Australian regulatory guidelines for OTC medicines (ARGOM)

15 April 2013

These Guidelines describe the information to be supplied with an application for registration of OTC (over-the-counter) medicines in the Australian Register of Therapeutic Goods (ARTG) (/industry/artg.htm). These medicines will be subject to evaluation by the Therapeutic Goods Administration, in accordance with Section 25 of the *Therapeutic Goods Act 1989*.

This information will enable the determination of the application for registration and, accordingly, the Guidelines are approved for the purposes of subsection 23(2) of the *Therapeutic Goods Act 1989* with effect from 1 July 2003.

The Guidelines also give guidance on the information required to be submitted for consideration of applications to vary information about therapeutic goods included in the Register, which are made under subsection 9D(1), (2) or (3) of the *Therapeutic Goods Act 1989*.

- ARGOM guidelines
- ARGOM appendices
- Tools for sponsors

ARGOM guidelines

These guidelines should be seen as interim and will be modified and updated as required prior to and during the 12 month period of phased implementation. Representatives of industry, health professionals and consumers are encouraged to review these documents over this period, and can submit feedback to OTCBPR@tga.gov.au (mailto:OTCBPR@tga.gov.au?Subject=ARGOM%20guidelines).

- ARGOM: Guidelines on changes to OTC medicines (/industry/otc-argom-changes.htm)
  This interim guideline on changes to OTC medicines has been updated to accommodate the new process for the pre-market evaluation of OTC medicines in Australia
- ARGOM: Guidelines on electronic OTC dossiers (/industry/otc-argom-electronic-dossiers.htm)
  The introduction of electronic dossiers for OTC medicine submissions is subject to staged implementation.
- ARGOM: Guidelines on post-market surveillance (/industry/otc-argom-postmarket-surveillance.htm)
  Products which are already being marketed are subject to a number of levels of surveillance by the TGA.
- ARGOM: Guidelines on route of evaluation (/industry/otc-argom-route-evaluation.htm)
  Medicines are evaluated by one of three regulatory units.
- ARGOM: Guidelines on the pre-market application and evaluation process for OTC medicines (/industry/otc-argom-premarket-process.htm)
  This interim guideline details the new regulatory processes for the approval of new and changed OTC medicines
- OTC N2 applications and OTC medicine monographs (/industry/otc-argom-otc-n2-monographs.htm)
  Requirements for the registration of new medicines via the N2 application route and OTC Medicine Monographs
- Target evaluation times for OTC medicine applications (/industry/otc-target-evaluation-times.htm)
  The TGA aims to complete the OTC evaluation process within a specified target time

ARGOM appendices

- ARGOM Appendix 1: Guidelines on efficacy and safety aspects of OTC applications (/industry/otc-argom-app1.htm)
  This part of the ARGOM describes the types of evidence that should be submitted for the various OTC medicine applications
- ARGOM Appendix 2: Guidelines on quality aspects of OTC applications (/industry/otc-argom-app2.htm)
  This part of the ARGOM describes the information regarding the quality of the product should be submitted for OTC medicine applications
- ARGOM Appendix 3: Guidelines on presentation aspects of OTC applications (/industry/otc-argom-app3.htm)
  This part of the ARGOM describes various aspects of presentation and gives guidance on what constitutes acceptable presentation for OTC goods
- ARGOM Appendix 4: Guidelines on OTC applications for new substances (/industry/otc-argom-app4.htm)
  This part of the ARGOM describes applications and safety data requirements for a new substance intended for use in an over-the-counter (OTC) medicine
- ARGOM Appendix 5: Guidelines on OTC applications for specific substances (/industry/otc-argom-app5.htm)

This part of the ARGOM is intended to assist sponsors in submitting acceptable applications for registration of over-the-counter (OTC) medicines

Tools for sponsors

- Frequently asked questions about the new OTC business process (commenced April 2013) (/industry/otc-tools-faq.htm)
  Frequently asked questions and answers on the new OTC BPR process which commenced on 15 April 2013 and will be implemented in stages over 12 months, with full implementation in April 2014

- Determining the correct application level and supporting information required for OTC medicines submissions (/industry/otc-tools-correct-level.htm)
  OTC medicine applications are categorised according to risk, with five risk levels for applications for new medicines and four risk levels for applications to make changes to existing medicines

- OTC application categorisation framework (/industry/otc-tools-ac-framework.htm)
  The OTC application categorisation framework defines the different OTC medicine application levels and the key application criteria

- OTC application route for umbrella branded medicines (/industry/otc-tools-umbrella-branded.htm)
  The OTC Application Categorisation Framework defines the different application levels for applications for new medicines, and changes to existing medicines. Within this framework, applications for umbrella brand extensions are identified as requiring an increased level of assessment when the risks to consumers are considered to be higher.

- OTC application placement flowchart (/industry/otc-tools-ap-flowchart.htm)
  This flowchart is a tool to assist the sponsor in categorising an application to register a 'new' medicine into the appropriate application level.

- OTC application placement question and answer tool (/industry/otc-tools-ap-qa.htm)
  Use this tool to determine the correct application level for an OTC medicine application by answering a series of questions.

- OTC dossier documents matrix (/industry/otc-tools-dossier-matrix.htm)
  This matrix provides a summary of which documents are required for each application level.

Web page last updated: Wednesday, 17 April 2013

URL: http://www.tga.gov.au/industry/otc-argom.htm