Health (Drugs and Poisons) Amendment Regulation (No. 1) 2015

Explanatory notes for SL 2015 No. 176

made under the

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 1)2015

Authorising law

Section 180 of the *Health Act 1937*

Policy objectives and the reasons for them

The objective of the *Health (Drugs and Poisons) Amendment (No. 1) 2015* (the Amendment Regulation) is to facilitate the controlled supply and use of cannabis for a) approved clinical trials, and b) for individual patients authorised under the *Therapeutic Goods Act 1989* (Cwlth) to use medicinal cannabis.

There is growing community interest in the therapeutic potential of cannabis-derived compounds for a number of conditions, including neuropathic pain, muscle spasticity associated with multiple sclerosis and cancer-related nausea.

The Queensland Government has partnered with the New South Wales Government for a clinical trial of medicinal cannabis to establish the quality, safety and efficacy of the product for childhood epilepsy.

In addition, the Therapeutic Goods Administration has given interim approval for a patient in Queensland to access medicinal cannabis pursuant to its Special Access Scheme, under the *Therapeutic Goods Act 1989* (Cwlth). The Special Access Scheme provides for the import and supply of an unapproved therapeutic good to individual patients on a case by case basis.

In Queensland, the *Drugs Misuse Act 1986* makes the production, possession and supply of cannabis an offence where such activities are done ‘unlawfully’, that is, without authorisation, justification or excuse by law.

The *Health (Drugs and Poisons) Regulation 1996* (the HDP Regulation) allows the chief executive of Queensland Health to grant endorsements to manufacture, obtain, possess, sell and prescribe restricted drugs and poisons for various purposes. However, cannabis is a schedule 9 (S9) poison. Section 270A of the HDP Regulation expressly prohibits the chief executive of Queensland Health from granting an approval to a person to use a S9 poison for therapeutic use.

Achievement of policy objectives

The Amendment Regulation addresses this issue by authorising the chief executive to approve a person to administer, dispense, manufacture, obtain, possess, prescribe, supply or use cannabis for or in connection with:

- an approved clinical trial, or
- an approval under the Special Access Scheme.

The Amendment Regulation also provides for a new exception to the general prohibition in against referring to an S9 poison in an advertisement. This new exception will allow a person to refer to cannabis in an advertisement in connection with an approved clinical trial. This will facilitate the conduct of approved clinical trials, including recruitment of subjects.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the *Health Act 1937*.

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

The Amendment Regulation is the only means of achieving the policy objectives in the short term.

Benefits and costs of implementation

The Amendment Regulation will not impose any additional costs.

Consistency with fundamental legislative principles

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

Consultation

The Office of Best Practice Regulation was consulted in relation to the requirements of the Regulatory Impact Statement (RIS) System and advised that a RIS is not required.

There has been no consultation external to Government on the Amendment Regulation, however, the changes made respond to community interest.

Notes on provisions

Short title

Clause 1 provides that the short title of the Amendment Regulation will be the *Health (Drugs and Poisons) Amendment Regulation (No. 1) 2015*.

Regulation amended

Clause 2 provides that the Amendment Regulation amends the HDP Regulation.

Amendment of s 74 (When endorsement is not needed), s 183 (When endorsement is not needed), s 186 (Acitretin, etretinate, isotretinoin and tretinoin), and s 270 (When endorsement is not needed)

Clauses 3 to 6 amend sections 74(3), 183(3), 186(2)(a) and 270(4). These sections make specific reference to clinical trials approved by the Therapeutic Goods Administration or a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Council Act 1992* (Cwlth).

To reduce repetition, this lengthy reference in each section has been simplified to 'an approved clinical trial', with the full reference then included in a new definition of *approved clinical trial* inserted by clause 10.

Amendment of s 270A (Approval must not be granted for therapeutic use of S9 poisons)

Clause 7 amends section 270A to make it subject to new section 270B. Accordingly, the chief executive will be able to grant approvals under new section 270B without contravening section 270A.

Insertion of new s 270B (Approval for cannabis)

Clause 8 inserts a new section 270B, which authorises the chief executive to grant an approval to a person to administer, dispense, manufacture, obtain, possess, prescribe, supply or use an S9 poison.

The chief executive may grant the approval only if two conditions are met. The first condition is that the S9 poison must be cannabis. The term *cannabis* is not defined, and therefore takes its ordinary meaning as any plant or plant derivative in the genus Cannabis, and includes a synthetic cannabis formulation.

The second condition is that the approval is for connected with either:

- an *approved clinical trial* (defined by clause 10), or
- an approval for the supply of cannabis for use in the individual treatment of a person, given under the *Therapeutic Goods Act 1989* (Cwlth), section 19(1).

Under section 18 of the HDP Regulation, the chief executive may grant an endorsement (defined in the HDP Regulation to include an approval) with or without conditions. Conditions may include, for example, that the cannabis must not be administered or used by smoking.

Amendment of s292 (Advertising of poisons)

Clause 9 amends section 292(5), to insert a new exception to the general prohibition in 292(4) against referring to an S9 poison in an advertisement. This new exception allows a person to refer to cannabis in an advertisement in connection with an approved clinical trial. This will facilitate the conduct of approved clinical trials, including recruitment of subjects.

This new exception does not extend to advertising in connection to an approval given under section 19(1) of the *Therapeutic Goods Act 1989* (Cwlth), because such an approval relates to treatment of a specific individual, and therefore would not involve any form of advertising.

Amendment of Appendix 9 (Dictionary)

Clause 10 amends the appendix 9, dictionary, to insert a definition of an *approved clinical trial*. An approved clinical trial means a clinical trial approved by either:

- the Therapeutic Goods Administration, or
- a human research ethics committee registered by the Australian Health Ethics Committee established under the *National Health and Medical Research Act 1992* (Cwlth).