Technical Alert

TGA Fees and Charges 2017 -2018 and Changes to Fees and Charges arising from Regulatory Reforms.

Dear CMA Member,

This month the TGA published the document Fees and charges: summary from 1 July 2017 providing an update regarding fees and charges.

In addition, the TGA has provided at the latest TGA Industry Forum, a summary of fees and charges proposed as a result of regulatory reforms, which will be introduced in changes to the Therapeutic Goods (Charges) Regulations. These fees are indicative and subject to Ministerial approval. All fee changes are subject to Regulation amendment and some correspond with Charges Act amendments.

A summary of the fees and charges are as follows:

New Permitted Indication

Application fee for a new permitted indication - $1,020.

Pathway 1 – Listed Complementary Medicines

The application fee for the current listing pathway will remain at $800 for the time being and an annual charge of $1,020.

Pathway 2 (new) – "Listed Assessed" Complementary Medicines

Fees for new "listed assessed" intermediate pathway have been separated into 3 categories. For the first category, a combined application and evaluation fee of $2,070 has been set and for the second and third categories has been set at $15,160.

Pathway 3 – Registered Complementary Medicines

The TGA will no longer use a "page count" fee structure. There will be 5 different application categories that range from a combined application and assessment fee of $3,590 for the first category to $38,270 for the fifth category. Combined variation fees will range from $1,380 to $9,950.

A new notification fee of $780 will be introduced for some minor variations.

New Complementary Medicine ingredients

Previously new substance evaluation fees have been set at $10,100 - $70,600. The new Charges bill proposes four categories, with a total application plus evaluation fee of $15,050 for the first two categories and $25,670 for the second two categories.

Proposed Review of Complementary Medicine annual charges

The TGA has provided that there is to be undertaken a review of annual charges for complementary medicines. The review is to take into consideration an increase in costs including new pharmacovigilance inspections, discontinuation of pre-approvals and new complaint handling function, increased post market compliance activity, and a review of currently under-recovered GMP fees.

The TGA has also provided that they intend to develop variation fees for listed medicines including low risk variation through notification.

ENDS