

NON-CONFIDENTIAL

Dear Gemma, David and Tom

We refer to:

- our last fortnightly update to the ACCC pursuant to NPSA authorisation AA100480-1 dated 3 September 2021;
- the fortnightly reporting condition set out in paragraph 36 of the ACCC's interim authorisation in NPSA's reauthorisation application AA1000571-1 dated 10 September 2021; and
- our email dated 16 September 2021

While there were no MSSR Working Group meetings in the last fortnight (as the group meets on a monthly basis), the key developments to report on include:

- [REDACTED]
- The DoH has issued updates to its current written directions for the Applicants to manage certain Medicines that are experiencing supply constraints due to COVID-19 related challenges, which was circulated to all of the Operating Applicants on 13 September 2021 [REDACTED]. The Operating Applicants are currently managing the following Medicines pursuant to various DoH directions. These updates include:
 - [REDACTED]
 - Please note that the expansion of the DoH directions to include the above new [REDACTED] SKUs as well as extension of duration of the direction in respect to existing affected [REDACTED] SKUs was due to ongoing global shortages of these SKUs which have precipitated as a direct result of the COVID-19 pandemic.
 - the addition of [REDACTED]
 - [REDACTED], there was a significant spike in demand and potential slump in availability of stock as identified by the Therapeutic Goods Administration (TGA) and the relevant Medicine sponsor [REDACTED]. As such, it was decided by the TGA and the Medicine sponsor to ask the DoH for a written direction that was inclusive of [REDACTED] for the Operating Applicants to act on so as to ensure Australians have adequate and equitable access to the stock available, and avoid an out of stock situation for [REDACTED] in Australia.
 - the extension of DoH directions for [REDACTED]
 - These extensions to the DoH directions were due to ongoing global shortages of these SKUs which have precipitated as a direct result of the COVID-19 pandemic.

For completeness, please note that the previous DoH direction for [REDACTED] expired on 31 August 2021 and the Operating Applicants have removed all supply restrictions in respect of this Medicine. However, they will continue to monitor supply and demand for [REDACTED] as a precautionary measure.

There have been no changes to the participants in the Proposed Conduct over the last fortnight.

We confirm that the ACCC can publish this email on its public register.

Please do not hesitate to contact us should you have any queries regarding the above.

Regards

[REDACTED]