Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

TGA USE ONLY

This form, when completed, will be classified as **'OFFICIAL'**.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at https://www.tga.gov.au/treatment-information-provided-tga.

Assurances to accompany an OTC new medicine N1 application

These assurances confirm that the application meets the requirements for an N1 level application.

The importance of assurances

The applicant completes a list of assurances confirming that the product meets the requirements for an N1 level application for a new over-the-counter (OTC) medicine.

Giving information that is false or misleading in a material particular is an offence under the *Therapeutic Goods Act 1989* (section 22A) and can give rise to civil penalties under the Act (section 22B).

Under subsection 24(2) of the Act, an application for registration of an OTC medicine lapses if:

- it contains information that is inaccurate or misleading in a material particular
- information that is inaccurate or misleading in a material particular is given to the TGA in connection with an OTC medicine application, including information given for the purposes of section 31 of the Act

Following approval, medicines found not to comply with standard and specific conditions of registration could be subject to regulatory action.

Completing this form

Completing this form provides the assurances required to accompany an OTC New medicine N1 application. Ensure you:

- **Provide all the assurances** in this form. If you cannot provide all of the **required** assurances, do not submit an OTC new medicine N1 application, because this is not the correct application level.
- Enter the required administrative details in Section 1.
- Select 'Yes' if you can provide the assurance. 'Not applicable' is only an option where a 'Not applicable' checkbox has been provided.
- Ensure this form is signed by a person authorised to conduct business on behalf of the applicant. This person must be listed on the TGA Business Services client database and may be a company employee or an agent.
- Include the completed form within Module 1.5.7 of an OTC new medicine N1 application.

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Section 1: Administrative

Proposed trade name	
Active ingredients	
Name of sponsor	
Name of agent (if applicable)	
Trade name and AUST R number of **parent** medicine	
Sponsor of parent medicine	
For the parent medicine, approval date of most recent label, PI and CMI	Label: PI: CMI:
Detail any advertising (labelling) exemptions that apply to the parent medicine under section 42DK(1) of the Therapeutic Goods Act	

Section 2: Assurances

General

No.	Assurance	
1	The sponsor of the parent medicine has authorised the TGA to access information on the parent medicine files and ARTG record to support this application. Note: • You need to provide a letter of authorisation from the sponsor of the parent medicine in Module 1.5.5. • This letter is required even if the sponsor of this application is the same as the sponsor of the parent medicine.	☐ Yes
2	Both the parent and proposed medicine comply with all applicable current standards, including (but not limited to): • RASML • the approved form for Product Information (if applicable) • the Poisons Standard • relevant Therapeutic Goods Orders • default pharmacopoeial standards.	☐ Yes

No.	Assurance	
3	The proposed medicine complies with Therapeutic Goods Order No. 95 – Child-resistant packaging requirements for medicines 2017 (TGO 95). Note 1: sponsors are required to hold evidence of performance testing for reclosable closures. Note 2: Blister packaging is generally considered to be compliant with requirements for child-resistant packaging.	☐ Yes ☐ Not applicable

Labelling

No.	Assurance	
1	I have assessed the medicine name using the Flowchart for determining the application route for OTC umbrella branded medicine and determined there is no restriction on the application level based on the use of an umbrella segment.	☐ Yes
2	The differences in the proposed and parent labels, PI and CMI are consistent with the permitted differences described in Making over-the-counter (OTC) New medicine N1 applications.	☐ Yes
3	Where an internet address or QR code is included, the information about the medicine on the website (including any direct links from that website) will be consistent with the information approved by the TGA for the medicine.	☐ Yes ☐ Not applicable
4	For flavour / fragrance / colour variants where claims are made that the medicine does not contain a particular excipient (e.g. gluten free, alcohol free, lactose free); the statement is true and in accordance with any relevant requirements in Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines (TGO 92).	☐ Yes ☐ Not applicable

Pack size

No.	Assurance	
1	The proposed pack size(s) have been approved for the parent medicine **OR** The pack size(s) differ from those approved for the parent medicine, **and**: a. The medicine is a solid dose form b. The new pack size does not introduce a higher schedule medicine than the parent medicine c. The container type and container material are unchanged. d. For new pack sizes (other than blister packs) that are not bracketed by stability data for the approved parent pack sizes, stability data has been/ will be generated to support the proposed pack size.	☐ Yes (Move to next section) ☐ Yes ☐ Yes ☐ Yes ☐ Yes ☐ Not applicable

Quality

No.	Assurance	
1	All quality aspects of the proposed medicine are identical to the parent medicine, other than differences that are specifically permitted in over-the-counter (OTC) New medicine N1 applications.	☐ Yes
2	Manufacturing process validation has been completed (or will be completed prior to supply in Australia) on a minimum of two commercial scale batches of product according to Good Manufacturing Practice.	☐ Yes

No.	Assurance	
3	The manufacturer's validation report and related information will be available for review, on request by the TGA, within 3 months of release for supply of the first production batch.	☐ Yes
4	The proposed manufacturers are identical to the parent **OR** The proposed manufacturers differ from the parent, **and**: a. The difference in manufacturing has been validated and shown to be of equivalent or better performance. b. For medicines that are sterile, the manufacturing sites that differ from the parent are only responsible for release for supply, secondary packaging or physical/ chemical testing.	☐ Yes (Move to next section) ☐ Yes ☐ Yes ☐ Not applicable
5	The finished product specifications are identical to those approved for the parent medicine and comply with all applicable standards. **OR** The finished product specifications are identical to those approved for the parent medicine other than aspects directly related to the flavour/ fragrance/ colour (e.g. visual identification) and the specifications comply with all applicable standards.	☐ Yes (Move to next section) ☐ Yes

Flavour/Fragrance/Colour variant(s)

No.	Assurance	
1	For a flavour/ fragrance/ colour variant: a. The total combined quantity of the affected flavour/ fragrance/ colour agents in the **parent medicine** are not more than 2 % w/w or w/v or v/v, **and** b. The total combined quantity of the affected flavour/ fragrance/ colour agents in the **proposed medicine** are not more than 2 % w/w or w/v or v/v.	☐ Not applicable (Move to declaration) ☐ Yes ☐ Yes
3	For medicines that differ from the parent in terms of colouring, the colouring conforms to the requirements in the guidance Colourings used in medicines for topical and oral use.	☐ Yes ☐ Not applicable
4	Stability data has been/ will be generated on the first two production batches of the new flavour/ fragrance/ colour variant.	☐ Yes

Declaration

I declare that:

- The information and assurances I have provided above are true and correct. ☐ Yes
- I am authorised to make this declaration and provide these assurances. ☐ Yes

Name			
Position (e.g. regulatory affairs officer, agent of the sponsor)			
Signature		Date	