



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

# OTC application route for umbrella branded medicines

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 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](http://www.tga.gov.au)>.

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## Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OMA – OTCME	April 2013

# Contents

<b>Introduction</b>	<b>5</b>
<b>What is umbrella branding?</b>	<b>5</b>
<b>Possible risks associated with umbrella branding</b>	<b>5</b>
<b>Flowchart for determining the application route for OTC umbrella branded medicines</b>	<b>7</b>

# Introduction

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. These applications are restricted to Level N4 and above for new medicines and Level C3 and above for applications to change the medicine name.

When determining the route for a particular application, the sponsor should assess the risk to consumers associated with the umbrella brand extension using the following information and the [Flowchart for determining the application route for OTC umbrella branded medicines](#) which must be used in conjunction with the [OTC application categorisation framework](#) to determine the correct level for an application.

## What is umbrella branding?

**'Umbrella branding'** refers to the marketing of two or more medicines under the same 'brand' name.

The **'umbrella segment'** is the part of a medicine name that is used in the name of more than one medicine to create a 'brand' for a range of medicines.

Umbrella brands are generally associated with:

- particular actives
- a therapeutic area or set of indications
- a particular sponsor or retailer

**'House brand'** is the term used to describe a range of medicines where the umbrella segment is typically associated only with the sponsor or retailer. These brands or ranges of medicines are not associated with any particular active ingredient(s), or therapeutic area and indications(s), and usually the brand spans a wide range of unrelated medicines.

## Possible risks associated with umbrella branding

The majority of umbrella branded ranges, such as 'house brands', do not pose safety or efficacy concerns. However, there are situations when the proposed extension to the umbrella brand range poses significant risks due to the potential for consumers to be confused regarding the differences between the proposed medicine and the current medicines within that umbrella brand. Examples of these are the extension of an umbrella brand to include medicines with different active ingredient(s), therapeutic areas or indication(s).

Medsafe and TGA assess the acceptability of extensions to umbrella brands against the guidance outlined in the relevant sections of the ARGOM and the NZRGM, and these guidelines should be referenced by all sponsors prior to submitting an application for an OTC medicine in either Australia or New Zealand.

*i. Negligible to low risk associated with the use of the umbrella segment.*

Applications where the umbrella segment poses a negligible to low risk to consumers can usually be managed by ensuring adequate differentiation across the range. Consequently, these applications have no restriction on their application route based on the umbrella segment of the medicine name and sponsors should determine the application route based on other criteria. This category often includes applications to register a medicine:

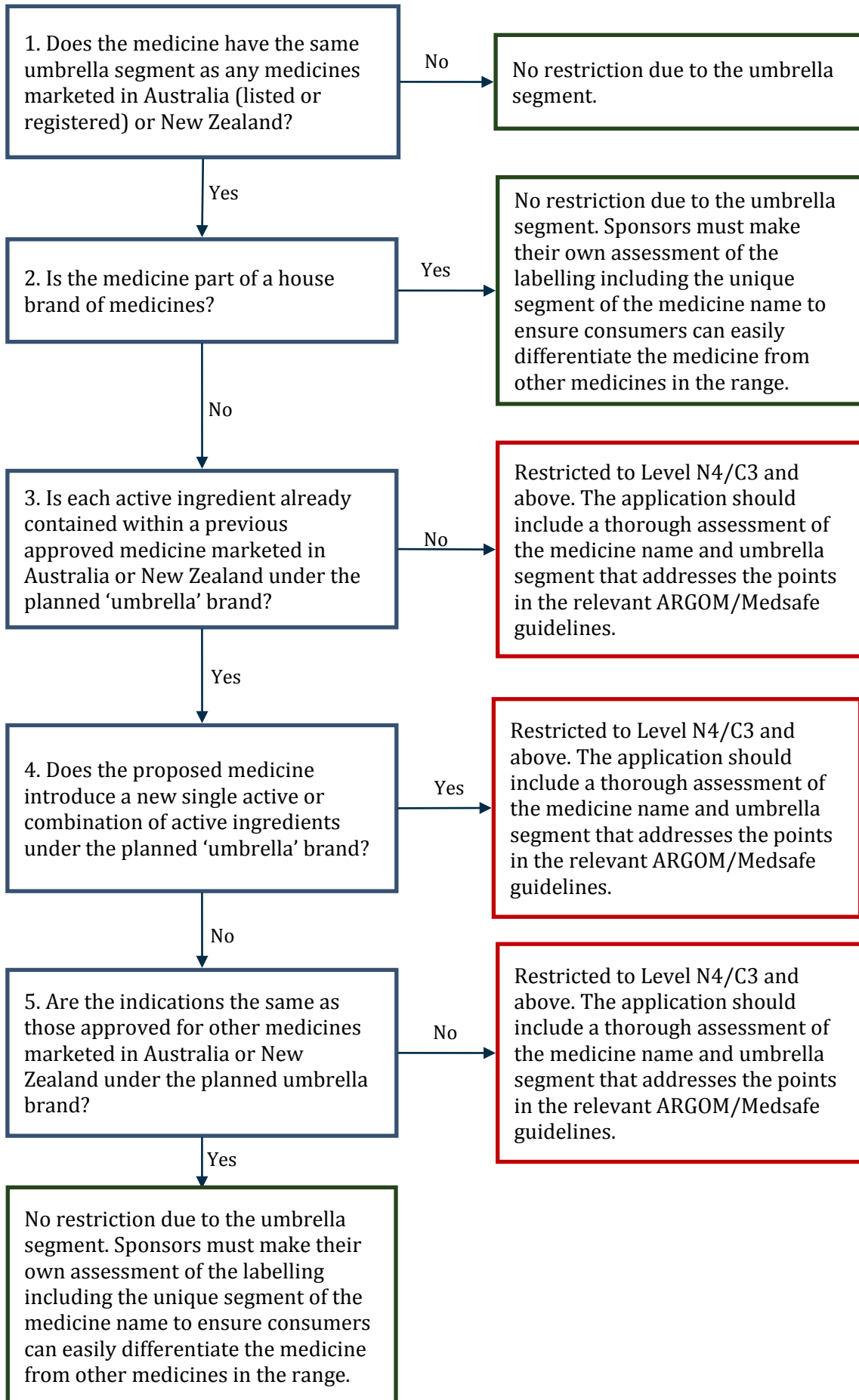
- within a house brand.
- with a different strength or dosage form to that previously approved within the umbrella brand.

*ii. Higher risk associated with the use of the umbrella segment.*

Applications that propose an extension of the umbrella brand into new active ingredient(s), therapeutic area or indications(s) that have not previously been included under the umbrella brand are considered to pose an increased safety and/or efficacy risk to consumers. For these types of applications, the suitability of the umbrella segment in the medicine name requires a higher level assessment in order to manage the risk. These types of applications will be restricted to Level N4 and above for new medicine applications and Level C3 and above for applications to vary the medicine name.

# Flowchart for determining the application route for OTC umbrella branded medicines

Use this flowchart to determine the assessment level for a medicine that has an umbrella segment in the medicine name. The [OTC application categorisation framework](#) and associated tools for application placement must also be used to determine the correct application level for an umbrella branded medicine. The *OTC application categorisation framework* details other criteria, such as requirements for safety and efficacy data that must be also be considered.





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Reference/Publication R13/279978