Australian Government
Department of Health
Therapeutic Goods Administration

OTC new medicine N1 applications

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TGA Health Safety Regulation

Contents

Introduction

This guidance is intended for applicants submitting an N1 level application to register a new OTC medicine and will:

- help you confirm whether you have an N1 level application
- detail the permitted differences from the parent medicine
- link to relevant information to compile an N1 level application dossier.

N1 applications

The OTC N1 application level comprises applications for 'clones' and flavour/fragrance/colour variants.

The terms 'clone' and flavour/fragrance/colour variant are applied to an OTC medicine that is identical to an existing fully evaluated medicine (the parent medicine) apart from certain permitted differences.

The sponsor of a clone or flavour/fragrance/colour variant registered on the Australian Register of Therapeutic Goods (ARTG) is fully responsible for the medicine.

N1 level applications have reduced requirements for supporting data as the proposed medicine is identical to a parent medicine. However, the application needs to meet certain requirements to be submitted at the N1 level.

Confirm you have an N1 level application

To confirm you can submit your application as an N1 level application:

- go to Determining the correct application level for OTC medicine applications
- check that your application meets all of the following criteria for an N1 level application.

If your application does not meet all of the criteria below, it is not an N1 level application. You will need to determine the correct application level to submit your application at the correct level.

Criteria for an N1 level application

- The sponsor of the parent medicine must authorise the TGA to access the information on the parent medicine files and ARTG record for the purpose of the N1 application.
- The parent medicine must be fully evaluated and not grandfathered (i.e. registered on the basis of satisfactory quality, safety and efficacy data). You cannot use medicines registered via an N2 application as a parent for an N1 application.
- The proposed medicine must be identical to the parent medicine in all respects, other than certain permitted differences.
- You must be able to provide all of the Assurances for N1 applications.
- The parent and proposed medicine must comply with all applicable current standards, including the RASML, the SUSMP, relevant Therapeutic Goods Orders (e.g. TGO 69, TGO 77,

TGO 78, TGO 80) and default pharmacopoeial standards. If the parent medicine is not compliant with current standards:

  - The parent sponsor will need to submit an application to bring the parent medicine into compliance with current standards before you submit the N1 application. Do not submit the N1 application until the parent sponsor has obtained approval for the application to change the parent medicine.

- The proposed medicine name cannot include an umbrella segment that requires a higher level assessment. Use the umbrella branding flowchart to determine what level of assessment is required.

Permitted differences from the parent medicine

The proposed medicine must be identical to the parent medicine in all respects, other than limited permitted differences in the:

- Sponsor details
- Medicine name
- Medicine labels
- Label graphics
- Product information and consumer medicine information
- Pack size (for solid dose products only, provided there is no change to the medicine schedule)
- Manufacturing sites
- Visual identification
- Flavour/ fragrance/colour agents.

If you want the proposed medicine to include differences beyond those permitted for an N1 level application you can either:

- Submit the application to register the medicine at the appropriate OTC new medicine application level (N2-N5).
- Submit an N1 level application that meets the N1 criteria and only includes the permitted differences.
- Once the clone or flavour/fragrance/colour variant is registered you can make other changes to the medicine by following the Process to change a registered OTC medicine.

Sponsor details

The sponsor of the clone or flavour/fragrance/colour variant can differ from the sponsor of the parent medicine, provided the sponsor of the parent medicine authorises the TGA to access the information on the parent medicine files and ARTG record for the purposes of the N1 application.

Medicine name

The proposed medicine name for an N1 level application cannot include:

- A claim or indication, unless it is either:
  - fully corresponding to a claim or indication allowed in the parent medicine name.
  - an indication that is consistent with the **complete** indications approved on the ARTG. Including a subset of the approved indications in the medicine name is not permitted for N1 applications.
- An umbrella segment that requires a higher level of assessment. During screening or evaluation we may request labels of the full range.

Ensure that the proposed medicine name complies with the guidelines on Presentation aspects of OTC applications.

Medicine labels

The labels and package insert for the proposed medicine must be identical to the parent medicine, other than the medicine name, design and layout, pack size details, sponsor or supplier details and logos.

