**Information for industry**

The type of application required to register a Pharmacy Only medicine containing melatonin will depend on several factors, including whether Medsafe has previously assessed the quality dossier for the product, and whether Medsafe has previously assessed the proposed indication.

**Previously approved product**

If Medsafe has previously assessed the quality dossier for the proposed product under a different classification, product name or for a different indication (i.e. if Medsafe has previously approved a ‘parent’ product with the same quality dossier), then the likely options are:

* Change the approved product through submission of a Changed Medicine Notification (CMN)
* If the proposed product, indications and dosage have previously been approved, then an additional classification can be registered by submitting an L1 NMA for a new pharmacy only presentation
* If the proposed indications and/or dosage have not previously been approved, then an L3 application will be required with clinical data\* to support safety and efficacy will be required.

**New product not previously approved by Medsafe**

If Medsafe has not previously assessed the quality dossier for the proposed product (i.e. there is no approved parent product), then the likely options are:

* For a generic version of a reference product that Medsafe has previously approved, then an L2 application will be required.
* If the product has new features that Medsafe has not previously approved for a melatonin-containing product (e.g. new dose form, strength, indications and/or dosage) then an L3 application with clinical data\* to support safety and efficacy will be required.

\* Literature based submissions that meet [TGA guidelines](https://www.tga.gov.au/how-we-regulate/supply-therapeutic-good/supply-prescription-medicine/pre-submission-planning-prescription-medicines/literature-based-submissions) can be submitted *in lieu* of new clinical trials to demonstrate safety and efficacy for new indications and/or directions for use.

The general guidance on [New Medicine Applications](https://www.medsafe.govt.nz/regulatory/current-guidelines.asp) provides further guidance for companies wishing to submit an application for consent to distribute a Pharmacy Only medicine containing melatonin in New Zealand. For specific questions contact medsafeapplications@health.govt.nz

**Bioequivalence**

Applications for new generic medicines (melatonin 2 mg, modified release tablets) will need to demonstrate bioequivalence to the New Zealand innovator product. Sponsors can refer to Medsafe’s guideline on the [Bioequivalence of medicines for further information](https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/bioequivalence-of-medicines.pdf)

**Labels for Pharmacy-Only packs of melatonin**

Sponsors should use Medsafe’s guideline on the [*Labelling of medicines and related products*](https://www.medsafe.govt.nz/regulatory/current-guidelines.asp) to design appropriate labelling for Pharmacy-Only melatonin products. Medsafe supports harmonising with Australia where possible.

In addition to the Label Statements Database entries which apply to individual product formulations, additional safety statements will be required on the labels of Pharmacy-Only melatonin products. For products that meet the criteria for submission under the L1 and L2 application categories, the following additional label statements will be required:

• Do not use if:

- you are under 18 years of age

- you are taking any other medicines for sleep

- you have liver problems

- you are pregnant or breastfeeding.

• Unless a doctor has told you to, do not use:

- for more than 30 days

- if you have kidney problems

- if you have an autoimmune disease.

• Consult a pharmacist or doctor before use if you are taking other medicines regularly.

• Do not drink alcohol while taking this medicine.

• This medicine may cause drowsiness. If affected do not drive or operate machinery.

For L3 applications, modified statements as relevant to the proposed dose form, strength and indications will be required.

The Medsafe pack size is harmonised with Australia for insomnia.

**Approved medicines containing melatonin:**

Melatonin is currently approved in Prescription and Pharmacy-only presentations. The approved products containing melatonin can be found on the [Medsafe website](https://www.medsafe.govt.nz/regulatory/DbSearch.asp):