
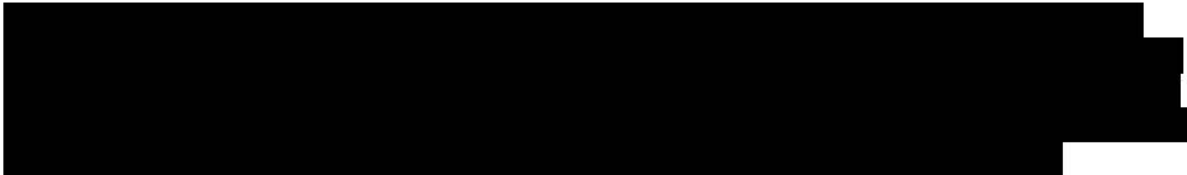


12 May 2020


Mr Joe Saunders
Director
Australian Competition and Consumer Commission
23 Marcus Clarke Street
CANBERRA ACT 2601

Dear Mr Saunders

Medicines Australia application for authorisation AA1000486 - request for update

1. We refer to your letter dated 29 April 2020 requesting Amgen's views in respect of the interim authorisation granted to Medicines Australia (**MA**), its members and the Generic and Biosimilar Medicines Association (**GBMA**) and its members (together, **Applicants**), by the ACCC on 3 April 2020 (**Interim Authorisation**).
2. Amgen is a member of MA and supports the purpose and limited scope of the Interim Authorisation, being to implement a coordinated strategy to address shortages in the supply of Critical Medicines and Critical Devices that arise as a result of COVID-19 (**Proposed Conduct**).
3. Amgen is one of the world's leading biotechnology companies. Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. Amgen Australia employs over 250 people and currently markets eleven products for the treatment of cancer, kidney disease, bone disease and other serious illnesses.
4. 
5. 
6. Amgen also anticipates that the supply of Critical Medicines and Devices will face renewed challenges as the Federal, State and Territory Governments consider a relaxation of the restrictions imposed on consumers and businesses, particularly as Australia heads into winter and the related health risks which typically emerge at that time of the year, by way of a second wave of COVID-19 infections.
7. To date, Amgen has not participated in any discussions pursuant to the Interim Authorisation regarding planning for shortages in the supply of Critical Medicines or Critical Devices. However, Amgen has provided information to MA as the central point of contact and coordination under the Interim Authorisation, within the terms of the Interim Authorisation, in order to ensure that the TGA is kept contemporaneously informed of any relevant developments that may affect the supply of Critical Medicines and Devices.

8. MA continue to play a central role in distributing up to date information regarding a range of topics that has allowed Amgen to monitor its own activities to ensure continuing supply of Critical Medicines and Devices. This information has arisen from:
- (a) its engagement with Government bodies, including the Therapeutic Goods Administration (**TGA**), Department of Health (**DOH**) and other related bodies that may affect the importation and exportation of supplies;
 - (b) its stakeholder engagement, including information arising from meetings between peak health and consumer bodies;
 - (c) MA developing communication and key messaging essential to addressing stakeholder and consumer perception about issues that may arise in relation to supply during COVID-19; and
 - (d) activities undertaken by the Federal Government to secure freight from export markets and information as to how sponsors may utilise freight secured by the Federal Government.
9. Amgen strongly supports the role of the TGA in identifying medicines and related supplies as Critical Medicines and Devices. Should the need arise in the future, Amgen's intention would be to only participate in discussions about Critical Medicines and Devices for which Amgen is a sponsor in Australia, and where the TGA is involved in the discussion.
10. In summary, Amgen considers that the scope and terms of the Interim Authorisation is appropriate to address potential supply shortages for Critical Medicines and Devices. In particular, Amgen considers that the period for which authorisation is sought of 6 months from the date of final authorisation, is sufficiently confined to ensure that any coordinated conduct does not extend beyond potential supply shortages that arise as a result of COVID-19.
11. Amgen appreciates the opportunity to provide this submission in relation to the Interim Authorisation.
12. Should you wish to discuss this submission or require further information, please contact [REDACTED] on the details below.

Yours sincerely,

[REDACTED]

[REDACTED]
Amgen Australia Pty Limited

Email: [REDACTED]