



Department of Health
Certification no: C-FILE-21962-23

Certified alternative way (to complying with the Poisons Standard, Part 2) of labelling a package containing a controlled drug, a restricted drug or a poison (labelling exemption)

Health (Drugs and Poisons) Regulation 1996 - section 11

I, Gregory Perry, Director, Healthcare Approvals and Regulation Unit and delegate of the Chief Executive, Queensland Health, do hereby certify the following alternative way of labelling a package containing a controlled drug, a restricted drug or a poison:

The Alternative Way

In Queensland, the products in Table 1 labelled as Schedule 4 medicines with the signal words 'Prescription Only Medicine' can be supplied by Generic Partners Pty Ltd and Apotex Pty Ltd as Schedule 3 (Pharmacist Only Medicine) products, provided all other aspects of the labelling other than the incorrect signal headings are compliant with the Poisons Standard.

Table 1: Product to which label exemption applies

ARTG ID	Description
250295	MELOTIN MR melatonin 2mg modified release tablet blister pack each pack containing 30 tablets

Conditions of certification

1. Retail supply is to be from pharmacies only and the incorrectly labelled products will need to be stored in pharmacies as Schedule 4 products.
2. Each supply to a consumer must include the Consumer Medicine Information approved by the Commonwealth Therapeutic Goods Administration for the medicine.
3. This certification is effective from 01 June 2021.
4. This certification expires on 31 May 2022 or until existing stock of Schedule 4 labelled product is exhausted, whichever is the earlier.

Certified at Brisbane this 20 day of May 2021 by Greg Perry

**Delegate of the Chief Executive
Healthcare Approvals and Regulation Unit
Queensland Health
Certification number: C-FILE-21962-23**

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