

Application of Better Regulation Principles

Poisons and Therapeutic Goods Amendment (COVID-19 Vaccine) Regulation 2021

Principle 1 - The need for government action should be established

The *Poisons and Therapeutic Goods Regulation 2008* (**Regulation**) currently enables a pharmacist to supply and administer specifically listed vaccines to patients without a prescription. As part of the phased roll-out of the COVID-19 vaccine, amendments to the Regulation are required to enable pharmacists to administer and supply approved COVID-19 vaccines. The *Poisons and Therapeutic Goods Amendment (COVID-19 Vaccine) Regulation 2021* (**Amending Regulation**) specifies a COVID-19 vaccine approved by the Health Secretary as a vaccine that can be administered and supplied by a pharmacist.

Separately, the Amending Regulation also enables authorised registered nurses and midwives to receive a wholesale supply of vaccines listed in an authority under the Regulation from a pharmacist, for administration to patients in the pharmacy. Currently, authorised nurses and midwives are required to receive wholesale supplies of vaccines and adrenaline directly from a wholesaler, and cannot receive these wholesale supplies direct from a pharmacist, even though they are for administration in the pharmacy. The Amending Regulation will enable pharmacists to wholesale supply these substances to authorised registered nurses and midwives to undertake vaccination services in a retail pharmacy.

Principle 2 - The objective of government action should be clear

The Amending Regulation seeks to better support vaccination programs in two key ways:

- Facilitating pharmacist supply and administration of approved COVID-19 vaccines; and
- Enabling authorised registered nurses and registered midwives to receive wholesale supplies of specific vaccines and adrenaline from a pharmacist to administer to patients in a pharmacy.

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. There is no non-regulatory way to enable pharmacists to administer and supply the COVID-19 vaccine without a prescription.

Principle 4 - Government action should be effective and proportional

The Amending Regulation is considered to be effective and proportional. The list of vaccines that can be administered by a pharmacist without a prescription is targeted to the vaccines listed in clause 48A which are appropriate for administration without a prescription. Further, the Amending Regulation enables the Health Secretary to impose conditions on any approval of a COVID-19 vaccine for administration by a pharmacist. This ensures that appropriate training conditions can be imposed on pharmacists in relation to administration and supply of the vaccine.

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

Rollout of the COVID-19 vaccine has been subject to a number of public announcements by both the Commonwealth Government and NSW Government. Consultation on the Amending Regulation has occurred with the Pharmaceutical Society of Australia, which supports the amendments. The Medical Services Committee does not support the Amending Regulation in relation to the supply of COVID-19 or pharmacists being involved in the roll-out of the COVID-19 vaccine. However, the involvement of pharmacists in the COVID-19 vaccine is a Commonwealth decision and it is appropriate for the Amending Regulation to support this.

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 staged repeal under the Subordinate Legislation Act 1989.