Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

OTC application placement flowchart

Version 1.1, May 2016

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
V1.0	Original publication	OMA – OTCME	April 2013
V1.1	Update to hyperlinks and superseded references	COMB - OTCME	May 2016

Contents

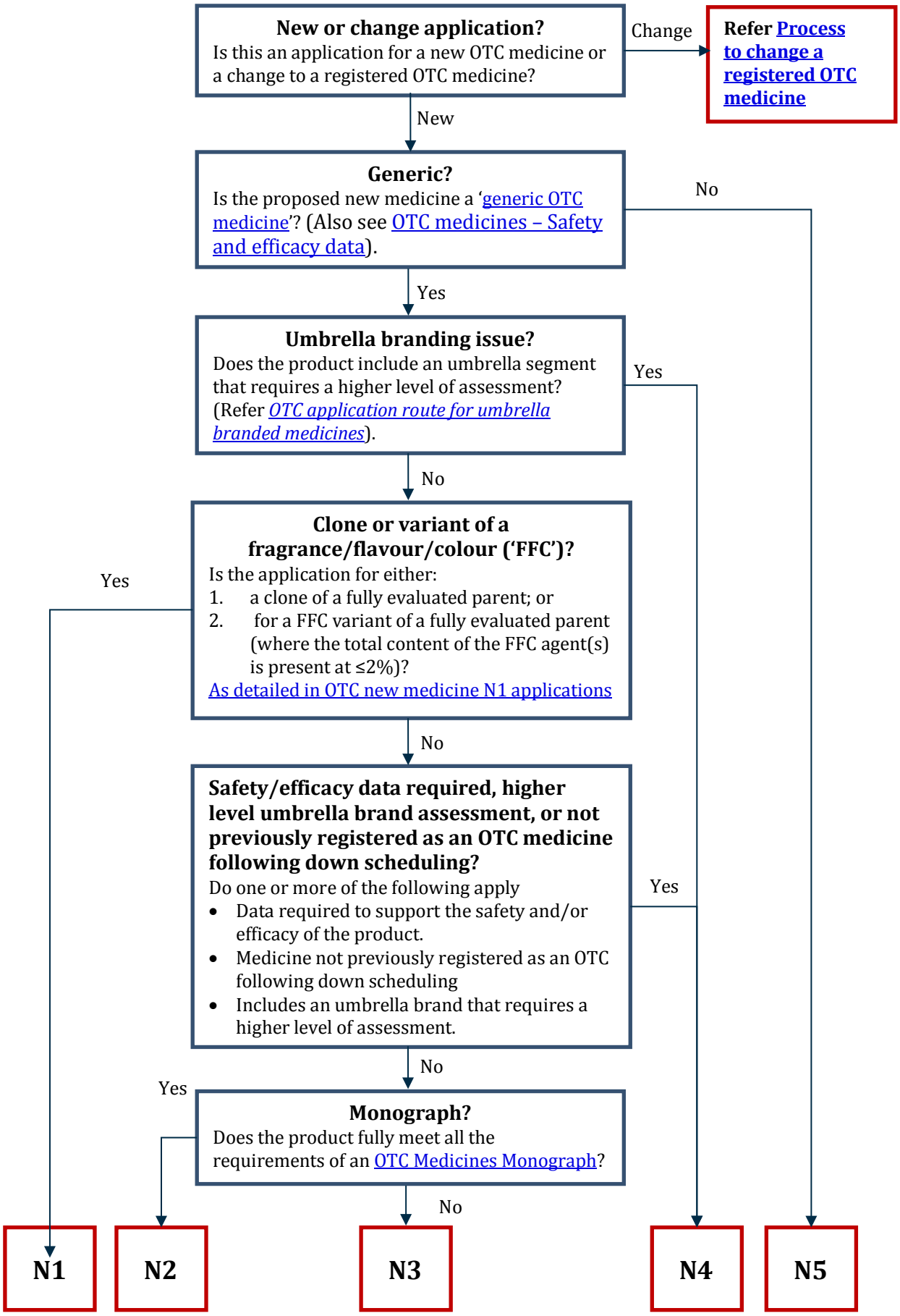
Introduction

The OTC application placement flowchart (the 'flowchart') is a tool to assist the sponsor in categorising an application to register a 'new' medicine into the appropriate application level. Sponsors wanting to change the details of a currently registered OTC medicine are referred to the *Guidelines on changes to OTC medicines*.

The flowchart has been developed primarily to assist the sponsor or regulatory affairs consultant experienced in the OTC regulatory environment to quickly categorise their application into the correct level. The sponsors who are less experienced in the OTC regulatory environment and those users less familiar with the terminology used in the flowchart, such as 'generic' medicine and 'umbrella branding issue', will still benefit from the use of the flowchart as a general guidance but would be advised to refer closely to the guidance documents specified within the document and the accompanying tools such as the *OTC application categorisation framework* and/or the *OTC application placement Q&A tool* to confirm the application level.

OTC application placement flowchart

See over the page.


New or change application?
Is this an application for a new OTC medicine or a change to a registered OTC medicine?
Change
Refer Process to change a registered OTC medicine
New
Generic?
Is the proposed new medicine a 'generic OTC medicine'? (Also see OTC medicines – Safety and efficacy data).
No
Yes
Umbrella branding issue?
Does the product include an umbrella segment that requires a higher level of assessment? (Refer OTC application route for umbrella branded medicines).
Yes
No
Clone or variant of a fragrance/flavour/colour ('FFC')?
Is the application for either:
1. a clone of a fully evaluated parent; or
2. for a FFC variant of a fully evaluated parent (where the total content of the FFC agent(s) is present at ≤2%)?
As detailed in OTC new medicine N1 applications
Yes
No
Safety/efficacy data required, higher level umbrella brand assessment, or not previously registered as an OTC medicine following down scheduling?
Do one or more of the following apply
• Data required to support the safety and/or efficacy of the product.
• Medicine not previously registered as an OTC following down scheduling
• Includes an umbrella brand that requires a higher level of assessment.
Yes
No
Monograph?
Does the product fully meet all the requirements of an OTC Medicines Monograph?
Yes
No
N1
N2
N3
N4
N5

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