

Australian Capital Territory

Public Health (Community Pharmacy) Risk Activity Declaration 2012 (No 1)

Disallowable Instrument DI2012–210

made under the

Public Health Act 1997, s 18 (Public health risk activities and procedures – declaration)

EXPLANATORY STATEMENT

Section 18 (1) of the *Public Health Act 1997* (the PHA) provides that the Minister may, by disallowable instrument, declare an activity that may result in the transmission of disease, or that may otherwise adversely affect the health of individuals in the context of the wider health of the community, to be a public health risk activity. Subsection 18 (3) of the PHA provides that a declaration made under subsection (1) shall indicate whether the declared activity is licensable, registrable or a non-licensable activity.

This instrument declares the operation of a community pharmacy to be a licensable public health risk activity under subsections (1) and (3) of section 18 of the PHA.

Clause 4 of this instrument defines terms used in the instrument, which include *Community Pharmacy*, *operate*, *pharmacy business*, and *pharmacy services*.

The definition of the term *Community Pharmacy* in the instrument is tied to the definition of that term appearing in the *Medicines, Poisons and Therapeutic Goods Act 2008* (the MPTG Act).

In the dictionary to the MPTG Act a community pharmacy is defined simply as 'a pharmacy at a place other than an *institution*'. The term *institution* is also defined in the dictionary to the MPTG Act, and means:

a hospital, residential aged care facility, residential disability care facility or other institution used for the accommodation, treatment and care of people suffering from mental or physical conditions.

The dictionary definition of *institution* in the MPTG Act also establishes that an institution, for the purposes of the MPTG Act, will also include a body prescribed in the *Medicines, Poisons and Therapeutic Goods Regulation 2008* (the MPTG Regulation) as an institution.

Utilising this power, a *correctional centre* and a *CYP detention place*, which is a detention place under the *Children and Young People Act 2008*, have been prescribed by section 652 of the MPTG Regulation as an *institution*.

Accordingly, a community pharmacy is a pharmacy that is not located at a hospital, residential aged care facility, residential disability care facility, a correctional centre, a CYP detention centre, or an institution used for the accommodation, treatment and care of people suffering from mental or physical conditions.

For the purposes of the declaration, the terms *operate*, *pharmacy business*, and *pharmacy services* are interconnected. To own and control a pharmacy business is, under the declaration, to operate a pharmacy business. A business that provides pharmacy services as a community pharmacy is considered a *pharmacy business*. *Pharmacy Services* includes the supply, compounding, or dispensing of a medicine, as well as the provision of advice and counselling on the effective use of a medicine.

Accordingly, if a person (natural or a corporation) owns and controls a business that supplies, compounds, or dispenses medicines together with the provision of advice and counselling on the effective use of medicines, that person will require a licence if the pharmacy business is a community pharmacy in accordance with the MPTG Act.

It is important to note that the operation of this declaration must be read in conjunction with section 62 of the Public Health Regulation 2000, as well as Part 9 of the *Health Act 1993*. Under section 62 of the Public Health Regulation 2000 it is an offence for a person to own a pharmacy business unless the person is a pharmacist, or is a complying pharmacy corporation.

The term pharmacist is defined in the dictionary of the *Legislation Act 2001*. Essentially, to be a pharmacist a person must hold relevant professional qualifications and be registered by the Pharmacy Board of Australia as a pharmacist.

There are a range of threshold requirements that must be met for a corporation to be considered a complying pharmacy corporation pursuant to section 128A of the *Health Act 1993*. Pivotal amongst these requirements is that the corporation is controlled, through the directorship, by pharmacists. Furthermore, the shareholder ownership of the corporation should also be limited to pharmacists, or close relatives of a pharmacist. Spouses, children, parents and siblings are obviously close relatives. Step-parents, step-children, a son-in-law, daughter-in-law or parent-in-law should also be considered to be close relatives. Although there may be greater complexity in evidencing who is a 'close relative' in families involving unmarried persons, or same sex persons, such relationships would not be excluded at law from the concept of a 'close relative'.

The person that owns and controls a pharmacy business is separate and distinct from the pharmacist in charge at a community pharmacy on any given day. The pharmacist in charge at a community pharmacy is responsible for the delivery of the actual pharmacy service; being the supply, compounding, or dispensing of a medicine, and the provision of advice and counselling on the effective use of a medicine. As such they have professional obligations and a range of duties under other legislation such as the Medicines, Poisons and Therapeutic Goods legislation. Nevertheless, they are not responsible for the ordinary business operations of the community pharmacy, such as matters involving employment and payment of staff, payment of rent, rates or services, or the design and fit out of the community pharmacy.

In effect, this declaration recognises that whilst the role and functions of a pharmacist in charge at a community pharmacy are well defined, there are aspects of a pharmacy business that are beyond the control of the pharmacist in charge, but which can still have a very significant impact on the provision of pharmacy services and, by extension, the wider health of the community. As such, pharmacists that may be from time to time a pharmacist in charge at a community pharmacy do not need to hold a licence under this declaration. Rather, it is the person or persons that own the pharmacy that will be required to hold a licence.

The most important consequence of the declaration of the operation of a community pharmacy business as a licensable public health risk activity is that it gives the Health Directorate, as the regulator, greater ability to scrutinise and regulate the operation of community pharmacies in the ACT. The full range of inspection and analysis powers under the PHA, such as the powers of entry and search and seizure powers, become available to the Health Directorate. Similarly, the declaration gives the Health Directorate greater enforcement powers. As the public health risk activity has been declared to be licensable, this enables enforcement action other than prosecution of offences to be utilised, such as the imposition of licence conditions, or the suspension or cancellation of a licence. Although significant penalties, in terms of a hierarchy of enforcement powers and consequences these are below that of prosecuting for an offence.

In regard to offences, there are 3 offences of most significance. Under section 133 of the PHA the Minister has the power to declare a code of practice that sets out minimum standard or guidelines relating to a public health matter or public health risk activity. If a code of practice pertaining to community pharmacies is declared, as is expected, section 20 of the PHA will require licence-holders to comply with the code of practice. Failure to do so is an offence, and will carry a maximum penalty of 50 penalty units, 6 months imprisonment, or both. As such, a licence holder will be obliged to comply with a code of practice declared under section 133 of the PHA.

It will also be an offence under section 21(2) to operate a pharmacy business that is a community pharmacy contrary to the requirements of the licence. This is of most significance if conditions are imposed on a licence. A licensee that commits this offence will face a maximum penalty of 50 penalty units.

Pursuant to section 21(1) it will be an offence for a person to operate a pharmacy business that is a community pharmacy without a licence. The maximum penalty that will be available for committing this offence is 50 penalty units, 6 months imprisonment, or both.

The instrument commences on 1 March 2013. The timeframe between notification and commencement is to allow sufficient time for implementation of the new laws; both by the Health Directorate, and by community pharmacy owners. This should enable adequate time for pharmacists and complying pharmacy corporations that own community pharmacies to apply for a licence, and for applications to be processed and licences issued. As sufficient lead time prior to the commencement of the declaration has been provided, no person that owns a community pharmacy can be considered to have been caught unaware, and thereby inadvertently have committed an offence under section 21(2) of the PHA.