Technical Alert

TGA Half Yearly Snapshot July to December 2020

The TGA have published a Half yearly performance snapshot on their website. The snapshot provides statistical information for the period 1 July 2020 to 31 December 2020 in relation to the TGA's regulation of therapeutic goods, tracking their progress against some of the priorities they have identified for the year against the annual TGA business plan.

New Approvals for Complementary Medicines

Registered complementary medicines

- 6 new medicines approved. This compares to 2 approved from 1 July to 31 December 2019.

Assessed listed medicines

- 1 new assessed listed medicine. This was the first listed assessed medicine approved.

Listed complementary medicines

- 1,079 new listed medicines. This was on par with 1 July to 31 December 2019 (1141).
- 2 new permitted ingredients

Listed Medicine Compliance Reviews

- **Initiated**
  - 2 Random reviews
  - 54 Targeted reviews
- **Completed**
  - 5 Random reviews
  - 37 Targeted reviews

The number of compliance reviews that were completed in the period 1 July to 31 December 2020 (42) was lower than the same period last year (105) and is related to the temporary diversion of resources required to respond to the COVID-19 pandemic.

A summary of the outcomes on completed reviews of listed medicines provides that, of the 30 medicines where compliance status was determined, there were 7 medicines with no compliance breaches and 23 with compliance breaches.

Of the 12 listed medicines where compliance status was unable to be determined, all were reported to have been cancelled by sponsors after a request for information from the TGA.

Complementary Medicines Laboratory Testing

The TGA tested 7 complementary medicines products, of which '57%' (4) are reported as 'failed', compared to 1 July to 31 December 2019 where 121 products were tested and '4%' are reported as 'failed'. There is a Database of TGA Laboratory Testing Results which is published on a semi-regular basis as well as a Laboratory Reports page (most recent for CMs is Green Lipped Mussel).

TGO 92 Labelling Consents for Listed and Registered Complementary Medicines

For the temporary expedited process for sponsors to request consent to supply products that do not comply with certain labelling requirements under TGO 92, due to adverse business impacts of the COVID-19 pandemic, 67 applications were received for listed medicines, 4 for RCMs, and one for both.

Access to unapproved therapeutic goods including medicinal cannabis products

In the period 1 July to 31 December 2020, the TGA

- approved 2020 Authorised Prescriber applications, including 1,832 applications for medicines, 1,682 for unapproved medicinal cannabis products, and 196 applications for medical devices
- processed a total of 78,308 applications and notifications through the Special Access Scheme (SAS), including 29,988 for unapproved medicinal cannabis products,
- processed large increases in SAS Category B applications for medicines, up 45% compared with the same period in 2019 (45,820 in 1 July to 31 December of 2020, compared with 27,714 from1 July to 31 December 2019). This is mainly attributed to increases in applications for unapproved medicinal cannabis products.

Pharmacovigilance Inspection Program

Between 1 July and 31 December 2020, the TGA inspected three medicine sponsors. Inspections were scheduled using a risk-based approach that included an assessment of the sponsor's pharmacovigilance system, product portfolio, and regulatory compliance history. Deficiencies were identified in each inspection with a total of one critical deficiency, 13 major deficiencies and 10 minor deficiencies.

Resources

More information is available in the full report, noting that some information is grouped for all medicines and therefore not specific to complementary medicines, such as the manufacturing inspections outcomes (p36).

- TGA web page: Half yearly performance snapshot: July to December 2020
- TGA business plan 2020-21