Application of Better Regulation Principles

Poisons and Therapeutic Goods Amendment (Restricted Substances) Regulation (No 2) 2021

Principle 1 - The need for government action should be established

The *Poisons and Therapeutic Goods Amendment (Restricted Substances) Regulation (No 2) 2021* (**Amending Regulation**) makes a time-limited extension to an amendment which was introduced in 2020 to assist in the COVID-19 response. A time-limited extension is required to support prescription and supply of medicines. Clause 36A of the *Poisons and Therapeutic Goods Regulation 2008* (**the Regulation**), which is due to expire at the beginning of 30 September 2021, enables restricted substances (prescription-only medicine), excluding prescribed restricted substances, to be supplied solely based on the image of a prescription. The Amending Regulation would extend this clause to 30 September 2022 to assist in the COVID-19 response to facilitate the continued prescription and supply of medicines (for example via telehealth consultations and within quarantine facilities).

The Amending Regulation also implements controls on the prescription and supply of ivermectin to seek to address inappropriate prescription and supply of this substance due to misinformation in the public sphere regarding ivermectin's use in prevention and treatment of COVID-19. The amendment seeks to ensure that prescription-only ivermectin supplies remain available to treat known conditions in humans such as topical-treatment-resistant scabies and gastrointestinal disorders.

Principle 2 - The objective of government action should be clear

The Amending Regulation will extend cl.36A which is still required to assist in the COVID-19 response. A separate amendment to require a person to be authorised before prescribing or supplying ivermectin seeks to address instances where ivermectin is being prescribed and supplied to prevent and treat COVID-19 despite this being contrary to its approved indications for use.

Principle 3 - The impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options

Non-regulatory options were considered in development of the Amending Regulation. While public messaging has sought to address inappropriate prescription and supply of ivermectin for COVID-19 treatment, the Amending Regulation implements clear mechanisms to address the risks posed by inappropriate prescription or supply of ivermectin in the community.

Principle 4 - Government action should be effective and proportional

The Amending Regulation is considered to be effective and proportional. The amendments to extend clause 36A for 12 months will facilitate medicine supply during the COVID-19 pandemic; any continuation of the amendments beyond this date will be subject to further consideration and subject to whether Commonwealth alternatives are fully implemented.

Principle 5 - Consultation with businesses and the community should inform regulatory development

The Commonwealth has issued public messaging on new controls at the Commonwealth level that regulate ivermectin. NSW does not automatically adopt the Commonwealth controls, however the Amending Regulation implements changes that seek to address the inappropriate prescription and supply of ivermectin in NSW.

Principle 6 - The simplification, repeal, reform, consolidation of existing regulation should be considered

The Amending Regulation amends the existing Regulation.

Principle 7 - Regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness

The Regulation is subject to the standard five-yearly staged repeal under the *Subordinate Legislation Act 1989.*