Technical Alert

Listed Medicines:
Online Applications Notification of Changes to 'Product Name' Entry Field &
Application and Submission User Guide

Dear Member,

Listed Medicine - Online Applications Notification of Changes to 'Product Name'

As sponsors would be aware, when applying to list a new medicine on the Australian Register of Therapeutic Goods (ARTG) via the listed medicines online portal (ELF), "Product Name" is one of the mandatory data entry fields. The current maximum length of this field is 300 characters.

The TGA have identified that a very small number of medicines listed on the ARTG have additional information entered into the Product Name field. This information is entered by the sponsor when listing a medicine and may include the ingredients, dosage and formulation. There are other data fields within ELF to appropriately record these medicine properties.

From 12 August 2013, along with the update to the ELF system, the Product Name field will be restricted to no longer than 100 characters. The TGA have identified approximately 18 products on the ARTG affected by this change and are working with sponsors to resolve the issue.

Sponsors will be advised to amend the ARTG of the affected product listing(s) in accordance with the information provided above using one of the following two options:

1. Subsection 9D (1) (of the Act) variation request - provided the product name is consistent with the currently listed product name, the delegate of the Secretary considers administrative correction of the product name on the sponsors behalf to an agreed name, of 100 characters or less. In order for this to occur, sponsors will need to provide the new name to the TGA by **31 October 2013** requesting a correction of the product name for the affected ARTG entry; or

2. Section 23 (of the Act) application - after **31 October 2013**, sponsors can make their own product name change within the listed medicines online application system noting that this will validate as a 'Grouping' application with the associated fee of $740.

Please note that the system will no longer validate current ARTG entries without the name being amended to the revised correct length of characters.

Listed Medicines - Application and Submission User Guide

In line with the new 'look and feel' for all listed medicine online application forms, the newly updated user guide is now available. It can be accessed under the 'Training > Documentation' link in the eBusiness user portal upon sponsor / agent log in.

The user guide is also accessible via the link below. It is a training document for the ELF system, which outlines the eBS and ELF systems, and provides users with instructions for creating and submitting applications.

Listed medicines application and submission user guide (pdf,7.71Mb)

For further information contact:

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