abbvie

26 March 2018
Reg ref: 57-gmp-fees-mar18

Therapeutic Goods Administration
Medical Devices and Product Quality Division
Manufacturing Quality Branch
PO Box 100
WODEN ACT 2606

Re: Consultation: Proposal to change the current GMP fees and charges

Dear Sir / Madam,

AbbVie Pty Ltd would like to thank the TGA for the opportunity to comment on the consultation above.

AbbVie is of the opinion that none of the proposed options offer any improvement on the existing inefficient processes and incentives for sponsors to submit better quality applications and therefore does not support these proposed options. Instead, AbbVie believes that the GMP processes, especially the CV pathway should be reviewed as it can take up to 2 years to get clearance. It is neither appropriate nor efficient for the same data provided by multiple sponsors to be re-evaluated for the same site.

AbbVie does not believe that increasing the fees and charges, and hence revenue, will result in more efficient and faster approval of GMP clearance. The GMP clearance section is obviously under resourced and any additional revenue should lead to more staff to deal with the number of GMP applications, but given the cap of number of FTEs in the department, this is unlikely scenario.

Also, budgets for the next few years have been agreed on, they are set and it is hard for sponsors to find money to cover the increase and additional fees.

Should you have any queries regarding this submission, please do not hesitate to contact me *via* email at [redacted]

AbbVie Pty Ltd
ABN 48 156 384 262

Level 7, 241 O'Riordan St
Mascot NSW 2020
Australia

+61 2 9035 8698 (OFFICE)
+61 2 9035 8741 (FAX)
abbvie.com

[redacted]

[redacted]

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