

## Application of Better Regulation Principles

### Poisons and Therapeutic Goods Amendment (Real Time Prescription Monitoring) Regulation 2021

#### Principle 1 - The need for government action should be established

The Government has committed to implementation of real time prescription monitoring (RTPM) to track the prescription and supply of medicines associated with a high risk of causing harm, dependence, or misuse (Budget FY2020-21). The Poisons and Therapeutic Goods Amendment (Real Time Prescription Monitoring) Regulation 2021 (**Amending Regulation**) amends the Poisons and Therapeutic Goods Regulation 2008 (**PTG Regulation**) to enable the collection, disclosure, and use of prescribing and dispensing data for *monitored medicines*. The Amending Regulation seeks to ensure that prescribers and suppliers of high-risk medicines are aware of previous prescribing/supplying events in relation to a patient. This is anticipated to help minimise doctor shopping and over-supply of high-risk medicines.

#### Principle 2 - The objective of government action should be clear

The Amending Regulation establishes a regime under which practitioners connected to electronic prescribing software provide information for the RTPM database. This will occur automatically via RTPM linkage with prescriber and dispenser software (which are defined in the regulation as *data source entities*). In turn, medical practitioners, nurse practitioners, dentists, and pharmacists can check the RTPM before prescribing or supplying such substances. The Health Secretary can also access the database for a range of prescribed purposes including to monitor the prescription and supply of monitored medicines, to share information with other regulatory authorities, and to disclose information to interstate RTPM equivalents.

#### 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. The Amending Regulation creates a clear statutory mechanism for the collection, disclosure, and use of prescribing and dispensing data for *monitored medicines*.

#### Principle 4 - Government action should be effective and proportional

The Amending Regulation is considered to be effective and proportional. Rather than applying to all prescription-only medication, the list of monitored medicines has been targeted to those medicines that are liable to misuse and diversion, such as drugs of addiction and specified high-risk prescription-only medication.

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

The Ministry of Health has engaged in a thorough consultation, including targeted written consultation with stakeholders, working groups (including representation from consumer advocates), and publishing a consultation paper on the proposed amendments on the NSW Government's *Have Your Say* website.

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

The Amending Regulation amends the existing PTG Regulation.

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

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