GSK Comments on TGA Consultation: Proposal to change the current good manufacturing practice (GMP) fees and charges

GlaxoSmithKline Australia Pty Ltd (GSK) welcomes the opportunity to comment on this consultation and is supportive of the TGA's efforts to improve the accuracy and transparency of cost recovery arrangements associated with GMP.

Following its review of the options proposed by Deloitte for GMP fees and charges to address the under recovery of GMP activities for medicinal products, GSK is supportive of Option 2, as this option improves the fee structure associated with recovering inspection hours, which is the biggest contributor to the under-recovery of regulatory costs across Medicines GMP, with minimal impact to sponsors.

GSK notes that Option 3 has been recommended by Deloitte in the review. This option shows a 200% increase in the GMP Clearance Application Processing Fee, whilst the fees associated with other activities have not increased to this extent. On average, GSK submits 40 GMP Clearance applications to the TGA with approximately 25% of those submitted via the Compliance Verification (CV) pathway. The proposed fee increase would significantly impact sponsors who submit a large number of GMP Clearance applications to the TGA, including GSK.

In order to reduce the increase of fees and charges associated with GMP Clearance applications, GSK respectfully requests that the TGA consider increasing the fees and charges associated with other GMP related activities, to ensure that costs are recovered from the areas which have shown the largest under-recovery. Based on the report, the biggest contributor to the under-recovery of regulatory costs is associated with recovering inspection hours, therefore, it would seem reasonable to increase the inspection fees and charges in order to address this.

GSK is not entirely objective to Option 3, however, believes that further review is required to ensure that any increase in fees and charges is reasonable in terms of the impact for both sponsors and manufacturers, in addition to increasing fees based on a risk/benefit approach. A further option for the TGA's consideration would be to increase the fees associated with the CV pathway, which is required for manufacturing sites located in countries which do not have a Mutual Recognition Agreement (MRA) with Australia. This could potentially reduce the significant increase in the GMP Clearance Application Processing Fee proposed in Option 3. Furthermore, should the fees and charges associated with GMP Clearance applications increase, efficiencies in processing timelines would be valued. GSK understand that the TGA have been working towards improved timelines in recent years, however sponsors are still experiencing long delays, specifically with applications submitted under the CV pathway, which can sometimes lead to the expiration of current GMP clearances whilst these CV applications are under review.

We thank the TGA for providing GSK with the opportunity to participate and provide feedback on this consultation.