Complementary Healthcare Council of Australia

Technical Alert

TGA Corrections to the listed medicines eBS validation rules

Dear Member,

Recently we advised you of developments the TGA were making to the Electronic Listing Facility (ELF) portal. As part of this process, corrections to the listed medicines eBS validation rules are being made to align with the operation of the Therapeutic Goods legislation, in particular the operation of the Therapeutic Goods (Groups) Order No. 1 of 2001.

The following changes to the validation rules are expected to be implemented in accordance with the Groups Order and made available in the ELF by the **6 January 2014**.

- Any single change to a listed medicine, or multiple changes within the same clause of the groups order, will result in a 'grouping' type application (the AUST L is retained), for example, changing the quantity of an excipient ingredient and adding a flavouring ingredient (both changes are in clause 5.2).
  An application fee equivalent to a new product is payable.

- Any multiple changes to a listed medicine across different clauses of the groups order, for example, changing the product name (clause 10) and an indication (clause 8) in the same application will result in a 'new' application (a new AUST L will be generated).

  For reference a list of grouping clauses will be published on the CHC website in January.

- All other validation rules will remain unchanged.

- Export Medicines will require the same change made to their validation rules for Section 26A applications as they share the listed medicines validation rules tables. Noting the change is **NOT** to be implemented for the Section 26 applications.

Please note the following application forms that are affected by this change:

- Listed medicines: General Listing, Composite Pack, Code Stock and Medicine Kit
- Export Medicines: General Listing, Composite Pack, Code Stock and Medicine Kit

Product variation
Following the inclusion of a product as a Listed medicine in the Australian Register of Therapeutic Goods (ARTG), sponsors may need to update certain product details. For example, developing marketing strategies, changes in product ingredients may prompt changes to product details or manufacturer details may need to be updated.

Where the intended change does not create another product altogether i.e. a 'separate and distinct' therapeutic good (see below), there are provisions in the legislation for certain details to be amended in a medicines' ARTG entry. However, if the intended change would create a 'separate and distinct' good sponsors are required to submit a new application to list the goods and a new AUST L number will be issued (unless the two medicines are eligible for 'grouping' under the Therapeutic Goods (Groups) Order.

The Electronic Listing Facility, (ELF 3) Guidance on Product Changes, has been developed to provide assistance to sponsors so that they are able to determine the regulatory impact and cost that making changes may have to currently Listed medicines.

When a change to the product record is made, ELF 3 will, upon validation, recognise the type of change made in accordance with the changes described in the change tables.

A summary of fees charged by the TGA for Listed medicines is available on the TGA website.

Provisions for product amendment
Where the intended change does not create a 'separate and distinct' good, a sponsor may request for certain details to be amended on a medicines' ARTG entry and maintain the same AUST L number (subject to the changes outlined in this Alert).

Minor changes to listed medicines on the ARTG (other than those listed for export only) are made via the ELF system.

The ELF system has been designed to allow sponsors to make the same minor changes to multiple current listings under certain circumstances using the 'Change multiple listings' form in ELF. These changes are limited to: product names, common manufacturing steps; and manufacturers.
Note that where the type of change incurs a fee, this fee is applicable to each medicine listing that is changed.

The 'Groups Order'

Eligibility for 'grouping' is determined by an Order made under section 16 of the Act – currently the Therapeutic Goods (Groups) Order No. 1 of 2001 (Groups Order). The usual fee for an application for new listing applies, but there is only one annual charge for the two grouped medicines.

The circumstances in which two or more therapeutic goods can be 'grouped' are set out in the Groups Order and include, for example, where a new medicine is listed by a sponsor that is intended to replace an existing medicine and differs from that medicine by only one of the following:

- particular kinds of excipients
- indications and/or directions for use; or
- product name.

When the Groups Order does not apply, the changed goods must have a separate ARTG entry and bear a separate AUST L number. If this is the case, the sponsor should apply for listing of the changed goods as if it were an entirely new product.

The provisions of the Groups Order (as applied to complementary medicines) may be summarised as follows.

Name change
Goods may be grouped when the only difference between the new goods and the existing goods is the name and when the new goods are to replace the existing goods in use.

Change in the amount of an excipient
Goods may be grouped when the formulation of the new goods is to be changed only by increasing or decreasing the amount of an excipient (but not adding or deleting an excipient) and when the new goods are to replace the existing goods in use.

Removal or addition of a fragrance, flavour, printing ink or colour
Goods may be grouped when the formulation is changed only by the addition or removal of a fragrance, flavour, printing ink or colouring agent and when the new goods are to be registered in place of the existing goods.

Revised indications and/or directions for use
Goods may be grouped when only the indications and/or directions for use are changed and the new goods are to be registered in place of the existing goods.

The CHC wishes to also remind members of the recent changes to the listed medicines online application form, 'new look and feel'. For more information, please click here.

For further information contact:
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