7 May 2020

Mr Simon Bell
ACCC
23 Marcus Clarke Street
Canberra ACT 2601

Your Ref: AA1000486

By Email: [redacted]

Medicines Australia application for authorisation AA1000486 – request for update

Dear Simon

We refer to your letter dated 29 April 2020 and respond to the questions raised therein as follows:

Is the Proposed Conduct working as expected?
Yes.

Is the Proposed Conduct taking place as described in the application and the interim authorisation decision?
Yes.

Are there any particular benefits or detriments that the Proposed Conduct is resulting in?
Sanofi was able to have the discussions with other suppliers in consultation with the TGA and MA to address a national shortage of a Critical Medicine. The Proposed Conduct has also enabled Sanofi to better assess and respond to the supply shortage issues we are currently facing with respect to this medicine.

The relevant members of the MA/GBMA Working Group are working closely with the TGA to understand whether the measures implemented by the Government in response to the shortage crisis for the Critical Medicine have been effective or whether we need to take further action.

Has your organisation engaged in the Proposed Conduct, and if so, what was your experience in doing so? If not, why not?
Yes, Sanofi has engaged in the Proposed Conduct in consultation with the TGA/MA.

The interim authorisation referred to the need for "consultation with the Federal Government Agencies such as the TGA" – however the nature of TGA/MA's involvement and role in facilitating the discussions between suppliers of a Critical Medicine was not fully articulated and roles and responsibilities were therefore unclear. Draft guidance was subsequently provided to support the process, however some uncertainties remained, recognising this was a new process.

Furthermore, there were some confusions regarding the extent of Sponsor's role in escalating a medicine to be added to the list of "Critical Medicines". After consulting with MA, Sanofi was able to obtain clarity from the TGA that one of the medicines which was experiencing high demand

would be treated as a “Critical Medicine” thereby enabling the discussions between MA/GMBA Working Group members to fall within the scope of the interim authorisation.

Your sincerely

Lawrence Shim
Sanofi – Head of Legal ANZ