

Medicines, Poisons and Therapeutic Goods (Fees) Determination 2009 (No 1)

Explanatory Statement

Disallowable instrument DI2009-59

made under the

Medicines, Poisons and Therapeutic Goods Act 2008, s 197 (Determination of Fees)

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the Act) commenced on 14 February 2009. Upon commencement the Act repeals and replaces the *Poisons and Drugs Act 1978*, the *Public Health (Prohibited Drugs) Act 1957* and the *Poisons Act 1933*, as well as supporting Regulations and instruments under those Acts. The Act also repeals and replaces large portions of the *Drugs of Dependence Act 1989*.

The Act adopts the Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP), developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth).

The objective of the Act, set out in Chapter 2 and as recommended by the Galbally Review, is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The 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 Act establishes an authorisation and licensing framework for medicines and poisons. This fee determination establishes the fees payable for a licence under this framework.

Schedule 1 of the determination establishes several fees. The fee for a Pharmacy Medicines Rural Communities licences is \$100, of which \$30 is non-refundable. Research and Education licences are set at \$30, of which the entire \$30 is non-refundable component. The fee for a first-aid kit licence is \$180, \$30 of which is non-refundable. All other licence fees are \$300, \$30 of which is non-refundable.

Fees are also determined for applications to amend a licence and for replacement of licences lost, stolen or destroyed. The fee imposed in these circumstances is \$30, of which the entire amount is non-refundable.

Accordingly, if a person applies for a medicines wholesaler's licence they are required to pay a \$300 fee. However, should their application be unsuccessful the applicant is entitled to a refund of the fee paid, minus the \$30 non-refundable component. The resulting refunded amount is therefore \$270.

The determination reflects that the fees contain a non-refundable component in order to assist with the administrative costs associated with the application. As such, these costs are incurred by the regulator irrespective of whether the licence or registration is granted or refused.

Although the Act permits licences to be issued for up to three years, a policy decision has been made requiring licences to be renewed annually. Accordingly, the fee prescribed is for a licence for one year.