Technical Alert

Updated User Guide (TGA Listed & Listed Assessed online applications)

Listed Medicines – NEW ELF functionality

Listed Assessed Medicines – NEW online application system launched

Updated User Guide (TGA Listed & Listed Assessed online applications)

The TGA have released a significantly updated Application and submission user guide, Version 4.0, March 2019 ('the User Guide') for Listed and Listed Assessed medicines, which reflects new changes in online functionality described below. In particular sponsors should note that Listed Assessed medicines applications are now made through the online application form.

Listed Medicines – NEW ELF functionality

New functionality has been launched in ELF for applications for listed medicine and composite packs:

- **9D(1) variation applications for listings now online.**

  Subsection 9D(1) of the Act permits a sponsor to apply to correct an ARTG entry which contains incorrect or incomplete information. Previously, 9D(1) applications were made by email or mail. New functionality in ELF now provides the ability for sponsors to apply for variations online. For these applications, sponsors will be able to upload the supporting documentation directly into the form.

- **'Changes made' can now be viewed when validating.**

  The ability for sponsors to view 'changes made' to the existing product record when validating a variation application. This is similar to the existing functionality in the Non-Prescription medicine application form.

Listed Assessed Medicines – NEW online application system launched

The TGA have launched an integrated online application system for AUST L(A) (assessed listed) medicine applications, based on the existing listed medicine application system (ELF).

Like ELF, the application system for AUST L(A) will automatically validate:

- Ingredients;
- Manufacturers;
- Dosage forms;
- Routes of administration.

AUST L(A) functionality:

- There is a *mandatory* free text box where sponsors enter indications that are to be assessed for efficacy by the TGA. (Reminder: the types of 'intermediate' level indications acceptable for AUST L(A) medicines are described on page 11 & 12 of the Guidelines).
- There is an *optional* ability to select permitted indications.
- Like the registered medicine application system, applicants can upload the supporting information (evidence) directly into the form.

Members are encouraged to forward any identified issues to technical@cmaustralia.org.au for attention by the Committee Secretariat.

ENDS