

Therapeutic Goods (Postponement) Regulation 2020

Explanatory notes for SL 2020 No. 151

made under the

Therapeutic Goods Act 2019

General Outline

Short title

Therapeutic Goods (Postponement) Regulation 2020

Authorising law

Section 15DA of the *Acts Interpretation Act 1954*

Section 2 of the *Therapeutic Goods Act 2019*

Policy objectives and the reasons for them

The objective of the *Therapeutic Goods (Postponement) Regulation 2020* (Postponement Regulation) is to postpone the automatic commencement of the *Therapeutic Goods Act 2019* by one year.

Section 15DA(2) of the *Acts Interpretation Act 1954* provides that if a law has not commenced within one year of its Assent, it automatically commences on the next day. However, a regulation may extend the automatic commencement date for up to two years after the Assent date.

The Therapeutic Goods Act received Assent on 26 September 2019. The purpose of the Therapeutic Goods Act is to enhance national consistency in the regulation of medicines, poisons and therapeutic goods, reduce the current regulatory burden and ensure appropriate safeguards are implemented to protect the health and safety of the community. The Act aims to reduce regulatory duplication by removing the need for the separate manufacturing, advertising, labelling and packaging requirements in the Queensland regulatory framework for medicines and poisons.

Prior to the emergence of COVID-19, the *Medicines and Poisons Act 2019* and Therapeutic Goods Act and supporting regulations were proposed to commence on 1 July 2020. Consultation on the supporting regulations, which was scheduled to occur in the first quarter of 2020, was postponed due to COVID-19, as the stakeholders to be consulted were those most focused on the COVID-19 response (for example, doctors, nurses, pharmacists and their professional bodies).

It is proposed to postpone commencement of the Therapeutic Goods Act to enable sufficient time to consult with stakeholders about the regulations. It is necessary for the regulations to be finalised so the scheme can commence in its entirety, with the Acts and supporting regulations commencing at the same time.

Achievement of policy objectives

The postponement regulation will extend the automatic commencement of the Therapeutic Goods Act by one year, to the end of 26 September 2021.

Consistency with policy objectives of authorising law

The postponement regulation is consistent with the policy objectives of the Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

There are no alternative ways of achieving the policy objectives.

Benefits and costs of implementation

The postponement regulation will allow sufficient time for consultation to be undertaken on the supporting regulations. There are no additional costs involved.

Consistency with fundamental legislative principles

The postponement regulation is consistent with the fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Consultation

No consultation was undertaken with stakeholders on the postponement regulation. Consultation with stakeholders on the supporting regulations is proposed to be undertaken before commencement of the Therapeutic Goods Act.

The postponement regulation was self-assessed by Queensland Health, in accordance with the *Queensland Government Guide to Better Regulation*, as being excluded from regulatory impact assessment under exclusion category (g) on the basis that the regulation is of a machinery nature. Consultation with the Queensland Productivity Commission is not required.

Notes on provisions

Short Title

Clause 1 provides the short title of the regulation is the *Therapeutic Goods (Postponement) Regulation 2020*.

Postponed commencement of uncommenced provisions

Clause 2 provides that under section 15DA(2) the *Acts Interpretation Act 1954*, the period before automatic commencement of the *Therapeutic Goods Act 2019* is extended until the end of 26 September 2021. This has the effect that the Therapeutic Goods Act will now automatically commence on 27 September 2021, unless commenced earlier.

Expiry

Clause 3 provides for the regulation to expire on 28 September 2021.