Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

OTC application categorisation framework

Version 1.0, March 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- 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 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	Original publication	OMA – OTCME	April 2013

Contents

Introduction

The OTC application categorisation framework defines the different OTC medicine application levels and the key application criteria.

New medicines—application categorisation framework

Risk rating	Application level		Definition of application level	Key application criteria
Negligible	New generic medicines	**N1**	An application submitted as a 'Clone', as described in ARGOM. An application for a flavour/fragrance/colour (FFC) variant of a fully evaluated parent where the total content of the FFC agent(s) affected is ≤ 2% w/w or w/v and where the product otherwise meets all the requirements applying to a 'Clone'. · the product name does not include an umbrella segment categorised as requiring a higher level of assessment. **New Zealand specific** Additional classification due to an additional pack size of a previously approved product.	· Parent product must have been fully evaluated for safety, efficacy and quality [cannot be a 'grandfather' registered product] and the parent product must comply with current standards, including RASML in Australia and the Medsafe Labelling Statements Database in New Zealand. · Full access to the rights of the parent product is provided.
		N2	An application which complies with an OTC Medicine Monograph, as described in ARGOM. · the product name does not include an umbrella segment categorised as requiring a higher level of assessment[1].	· The product complies fully with the requirements of a specific OTC Medicine Monograph together with the *Requirements for OTC New Product N2 applications (using OTC Monographs)* document.

Risk rating	Application level	Definition of application level	Key application criteria
Low	**N3**	New application for a 'generic' medicine (as defined in ARGOM Appendix 1) other than those 'generic' applications in levels N1, N2 or N4 · the product name does not include an umbrella segment categorised as requiring a higher level of assessment[1].	· Does not entail evaluation of safety and efficacy data; safety and efficacy data are not required for applications at this level and should not be provided. · Does not include applications included in Appendix X. · Quality (CTD module 3) data are evaluated in full. However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the regulator, then the sponsor may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product).
	N4	An application for a 'generic' medicine where the medicine: 1. is included in Appendix X (but which is not a level N1 application) and/or 2. includes an umbrella branded product name where the umbrella segment is categorised as requiring a higher level of assessment[1] and/ 3. requires supporting safety and/or efficacy (clinical/ toxicological) data and a justification for not providing such data.	· Quality (CTD module 3) data are evaluated in full. However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the regulator, then the sponsor may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product).

Risk rating	Application level		Definition of application level	Key application criteria
Moderate	Generic extensions / NCE	N5	An application for a new product that is an extension to a 'Generic category' product including: · new therapeutic indications · new strengths · new dosage forms · new directions · new combination products · different patient population An application for a product containing a new chemical entity as an active ingredient.	· Safety and/or efficacy data (supporting clinical and/or toxicological data) or justification for not providing such data are required. · Quality (CTD module 3) data are evaluated in full. However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the regulator, then the sponsor may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product).

[1] Refer to *OTC Application Route for Umbrella Branded Medicines* for the determination of correct application level for umbrella branded medicines

Appendix X

· Modified release products (excluding enteric coated tablets/capsules).

· Application for a generic of a registered product where bioequivalence data are required or where a justification for not providing bioequivalence is required.

· Product includes a new excipient, an excipient with a new route of administration or an excipient at a higher concentration than that which has previously been approved.

- Applications for products where a brand equivalence statement is requested and where bioequivalence evaluation is required, where a justification for not providing bioequivalence is required.
- Formulation dependent topical products.
- An application for an OTC product as a result of a change in scheduling for the particular product from the 'Prescription Only Medicine' schedule to a lower (OTC) schedule, where no such products are previously approved as an OTC medicine.

Changes to approved medicines—application categorisation framework

NOTE: Where a change application includes multiple changes covering different categories, the whole application is to be classified at the level of the highest category change in the application.

Risk rating	Appliation level	Definition of application level	Key application criteria
Negligible	**C1**	**Quality and non-quality changes** · Includes minor non-quality and quality related chan	Changes identified in the 'Changes Table' (refer ARGOM) as Application Level **C1**. **Australia specific** This category would be equivalent to the types of changes previously categorised as an 'N' (notification) in ARGOM Ch.11 **New Zealand specific** This category would be equivalent to the types of changes previously categorised as a 'Self-Assessable' change in the NZRGM

Risk rating	Appliation level	Definition of application level	Key application criteria
Low	C2	**Quality changes**[1] · Changes to quality aspects of a product excluding changes described in levels C1 or C4 **Non-quality changes - no safety & efficacy data required**[1] · Changes to the non-quality aspects of the product excluding changes described in C1, C3 or C4 and excluding changes requiring the provision of safety and efficacy data (or a justification for not providing such data).	Changes identified in the 'Changes Table' (refer ARGOM) as Application Level C2. · Includes changes to product name except those changes involving an umbrella branded product where the umbrella sequence is categorised as requiring a higher level of assessment[2]—assessed in level C3. This application level can include changes to a product involving a new indication or directions for use / new patient population but only where the provision of safety & efficacy data are not required. For example, a new indication for a registered product where that indication has been previously evaluated and approved for a very similar ('generic') product. **New Zealand specific** If changing the product name: · a change application is required if the product is replacing an existing product · a new product application is required if adding a new product.

Risk rating	Appliation level	Definition of application level	Key application criteria
	C3	**Umbrella branding: higher level of assessment[1]** · Changes to the product name where the new name includes an umbrella segment categorised as requiring a higher level of assessment[2] **Non-quality changes - safety & efficacy data may be required[1]** · Changes requiring evaluation of safety and/or efficacy data (or a justification for not providing such data) to support changes to labelling (incl. PI or Data sheet / CMI) except those changes described in C4	Changes identified in the 'Changes Table' (refer ARGOM) as Application Level C3.

Risk rating	Appliation level	Definition of application level	Key application criteria
Moderate	C4	**Non-quality changes – data are required**[1] · Where safety and efficacy data (clinical and/or toxicological) are required to support the proposed changes or where a justification for not providing such data would be required. **Quality changes**[1] [New Zealand specific] · New type of manufacturing process for a finished product · New manufacturing process for an active ingredient · New container / closure / packaging · Formulation changes	Changes identified in the 'Changes Table' (refer ARGOM) as Application Level C4.

[1] New Zealand specific: may be referred for assessment under section 2[illegible] of the *Medicines Act 1981*

[2] Refer to *OTC Application Route for Umbrella Branded Medicine*[illegible] for the determination of correct application level for umbrella branded medicines

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