Technical Alert

Royal Assent of Therapeutic Amendment Bill No. 1 of 2017 and introduction of associated reforms, including final Draft List of Permitted Indications

New Poisons Standard, 1 March 2018

Royal Assent of Therapeutic Amendment Bill No. 1 of 2017 and introduction of associated reforms, including final Draft List of Permitted Indications

The Bill has received Royal Assent from the Governor General and therefore, the TGA have moved forward the implementation date of the reforms to today, **Tuesday 6 March 2018**. The updated Therapeutic Goods Act is not yet registered on the Federal Register of Legislation but when registered will be available here.

Permitted Indications

The list of Permitted Indications will be made as a legislative instrument. This instrument will be made once the TGA delegate has the required delegations. This could take between 2 – 5 business days. Due to the anticipated introduction, the Listed Medicines applications in the TGA Business Services Portal will be unavailable for an estimated 2-5 business days until the permitted indications list is published. This is to prevent sponsors from making an incorrect certification when applying to list a medicine. During the outage the TGA eBS system will be updated with new functionality to allow applicants to select permitted indications. A message will be posted on the TGA Business Services Portal to advise applicants.

Members have requested guidance or training about how to use permitted indications. The TGA website will be updated in coming days with an updated ELF User Guide and other links on the TGA website including a Permitted Indications Guidance document. Sponsors are encouraged to test the new system when it becomes available, and questions can be directed to the Listed Medicines helpdesk on **1800 773 312**. Please advise CMA if there are implementation difficulties and enough interest we may request specific training sessions.

Final Draft List of Permitted Indications

The first Permitted Indication Determination is being finalised for legal sign-off by the Delegate of the Minister, at which time (in the next 1-5 business days) the Listed Medicine application system will be made available again with the list of Permitted Indications.

In the duration, to assist with business planning, CMA has obtained copies of the final draft list, which is available here:

- Final *draft* list of indications (not yet approved by Delegate, waiting for delegations to be confirmed by the Minister and delegate sign-off.) *You will need to be logged in with your member details on the CMA website to access this document*.

Market exclusivity for new ingredients

The two year market exclusivity can be granted once the Act changes receive Royal Assent, which could be any day. However, it is expected that in practice this will be implemented at the introduction of the 26BB Permissible Ingredients Determination in June. Applicants with ingredients currently subject to approval will be contacted by the TGA where necessary.

New Assessed Listed Medicines Pathway & Pre-Submission Meetings

Applications for the new assessed listed medicines pathway will be made available when corresponding regulations come into effect, around mid-March. The TGA have updated their pre-submission guidance on the TGA website to account for the new pathway. The TGA website has been updated to reflect the inclusion of assessed listed medicines as part of the pre-submission process, here. The TGA can make pre-submission meeting appointments with sponsors in anticipation of the upcoming introduction of the new pathway.

When the application system is made available, the TGA will release the first version of the guidance and evidence requirements for the new pathway, recognising that there will be an implementation phase of approximately 12 months which is likely to result in updates to this guidance.

New Poisons Standard, 1 March 2018

A new Poisons Standard has been made, incorporating a number of specified chemical substances for the first time. Please note that new editions of the Poisons Standard are now named with the month and year (rather than edition number).

Poisons Standard March 2018 is available on the FRL website here, and incorporates a number of new chemical entities which were considered by the ACCS.

These are primarily used in household chemicals, dyes and cosmetics and include:

- 3-nitro-p-hydroxyethylaminophenol, hydroxyethyl-3,4-methylenedioxyaniline;
- 1,3-bis(2,4-diaminophenoxy)propane;
- 2,2'-[(4-amino-3-nitrophenyl)imino]bisethanol;
- HC Violet 1;
- 1-deoxy-1-(methylamino)-d-glucitol N-coco acyl derivatives;
- o-toluidine; and
- o-anisidine.

ENDS

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