

Explanatory Statement

Medicines, Poisons and Therapeutic Goods (Fees) Determination 2014 (No 1)

Disallowable Instrument DI2014-300

made under the

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

The *Medicines, Poisons and Therapeutic Goods Act 2008* establishes an authorisation and licensing framework for medicines and poisons.

This instrument revokes and replaces DI2013-311, notified on 19 December 2013.

This instrument sets fees for the application of licences under the Act, as well for the amendment or replacement of licences. The Determination comes into effect on 1 January 2015 and increases the fees by 4.0% (rounded to the nearest dollar), as set out below:

Fee name	Old Fee	New Fee
Application for licence ~ pharmacy medicines rural communities licence	\$ 115.00	\$ 120.00
Application for licence ~ first-aid kit licence	\$ 206.00	\$ 214.00
Application for licence ~ medicines wholesalers licence	\$ 343.00	\$ 357.00
Application for licence ~ opioid dependency treatment licence	Nil	Nil
Application for licence ~ dangerous poisons manufacturers licence	\$ 343.00	\$ 357.00
Application for licence ~ dangerous poisons suppliers licence	\$ 343.00	\$ 357.00
Application for licence ~ controlled medicines research and education program licence	\$ 34.00	\$ 35.00
Application for licence ~ dangerous poisons research and education program licence	\$ 34.00	\$ 35.00
Application for licence ~ prohibited substances research and education program licence	\$ 34.00	\$ 35.00
Amendment of a licence	\$ 34.00	\$ 35.00
Replacement of licence lost, stolen or destroyed.	\$ 34.00	\$ 35.00

The non-refundable portion of the fees increases from \$34.00 each to \$35.00 each.

The fees determined are based on a one year licence. Subject to some limitations, licences can also be issued for longer terms, up to a maximum duration of three years. Where a longer term is granted, the determined fee is multiplied to correspond with the term of the licence. For example, the fee payable for a two year licence is twice the fee specified in column 4.

For every licence for which a fee is payable, there is a non-refundable amount that has been included to cover the costs associated with the processing and administration of the application. Such costs are incurred by the regulator irrespective of whether a licence is granted or refused. The non-refundable portion of the fee is not affected by the term of the licence. Accordingly, the fee to be paid for a three year licence will have the same non-refundable amount as a one year licence.