



Department of Health

Certification no: C-FILE-21962-017

## **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 Sandoz 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

<b>ARTG ID</b>	<b>Description</b>
Aust R 187214	SUMATRIPTAN Sandoz® packs of two tablets each containing 50 mg of sumatriptan

#### **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 1 February 2021.
4. This certification expires on 31 May 2021 or until existing stock of Schedule 4 labelled product is exhausted, whichever is the earlier.

Certified at Brisbane this 11<sup>th</sup> day of January 2021 by Greg Perry

**Delegate of the Chief Executive  
Healthcare Approvals and Regulation Unit  
Queensland Health**

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