Health (Drugs and Poisons) Amendment Regulation (No. 1) 2016

Explanatory notes for SL 2016 No. 23

made under the:

Health Act 1937

General Outline

Short title

Health (Drugs and Poisons) Amendment Regulation (No. 1) 2016

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 Regulation (No. 1) 2016* (the Amendment Regulation) is to endorse pharmacists under the *Health (Drugs and Poisons) Regulation 1996* (HDPR) to administer a vaccine to an adult under the *Drug Therapy Protocol – Pharmacist Vaccination Program* (DTP), without requiring the written or oral instruction of a medical practitioner.

The amendments will facilitate pharmacy vaccination programs intended to raise adult vaccination rates for influenza, measles, mumps, rubella, diphtheria, tetanus and pertussis (whooping cough).

The safety and efficacy of this approach has been the subject of a trial by the Queensland branches of the Pharmacy Guild of Australia (PGA) and the Pharmaceutical Society of Australia (PSA) of community pharmacist vaccination of adults (Queensland Pharmacist Immunisation Pilot I and II (QPIP I and QPIP II)).

On the basis of QPIP I results and early QPIP II results, the trial has been extremely successful. Over 22,000 influenza vaccinations, 1,450 pertussis (whooping cough) vaccinations and 30 measles vaccinations were provided in 2015. Influenza vaccinations doubled from the previous year when QPIP I provided 10,000 vaccinations. Overall satisfaction with the service was high at 96% in QPIP I. Many people indicated the ability to "drop-in" was a factor in the satisfaction. Approximately 15% of people vaccinated in QPIP I had never been vaccinated before.

Achievement of policy objectives

To enable ongoing community pharmacy vaccination programs for adults the Amendment Regulation amends the HDP Regulation to provide that a pharmacist is authorised to –

- administer a vaccine to an adult under the DTP; and
- administer adrenalin of a strength of 0.1% or less for managing anaphylaxis under the DTP.

The Amendment Regulation makes a number of minor and technical amendments to improve the readability of the HDPR.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with 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 effective means of achieving the policy objectives.

Benefits and costs of implementation

The Amendment Regulation is expected to facilitate a rise in adult immunisation rates for target infectious conditions, to the benefit of vaccinated individuals and the community generally. No significant costs have been identified. The amendments are enabling in nature and do not mandate pharmacist participation in pharmacy vaccination programs.

Consistency with fundamental legislative principles

Sub-delegation of power

The Amendment Regulation amends the HDP Regulation to authorise an endorsed person to take action under a DTP.

Allowing external documents that are not subject to Parliamentary scrutiny to stipulate the circumstances under which a health practitioner may use various substances, may be seen to breach section 4(2)(b) of the *Legislative Standards Act 1992*, which requires legislation to have sufficient regard to the institution of Parliament.

DTPs support the provision of health care in Queensland, setting out the circumstances and conditions under which certain health practitioners may use stated controlled or restricted drugs or poisons, based on current best clinical practice. DTPs take into account the qualifications, training and clinical experience of the relevant health practitioner to safely and appropriately use the specified drugs and poisons.

DTPs are developed and revised through a process of stakeholder consultation and multidisciplinary clinical governance that covers the care of patient groups that would be treated under each DTP. In developing each DTP, consideration is given to the health care needs of specific patient populations, how this care can be provided in a timely and safe manner, and requirements for medical advice, referral or transfer to higher levels of care.

DTPs are generally reviewed every two years. This involves a robust review of clinical guidelines, following procedures recommended in the National Health and Medical Research Council Guidelines on Clinical Guideline Development, as well as feedback and input from expert clinicians from public health services, and clinical networks.

All DTPs made under the HDP Regulation are published on the Department of Health's website at www.health.qld.gov.au.

It is considered that the rigour surrounding the development of DTPs, coupled with their use in ensuring Queenslanders receive health care based on best clinical practice, justifies the need to sub-delegate by referring to external documents in the HDP Regulation.

Consultation

The Department of Health consulted with the following stakeholders about the proposed substantive amendments to the HDP Regulation:

- Pharmacy Guild of Australia
- Pharmaceutical Society of Australia (Qld Branch)
- Allied Health Professions Office of Queensland
- Health Consumers Queensland
- Queensland Aboriginal and Islander Health Council
- Office of the Health Ombudsman
- Australian Health Practitioner Registering Authority
- Royal Australian College of General Practitioners (Qld Branch)
- Public Health Association Queensland
- Nurse Practitioners Association - Australian College of Nurse Practitioners
- Pharmaceutical Defence Limited
- Hospital and Health Services, including Primary Health Networks
- Queensland Nurses Union

The principal purpose of the consultation was to determine the possible public health and safety benefits of amending the HDPR to allow Pharmacists to vaccinate adults and whether there are any safeguards that would be necessary or barriers to safe service provision.

No other external consultation was undertaken as the remaining amendments are minor and technical in nature, or streamline and clarify the operation of existing provisions in the legislation.

Notes on provisions

1 Short title

Clause 1 provides that the short title of the Amendment Regulation will be the *Health (Drugs and Poisons) Amendment Regulation (No. 1) 2016*.

2 Regulation amended

Clause 2 provides that the regulation amends the *Health (Drugs and Poisons) Regulation 1996* (HDPR).

3 Amendment of s 163 (Environmental Health Officers)

Clause 3 omits the words 'a restricted drug that is' from section 163 of the HDPR. Those words will be contained in the new definition of 'vaccine' inserted by clause 7. Accordingly, this is a technical amendment only.

4 Amendment of s 171 (Pharmacists)

Clause 4 inserts a new subsection 4A into section 171 of the HDPR. The new subsection provides that a pharmacist is authorised to administer a vaccine to an adult under the pharmacist vaccination program DTP. Definitions of 'vaccine' and 'pharmacist vaccination program DTP' will be inserted by clause 7. The definition of vaccine restricts the operation of the new section 171(4A) to vaccines which are restricted drugs.

The effect of this amendment is that pharmacists will be authorised to administer vaccines to adults in accordance with the pharmacist vaccination program DTP, without requiring the oral or written direction of a medical practitioner.

Clause 4 also renumbers sections 171(4A) and (5) to become sections 171(5) and (6), respectively.

5 Amendment of s 174 (Queensland Ambulance Service)

Clause 5 omits the words 'a restricted drug that is' from sections 174(4)(b) and (5)(b) of the *Health (Drugs and Poisons) Regulation 1996* (HDPR). Those words will be contained in the new definition of 'vaccine' inserted by clause 7. Accordingly, this is a technical amendment only.

6 Amendment of s 257 (Pharmacists)

Clause 6 inserts a new subsection 1A into section 257 of the HDPR. The new subsection provides that a pharmacist is authorised to administer adrenalin of a strength of 0.1% or less, for managing anaphylaxis under the pharmacist vaccination DTP.

The effect of this amendment is that pharmacists will be authorised to administer adrenalin by a method specified in the DTP to a patient who has an anaphylactic response to a vaccine, without requiring the oral or written direction of a medical practitioner.

Clause 6 also renumbers sections 257(1A) and (2) to become sections 257(2) and (3), respectively.

7 Amendment of appendix 9

Clause 7 amends the dictionary in appendix 9 of the HDPR to insert definitions of *pharmacist vaccination program DTP* and *vaccine*.

The definition of *pharmacist vaccination program DTP* is necessary as the amending regulation introduces that term to the HDPR.

The definition of *vaccine* is a technical amendment only. It is intended to improve the readability of the HDPR. Clauses 3 and 6 of the Amendment Regulation make related amendments.

© State of Queensland 2016