Australian Government
Department of Health
Therapeutic Goods Administration

Final decisions and reasons for decisions by delegates of the Secretary to the Department of Health

26 May 2017

Notice under subsections 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations)

The delegates of the Secretary to the Department of Health hereby give notice of delegates' final decisions for amending the *Poisons Standard* (commonly referred to as the *Standard for the Uniform Scheduling of Medicines and Poisons* - SUSMP) under subsections 42ZCZX of the Therapeutic Goods Regulations 1990 (the Regulations). This notice also provides the reasons for the decision and the date of effect (implementation date) of the decision.

The delegate's final decision and reasons relate to scheduling proposals considered as delegate-only matters, i.e. not referred to an expert advisory committee.

Matters not referred to an advisory committee

According to subsections 42ZCZT/42ZCZU of the Regulations a delegate may decide not to refer a scheduling proposal to an expert advisory committee for advice and instead may make a delegate-only decision. When deciding not to refer a matter to a committee, the delegate considers the scheduling guidelines as set out in the *Scheduling Policy Framework for Chemicals and Medicines* (SPF, 2015), available at SPF, February 2015.

Publishing of the amendments to the Poisons Standard

The amendments to the Schedules, Appendices or other parts of the *Poisons Standard* are published electronically on the Federal Register of Legislation (FRL) as amendments to the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP) prior to the date of effect (implementation date) of the final decisions. Further information, including links to the *Poisons Standard* on FRL, is available at SUSMP.

Final decisions on matters not referred to an expert advisory committee

1. New Chemical Entities – medicines for human therapeutic use

Summary of delegate's final decisions

Substance	Final decision
Brexpiprazole	**Schedule 4 – New Entry** BREXPIPRAZOLE. **Appendix K – New Entry** BREXPIPRAZOLE **Index – New Entry** **BREXPIPRAZOLE** Schedule 4 Appendix K *Implementation date:* ***1 June 2017*****.**

1.1 Brexpiprazole

Scheduling proposal

The delegate considered an application from the Therapeutic Goods Administration (TGA) for the scheduling of brexpiprazole, a new chemical entity (NCE) for a human therapeutic medicine.

Substance summary

Brexpiprazole is a novel serotonin-dopamine activity modulator with partial agonist activity at serotonin 1A (5-HT1A) and D2/3 receptors, combined with potent antagonist effects on 5-HT2A, α1B-, and α2C-adrenergic receptors.

Brexpiprazole is indicated for the treatment of schizophrenia in adults.

Scheduling status

Brexpiprazole is not specifically scheduled or captured by any group entries in the current Poisons Standard.

International regulations

Brexpiprazole is not classified in New Zealand. Brexpiprazole is a prescription medicine in Canada and the USA.

Delegate's consideration

The delegate decided to make a delegate-only decision. The delegate considered the following in regards to this application for scheduling:

- Subsection 52E(1) of the *Therapeutic Goods Act 1989* (TG Act);
- The Scheduling Policy Framework (2015) scheduling factors;

- The new drug application;
- The delegate consulted with members of the Advisory Committee for Medicines Schedule (ACMS) for advice according to subsection 52E(4) of the TG Act; however no formal referral to a committee meeting occurred; and
- Other (Mod 2).

Delegate's final decision

The delegate has made a final decision to amend the Poisons Standard to include Brexpiprazole in Schedule 4 and Appendix K, with an implementation date of **1 June 2017.**

The delegate has decided that the wording for the schedule entry will be as follows:

Schedule 4 – New Entry

BREXPIPRAZOLE.

Appendix K – New Entry

BREXPIPRAZOLE

The delegate decided that the relevant matters under subsection 52E(1) of the *Therapeutic Goods Act 1989* are: (a) the risks and benefits of the use of a substance; (b) the purpose and the extent of use of a substance; (c) the toxicity of a substance; and (d) the dosage, formulation, labelling, packaging and presentation of a substance.

The delegate decided that the reasons for the final decision comprise the following:

- Brexpiprazole is a new chemical entity with no clinical/marketing experience in Australia.
- Brexpiprazole may be related however, to Aripiprazole which is available in Australia with a satisfactory risks/benefits analysis.
- Brexpiprazole is marketed overseas with satisfactory risks/benefits.
- The potential for abuse of brexpiprazole is unlikely.