NSW GOVERNMENT Health

POISONS AND THERAPEUTIC GOODS REGULATION 2008

EXEMPTION

Labelling exemption under clause 10(1)

I, BRUCE BATTYE, Director Pharmaceutical Operations, a duly appointed delegate of the Secretary, NSW Health, make this instrument pursuant to clause 10(1) of the *Poisons and Therapeutic Goods Regulation 2008* (NSW) [the Regulation].

BRUCE BATTYE
Director Pharmaceutical Operations
(Delegation Number PH356)

Date: 28/5/24

Exemption for bilastine tablets in packs labelled with the signal words 'PHARMACIST ONLY MEDICINE'.

1 Application

A person licensed or authorised to supply Schedule 2 and 3 poisons under the Regulation may supply *Allertine*® packs of ten or thirty tablets each containing 20 mg of bilastine (AUST R 387574) which has been labelled as a Schedule 3 poison (that is, labelled "PHARMACIST ONLY MEDICINE"), despite being a Schedule 2 poison from 1 June 2024.

2 Conditions – clause 10(2)

1) The exemption under clause 10(1) of the Regulation commences on 1 June 2024 and expires on 1 June 2025.

2) The exemption applies only to *Allertine*® packs of ten or thirty tablets each containing 20 mg of bilastine which from 1 June 2024 will be included in Schedule 2.

3) Each supply to a consumer must include the Consumer Medicine Information approved by the Commonwealth Therapeutic Goods Administration for the medicine.

4) The exemption does not apply to products supplied by persons who are not licensed or authorised to supply Schedule 3 poisons.

3 Duration

This exemption expires on 1 June 2025.