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5 March 2018

Mr Ben Noyen
Manufacturing Quality Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

RE: Consultation: Good Manufacturing Practice (GMP) Fee Model Review

Dear Sir,

Bristol-Myers Squibb, a diversified global BioPharma company, is pleased to have the opportunity to offer comments on the TGA consultation relating to a review of the current Good Manufacturing Practice (GMP) fee model. Bristol-Myers Squibb Australia (BMSA) is a sponsor of innovative biopharmaceutics registered on the Australian Register of Therapeutic Goods. BMSA does not manufacture goods locally, and relies on the granting of TGA approvals for overseas entities who perform manufacturing activities supporting the release of our medicines to the Australian market.

BMSA acknowledges the TGA's transparency regarding cost recovery arrangements for regulatory functions, and the Department of Health's responsibility to periodically review existing and potential charging activities. BMSA also acknowledges the challenges faced in balancing a multi-faceted cost recovery model, ensuring fair and equitable distribution of fiscal responsibility amongst concerned stakeholders. In principle, BMSA supports cost recovery for the services offered by the TGA.

In relation to the TGA-preferred Option 3:

- BMSA supports full cost recovery of all inspection hours, and the removal of implied 'free' inspection hours. BMSA also supports the introduction of an annual charge to replace 'high'

and ‘low’ level of activity, thereby reducing annual burden on local manufacturers. Both of these issues were clearly identified in the problem statement.

- However, under-recovery relating to GMP clearance activities was not clearly identified as a key issue within the problem statement. The proposed increase to the GMP Clearance Application Processing Fee (Option 3), up 102.56% from AUD$390 to AUD$790, suggests the unit cost for completion of that particular service is currently under-recovered by more than 100% – i.e. the time/effort taken to process a GMP Clearance Application is double that which the current fee structure suggests.

  Page 4 of the consultation document (Option Two (Minimal Change)) refers to under-recovery in GMP Clearances *“which have become an increasing part of the Manufacturing Quality Branch’s Business.”* It is therefore unclear whether this proposed increase is a true representation of the efficient unit cost of the service provided, or a resourcing, budgetary or other consideration.

  We feel further clarification is required in order to support Option 3 as proposed.

BMSA acknowledges the efforts TGA have made in recent years to explore the utility of recognising the outputs of comparable overseas regulators. BMSA encourages the TGA to explore similar opportunities in GMP, for example increased recognition of US FDA inspections leading to lower compliance verification burden to the TGA.

BMSA appreciates the opportunity to provide comments and respectfully requests that TGA give consideration to our feedback. We would be pleased to provide additional pertinent information or clarifications as may be requested.