Ensure that any proposed difference from the parent labels complies with the guidelines on Presentation aspects of OTC applications.

Label graphics

The proposed labels graphics can differ from those approved for the parent medicine provided:

- Any graphics are consistent with the ARTG details for the medicine.
- Any graphics that represent the action of the medicine directly correspond to an equivalent graphic approved for the parent medicine.
- The graphics comply with the guidelines on Presentation aspects of OTC applications.

Examples

- The proposed labels of a medicine can include a graphic of a child if it is consistent with the target population. However, the labels cannot include a graphic of a sleeping child (implies a sedating action) unless the parent labels have been approved with a similar graphic of a sleeping child.
- If the parent labels have a graphic of a head with a target on the nose, the clone labels could include an equivalent graphic but not a graphic of the head with the nose and forehead targeted.
- The proposed labels can include an accurate illustration of the dosage form even if this is not present on the parent labels.

Product information and consumer medicine information

The product information and consumer medicine information must be identical to the parent, other than the medicine name, sponsor name, pack size and flavour/ fragrance/colour details.

Provide both a product information and consumer medicine information for the proposed clone or flavour/ fragrance/ colour variant if the parent medicine has been approved with a PI and CMI. This requirement for N1 applications applies regardless of the medicine schedule.

Approved form for product information

For restricted medicines or if the PI was requested by the Secretary:

- The PI for the parent and proposed medicine must be in the approved form for providing Product Information.

If the parent medicine product information is not in the approved form, the parent sponsor will need to submit an application to update the PI before you submit the N1 application.

Pack size

The proposed pack size(s) can differ from the parent only for solid dosage forms where there is no change in medicine schedule or container material.

For new pack sizes of solid dosage forms other than blister packs; if the proposed pack size is not bracketed by stability data obtained for the parent pack sizes you will need to:

- Provide an assurance that you will undertake stability studies on at least the first two production batches to support the proposed pack size(s).

Manufacturing sites

For non-sterile medicines, the manufacturing sites for the proposed medicine can differ from the parent.

For sterile medicines, manufacturing sites that are only responsible for release for supply, secondary packaging and physical and chemical testing can differ from the parent.

Ensure that you have valid evidence of Good Manufacturing Practice (GMP) for the manufacturers that perform each step of manufacture. (See Step 5 in the OTC Medicines registration process.)

Visual identification

The visual identification can differ from the parent only when it is either a direct consequence of:

- the new flavour/fragrance/colour agent(s)
- a difference in debossing/embossing/printing to remove or add identifying marks.

Removal or addition of break marks is not permitted for an N1 application.

Flavour/ fragrance/ colour variants

The flavour/fragrance/colour agents (including printing inks) in the proposed medicine can differ from the parent medicine.

The total combined content of the affected flavour/fragrance/colour agents (including printing inks) cannot exceed 2% w/w or w/v in either the parent or the proposed medicine.

Ensure that the proposed raw material specifications for new flavour/fragrance/colour comply with applicable standards.

You will need to give an assurance that you will undertake stability studies on at least the first two production batches.

If the new flavour/fragrance/colour includes excipients that must be declared on the label (First schedule of the Therapeutic Goods Order No. 69) ensure that the labels have been updated accordingly.

If the medicine label includes any claims that it does not contain a particular excipient (e.g. gluten free, sugar free, lactose free) ensure the claims are true in regard to the components of the new flavour/fragrance/colour.

Related guidance

- Quality aspects of OTC medicine applications
- Colourings used in medicines for topical and oral use
- Notification of a proprietary ingredient form

Compiling the information and assurances for N1 applications

Ensure your application contains all of the required information in the correct format to be effective under section 23 of the *Therapeutic Goods Act 1989* to pass screening in Step 9 of the in the OTC medicines registration process and accepted for evaluation.

- Ensure that you provide all of the Assurances for N1 applications.
- Check that you have met the requirements detailed in:
  - CTD Module 1: OTC medicines
  - Mandatory requirements for an effective OTC application, particularly, CTD Module 3.2.P.4 (excipient specifications for flavour/ fragrance/colour variants)
  - General dossier requirements.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	OTC Medicines and Regulatory Guidance Team	30 November 2015

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