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Department of Health
Therapeutic Goods Administration

OTC application categorisation framework

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TGA Health Safety Regulation

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Introduction

The OTC application categorisation framework defines the different OTC medicine application levels and identifies the key application criteria. This document assists sponsors to identify the appropriate application level when applying to register an OTC medicine or make a change to a registered OTC medicine.

New medicines

Table 1 New generic medicines - negligible risk

Application level	Definition of the application level	Key application criteria
N1	An application submitted as a 'Clone' described in the OTC new N1 applications 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 medicine otherwise meets all the requirements applying to a 'Clone'. The medicine name does not include a risk associated with an umbrella branding segment that requires a higher level of assessment.	Parent medicine must have been fully evaluated for safety, efficacy and quality [cannot be a 'grandfather' registered medicine] and must comply with current standards, including RASML[1]. Full access to the rights of the parent medicine is provided
N2	An application which complies with an OTC Medicine Monograph, as described in OTC N2 applications and OTC medicine monographs. The medicine name does not include a risk associated with an umbrella branding segment that requires a higher level of assessment.	The medicine complies fully with the requirements of a specific OTC Medicine Monograph together with the Requirements for OTC new medicines N2 applications (using OTC Monographs).

[1] Required Advisory Statement for Medicine Labels

Table 2 New generic medicines - low risk

Application level	Definition of the application level	Key application criteria
N3	New application for a 'generic' medicine other than those in levels N1, N2 or N4 The medicine name does not include a risk associated with an umbrella branding segment that requires a higher level of assessment.	Does not entail evaluation of safety and efficacy data. Do not provide safety and efficacy data for applications at this level. Requires full evaluation of Quality data (CTD module 3). However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the TGA, then you may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product).
N4	An application for a 'generic' medicine that: · requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing the data. Examples of such applications are included below this table and/or · has not previously been registered as an OTC medicine following down scheduling and /or · includes a risk associated with an umbrella branding segment requiring a higher level of assessment.	Requires evaluation of Quality data (CTD module 3). However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the TGA, then you may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product).

Examples of generic applications requiring safety and/or efficacy data

- Modified release medicines (excluding enteric coated tablets/capsules)
- A generic medicine application requiring bioequivalence data or a justification for not providing the data
- Medicines with:
  - a new excipient
  - an excipient with a new route of administration
  - an excipient at a higher concentration than that which has previously been approved.
- Applications for medicines that require both:
  - a brand equivalence statement

- bioequivalence data or a justification for not providing the data

· Formulation dependent topical medicines.

Table 3 New non-generic medicines (generic extensions/NCE) - moderate risk

Application level	Definition of the application level	Key application criteria
N5	An application for a new medicine that is an extension to a 'Generic category' medicine including: · New therapeutic indications · New strength · New dosage form · New directions · New combination medicines · Different patient population · An application for a medicine containing a new chemical entity as an active ingredient.	Requires both: Safety and/or efficacy data (supporting clinical and/or toxicological data) or a justification for not providing such data Quality data (CTD module 3). However, in the circumstance where all quality aspects of the product are identical to a product which has previously been fully evaluated by the TGA, then you may provide an abbreviated module 3 dossier (including finished product specifications for the proposed product)

Changes to medicines

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.

Table 4 Changes to medicines - negligible risk

Application level	Categorisation of application level	Key application criteria
CN	Changes identified in the Changes Table as application level CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes changes classified as 'negligible risk' to the **quality** and **non-quality** aspects of a medicine. Does not require assessment of safety, efficacy and/or quality data (or a justification for not providing such data).
C1	Changes identified in the Changes Table as application level C1	Includes changes classified as 'negligible risk' to the **quality** and **non-quality** aspects of a medicine. Does not require assessment of safety, efficacy and/or quality data (or a justification for not providing such data).

Table 5 Changes to medicines - low risk

Application level	Categorisation of application level	Key application criteria
C2	Changes identified in the Changes Table as application level C2	Includes changes classified as 'low risk' to the **quality** and **non-quality** aspects of a medicine. Does not require assessment of safety and/or efficacy data (or a justification for not providing such data). May require assessment of quality data.

Application level	Categorisation of application level	Key application criteria
C3	Changes identified in the Changes Table as application level C3	Includes changes: · classified as 'low risk' to the **quality** and **non-quality** aspects of a medicine and requires assessment of supporting safety and/or efficacy data or a justification for not providing the data and/or · to the medicine name where the new name includes a risk associated with an umbrella branding segment requiring a higher level of assessment.

Table 6 Changes to medicines - moderate risk

Application level	Categorisation of application level	Key application criteria
C4	Changes identified in the Changes Table as application level C4	Includes **non-quality** changes classified as 'moderate risk'. Requires assessment of safety and/or efficacy data (clinical and/or toxicological) to support the proposed changes or a justification for not providing the data.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OMA – OTCME	April 2013
V1.1	· Updated and converted the tables to be web accessible · Revised the information regarding changes to medicines to remove the repetition. · Changed table heading to more accurately represent the content i.e. replacement of the word 'definition' with 'categorisation'. · Removed any unnecessary text and included hyperlinks to core guidance. · Included risk rating for each table · Deleted references to the New Zealand specific Information.	OTC Medicines and Regulatory Guidance	30 November 2015
V1.2	Updated to include CN application level	OTC Medicines Evaluation Section / Scientific Operations Management Section	June 2017

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