THE LEGISLATIVE ASSEMBLY FOR

THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS AMENDMENT REGULATION 2020 (No 1)

SL2020-13

EXPLANATORY STATEMENT

Circulated by the authority of
Rachel Stephen-Smith MLA
Minister for Health

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 1)

Overview

The Therapeutic Goods Administration (TGA) administers the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP), which classes medicines and poisons into schedules. The ACT adopts the SUSMP under the Medicines, Poisons and Therapeutic Goods Act 2008 (the MPTG Act) to regulate the supply of scheduled medicines in the ACT. The SUSMP also contains appendices which subject some substances listed in the schedules to additional exceptions or restrictions.

The objective of the MPTG Act is to promote and protect public health and safety by minimising medicinal misadventure with, and diversion of, regulated substances, and the manufacture of regulated substances that are subject to abuse. The MPTG Act also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively. The MPTG Act outlines a range of offences relating to dealings with regulated substances according to their listing in the SUSMP.

The Medicines, Poisons and Therapeutic Goods Regulation (the MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The MPTG Regulation sets out which health professionals can prescribe, administer and dispense medicines, and conditions relating to such dealings. Some provisions of the MPTG Regulation prescribe additional information required for licences or authorisations, whereas other provisions impose statutory licence conditions. There are also provisions of the Regulation that specify requirements for activities such as labelling or packaging.

In 2016 the MPTG Regulation was amended by SL2016-5 to insert section 352 which authorises pharmacists and intern pharmacists to administer vaccines without a prescription in accordance with a direction of the Chief Health Officer. Under that section, the authorisation of pharmacists and intern pharmacists to administer vaccines is subject to directions made by the Chief Health Officer by way of a disallowable instrument. The directions made by the Chief Health Officer address such matters as minimum training standards, and requirements concerning the pharmacy's premises and record keeping.

The majority of other Australian states now enable pharmacists to administer vaccines to children; including Queensland, Tasmania, Western Australia, New South Wales and South Australia. On 12 March 2020 it was announced that Victoria was also making similar changes which are to commence on 1 April 2020.

Since 2019 the Pharmaceutical Society of Australia and the Pharmacy Guild of Australia have included standard childhood immunisation modules in their pharmacist vaccination training, and are making these modules available to pharmacists who completed their training prior to 2019.

In the ACT the authorisation of pharmacists to administer a vaccine without a prescription is currently limited to adults. This amendment Regulation will remove the current restriction from section 352, enabling age restrictions for various types of vaccines to be directed by the Chief Health Officer by disallowable instrument. These changes will thereby bring the ACT into line with New South Wales, South Australia, Western Australia, Queensland, Tasmania and Victoria.

Clauses

Clause 1 – Name of regulation

The first clause of the Regulation declares the name of the Regulation to be the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 1)*.

Clause 2 – Commencement

Pursuant to this provision, the Regulation is to commence on the day after it is notified on the ACT Legislation Register.

Due to the operation of section 75(1) of the *Legislation Act 2001* (the Legislation Act), the naming and commencement provisions of this Regulation, clauses 1 and 2, commence automatically on the day the Regulation is notified. A note to that effect is included in the provision.

Clause 3 - Legislation amended

This provision alerts the reader that this Regulation amends the MPTG Regulation.

Upon commencement this Regulation will alter the MPTG Regulation in accordance with the provisions that this Regulation contains. This Regulation will then be immediately repealed.

Consequentially, from the date that this Regulation commences a new republication of the MPTG Regulation will be available. That new republication will feature the alterations made by this Regulation.

Clause 4 – Authorisation for pharmacist and intern pharmacist to administer vaccine without prescription – Act, s 37 (1) (b) Section 352

Section 352 is amended by this provision by replacing every reference to “an adult” in the section with the words “a person”.

The effect of this simple change will be to remove from the Regulation what amounted to an age restriction (i.e. persons 18 years of age or older) with respect to whom pharmacists could lawfully administer vaccines. Whilst the effect of this amendment will notionally mean that pharmacists can administer vaccines to persons of any age, pharmacist vaccinations will be still be subject to directions issued by the Chief Health Officer by way of disallowable instrument. It is through such directions from the Chief Health Officer that restrictions on such things as the age of the person to whom the medicine is to be administered will be imposed, as well other restrictions such as required training of pharmacists, record keeping, and the handling of adverse events.

It should be noted that the use of the term “persons” in the amendment will limit the administration of vaccines to human beings. This restriction is necessary as the Medicines, Poisons and Therapeutic Goods legislation does apply to veterinary practitioners and veterinary medicines.