



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

OTC application placement question and answer tool

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 <<https://www.tga.gov.au/publication/otc-n2-applications-and-otc-medicine-monographs>>.

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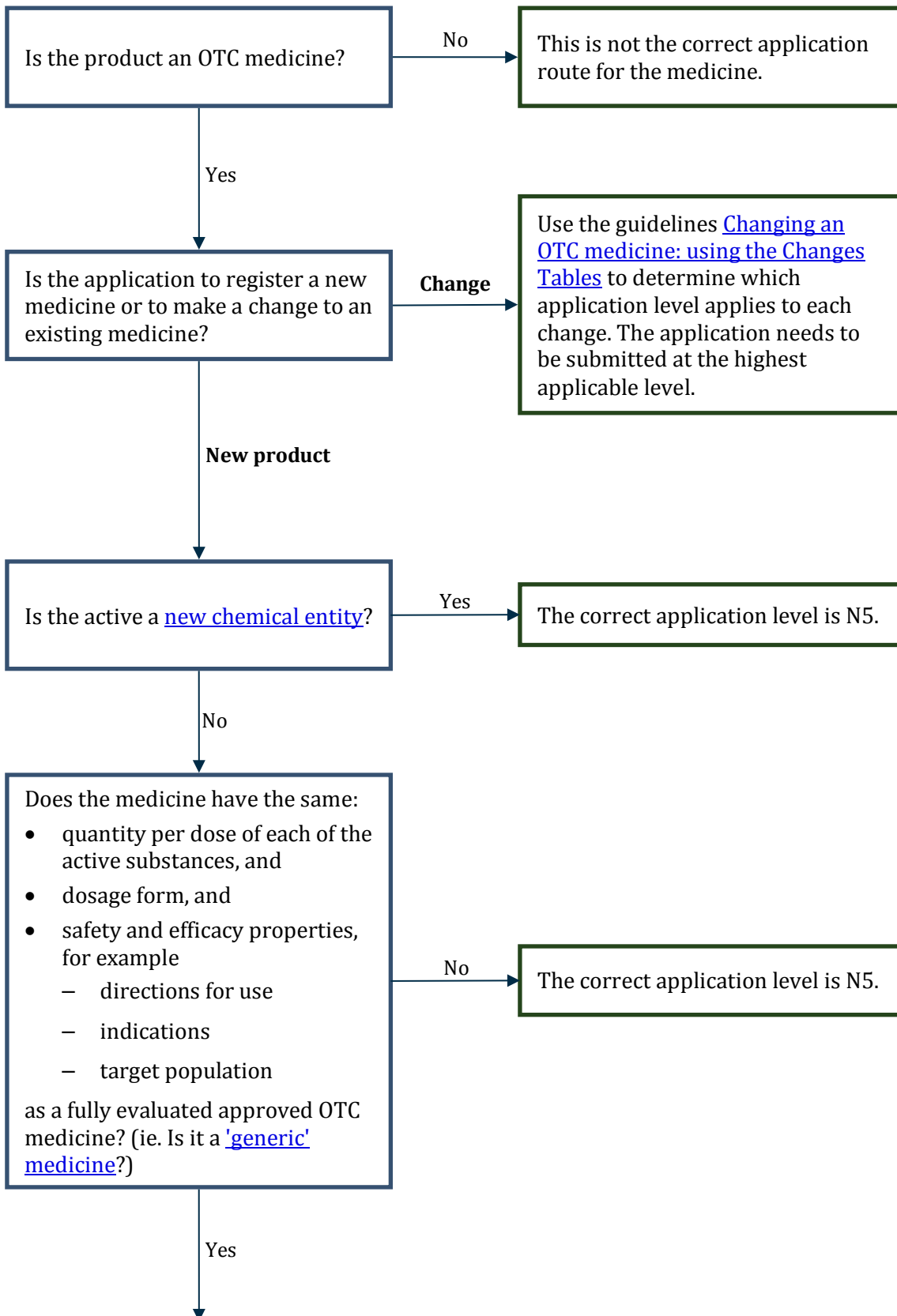
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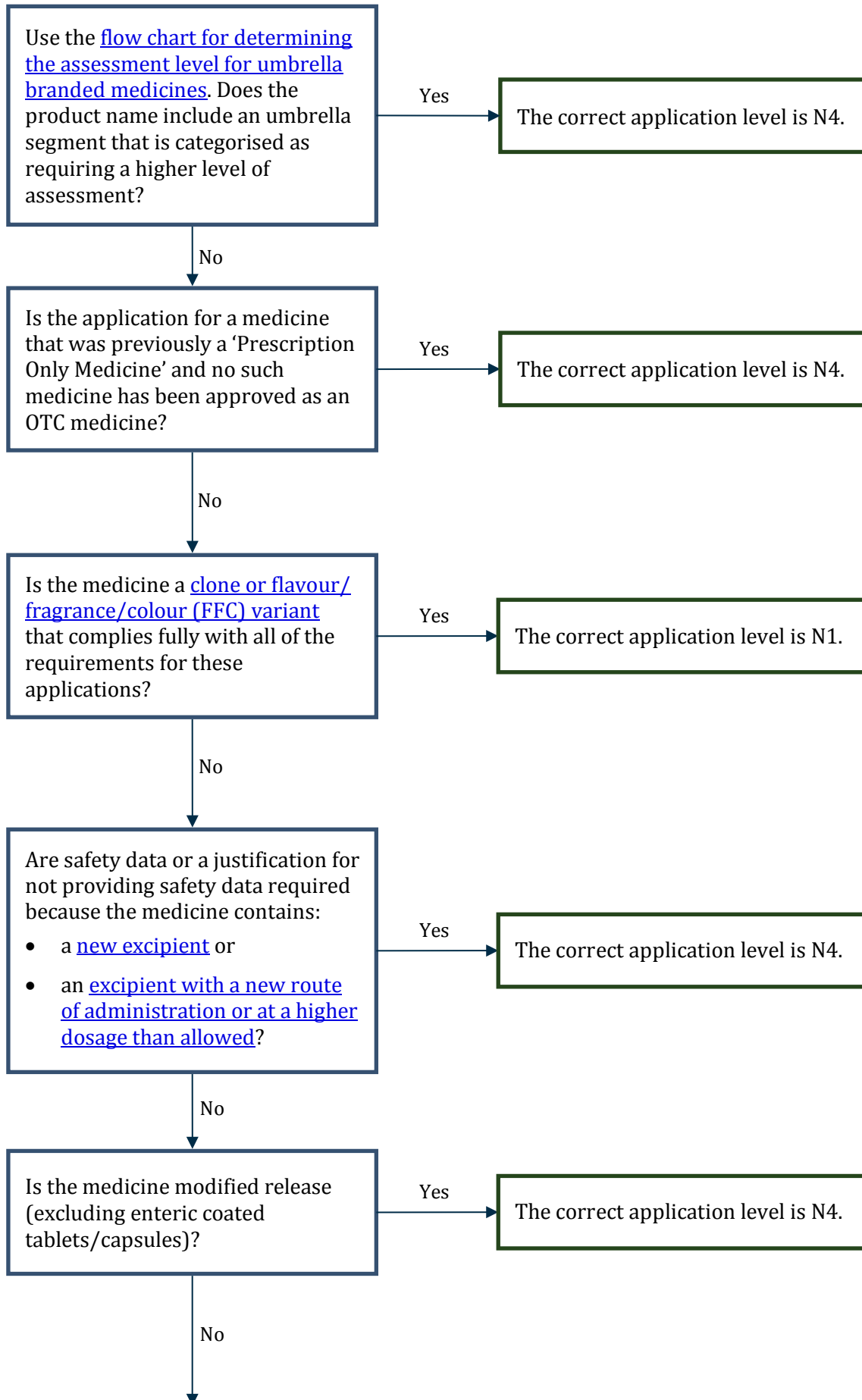
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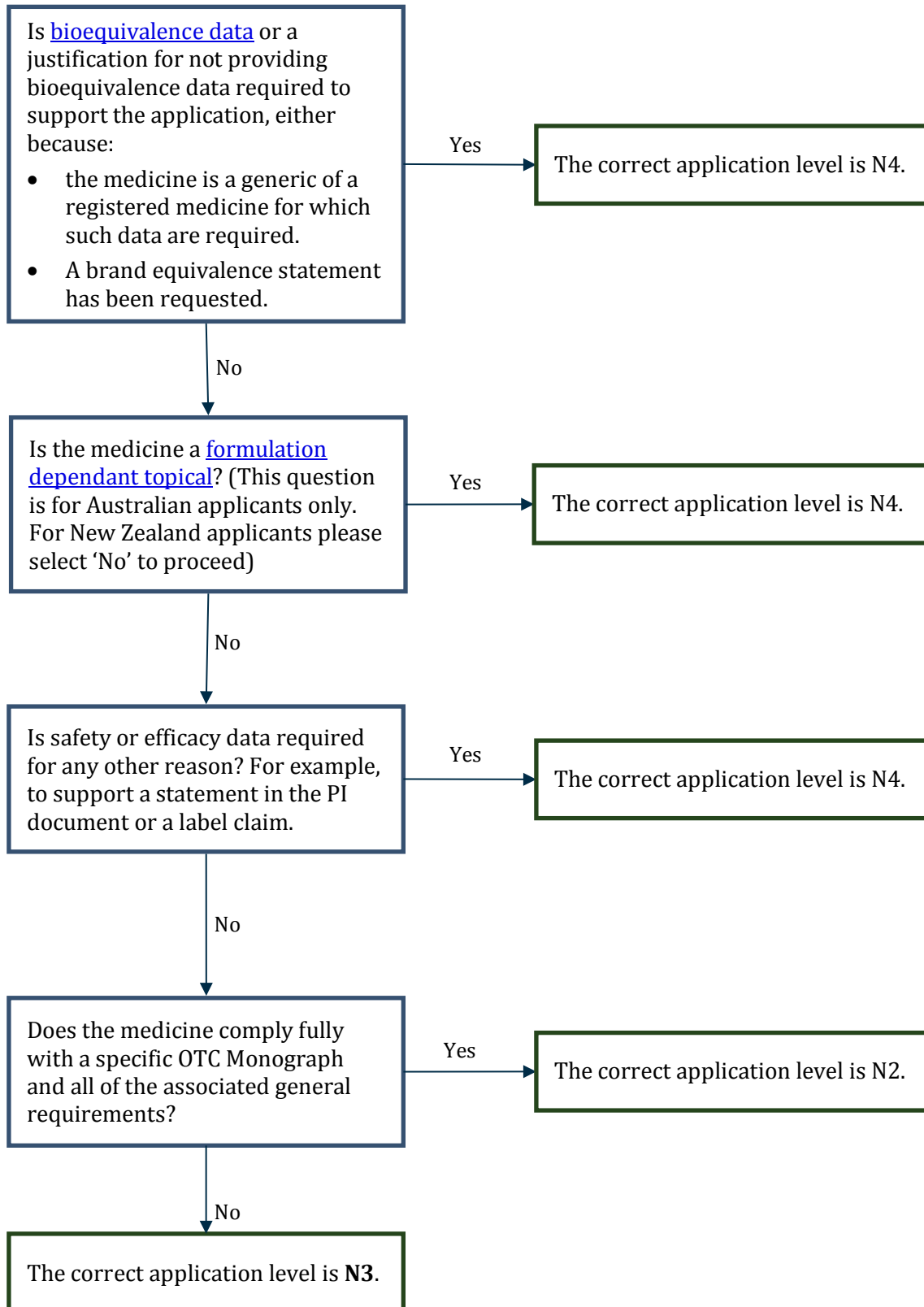
Version history

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V1.1	Update to hyperlinks and superseded references	COMB-OTCME	May 2016

Use this tool to determine the correct application level for an OTC medicine application by answering a series of questions.







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