



Therapeutic Goods (Medicines—Listing) Approval of Application Forms and Specification of Office to which Application Must be Delivered

I, Larry Kelly, Acting Deputy Secretary, Health Products Regulation Group, a delegate of the Secretary of the Department of Health for the purposes of section 23C of the *Therapeutic Goods Act 1989*, make the following instrument under paragraphs 23C(2)(a) and (b) of that Act.

Dated *29 March* 2018

A handwritten signature in black ink, appearing to read 'Larry Kelly'.

LARRY KELLY
Delegate of the Secretary of the Department of Health

1 Name

This instrument is the *Therapeutic Goods (Medicines—Listing) Approval of Application Forms and Specification of Office to which Application Must be Delivered*.

2 Definitions

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

code stock means an existing medicine that is made available for use as by one or more sponsors under their own brand name.

medicine kit means a kit within the meaning of subsection 7B(1) of the Act.

TGA means the part of the Department of Health known as the Therapeutic Goods Administration.

Note: *Composite pack* is defined in subsection 3(1) of the Act as having the meaning given by subsection 7B(2) of the Act.

3 Applications to which this instrument applies

This instrument applies to an application to list a medicine under section 26 or 26A of the Act.

4 Form of application

- (1) The approved form for an application to which this instrument applies, other than an application mentioned in subsection (2), (3), (4) or (5), is as follows:
 - (a) if the listing is for export only—the online form titled *Export Only General Application* in the TGA’s electronic lodgement facility;
 - (b) in any other case—the online form titled *General Listing Application* in the TGA’s electronic lodgement facility.
- (2) The approved form for an application relating to a composite pack is as follows:
 - (a) if the listing is for export only—the online form titled *Export Only Composite Pack Application* in the TGA’s electronic lodgement facility;
 - (b) in any other case—the online form titled *Composite Pack Listing Application* in the TGA’s electronic lodgement facility.
- (3) The approved form for an application relating to a medicine kit is the online form titled *Medicine Kit Listing Application* in the TGA’s electronic lodgement facility.
- (4) The approved form for an application relating to a medicine prepared from code stock is the online form titled *Medicine prepared from a code stock* in the TGA’s electronic lodgement facility.

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- (5) The approved form for an application relating to changes to multiple current listings is as follows:
- (a) if the current listings are for export only—the online form titled *Variation Change Multiple Listings Application* in the TGA’s electronic lodgement facility;
 - (b) in any other case—the online form titled *Change Multiple Listings Application* in the TGA’s electronic lodgement facility.

Note: The TGA’s electronic lodgement facility is on the TGA Business Services website (<https://adfs.tga.gov.au>).

5 Office to which application must be delivered

An application must be delivered to the office of the TGA, using the TGA’s electronic lodgement facility.