Technical Alert

Permitted Indication Process

Revised Permitted Indication List

The TGA released a revised permitted indication list on 24 October. The list introduced a number of changes, the primary change that symptoms (such as runny nose) can now be independently linked to conditions (such as colds and flu). This ability to cross-reference reduces the overall size of the list and provides sponsors more flexibility in choosing which symptoms are associated with which conditions. The TGA fact sheet on using and linking indications is available here. They have also provided an additional fact sheet on the reasons behind the terminology used in indications, available here.

The revised list also removes some indications based upon the assessment that certain indications were implying serious conditions.

Extensions

The TGA have provided that they are not able to provide a general extension to the consultation ending 31 October 2017, but is providing individual stakeholders with extensions where accompanied by reason(s) to request an extension. Submissions or extension requests can be directed to complementary.medicine.reforms@health.gov.au

Implementation

The TGA is expecting the first Permitted Indication Determination to pass on the 7 December 2017, in time for the proposed effective date of 1 January 2018.

Sponsors are advised not to use the draft list as a basis for forming permitted indications for products until the final list is available, as the draft list is subject to change.

Future Indication Applications

From 1 January, applications for new indications may be made in accordance with the directions on the TGA website, and must be accompanied by a cost-recovery application fee. The fee as currently proposed by the TGA is $1,020.

CMA has raised concerns about possible oversights in the production of the new list during the consultation period. The TGA have provided that if there has been a significant oversight in the development of the list prior to the implementation of the new legislation in January 2018, then they will explore the avenue of adding a permitted indication to the list in the absence of a formal application and without charging the application fee. We encourage members to discuss with CMA Regulatory the possibility of whether an oversight has occurred before submitting a paid application.

ENDS