



Australian Government
Department of Health
Therapeutic Goods Administration

Target evaluation times for OTC medicine applications

Version 1.3, June 2017

TGA Health Safety
Regulation

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Introduction

The TGA aims to complete the OTC medicine evaluation process within a specified target time.

The target times for the evaluation phase differ for the application levels. Lower application levels have shorter target times and fewer rounds of formal Request for information than higher level applications.

Note. The target evaluation times are for the TGA time only, which does not include 'sponsor time'. 'Sponsor time' is the time taken by the sponsor to respond to a request for information from the TGA.

Related information

- [OTC medicines registration process](#)
- [Process to change a registered OTC medicine](#)

Target total evaluation and standard request for information response times

Application level	Target total evaluation time (TGA time - working days)	Number of Requests for Information (RFI)	Standard time allowed for sponsors to respond to the RFI (working days)
N1	45	1	5
N2	55	1	15
N3	150	2	1 st – 43 2 nd – 21
N4	170	2	1 st – 43 2 nd – 21
N5	210	2	1 st – 43 2 nd – 21
CN	N/A – automated approval	N/A	N/A
C1	20	1	5
C2	64	1	15

Application level	Target total evaluation time (TGA time - working days)	Number of Requests for Information (RFI)	Standard time allowed for sponsors to respond to the RFI (working days)
C3	120	2	1 st – 43 2 nd – 21
C4	170	2	1 st – 43 2 nd – 21

Target first round evaluation times

C2 applications

A target first round evaluation time of 43 working days applies to C2 applications submitted on or after 9 April 2014.

The TGA will introduce target first round evaluation times for other OTC application levels progressively, as supporting data becomes available.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OMA – OTCME	15/04/2013
V1.1	<ul style="list-style-type: none"> • Changed all target times so that they are expressed in working days rather than calendar days. • Reduced the target total evaluation time for C2 applications. • Introduced a first round evaluation target time for C2 applications. • Revised explanatory text and headings to improve clarity. 	OMA – OTCME	20/05/2014
V1.2	As part of the ongoing refinement of the OTC business process, the target evaluation times for N2 applications were reviewed. The target total evaluation time for OTC N2 applications has been reduced from 75 days to 55 days.	COMB-OTCME	01/11/2015
V1.3	Update to reflect the new notification process (CN) commencing 1 July 2017.	OTC Medicines Evaluation Section / Scientific Operations Management Section	June 2017

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
<https://www.tga.gov.au>

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