31 July 2020

Mr Simon Bell
Assistant Director - Adjudication Branch
Australian Competition and Consumer Commission
Level 17, 2 Lonsdale Street
Melbourne VIC 3000

Dear Mr Bell

Application for authorisation AA1000486 - Medicines Australia - submission in response to ACCC's Draft Determination

1. We refer to your email to Clayton Utz dated 21 July 2020 inviting Medicines Australia (**MA**) to consider responding to the submission made by the NSW Ministry of Health (**NSW Health**) dated 17 July 2020 (**NSW Health Submission**). The purpose of this letter is to set out MA's response to that submission.

MA's response to NSW Health's Submission

2. The NSW Health Submission is made against the backdrop of a competitive tender process that NSW Health plans to commence in or about the second quarter of 2021 (**NSW Health 2021 Tender**). The tender would relate to the supply of medicines and devices after the completion of the assessment and award of tenders, which it is anticipated will be supplied in the second half of calendar 2021. NSW Health has indicated that the NSW Health 2021 Tender will be for the procurement of medicines, including prescription only medicines, and associated devices and services. It appears that NSW Health makes its submission on the basis that some of the medicines and devices that are the subject of the NSW Health 2021 Tender may be identified as Critical Medicines or Devices.

3. NSW Health submits that the Proposed Conduct as described in the Draft Determination is:

   (a) considerably broader than is necessary to address supply issues arising from the COVID-19 pandemic; and

   (b) is likely to have a materially adverse impact on the NSW Health 2021 tender process.

4. MA acknowledges these concerns and the importance of the proposed tender process. However, MA considers that, when properly analysed, the risks identified to the tender process are not, or are not likely to be, material. This is because the Proposed Conduct is centrally about the security of supply of certain Critical Medicines and Devices identified by the TGA, cannot relate to price, and cannot be given effect to beyond the period of the authorisation period. The authorised conduct cannot be undertaken outside of a MA/GBMA Working Group which is always held with the TGA and includes legal counsel oversight to ensure that the authorised conduct is adhered to.

5. Therefore, MA submits these concerns should not displace the current terms of the proposed authorisation as set out in the Draft Determination having regard to:

(a) the matters set out in Confidential Annexure A;

(b) the limited and specific scope of the Proposed Conduct undertaken by MA/GBMA Working Group members in accordance with the Draft Determination, in responding to potential supply shortages arising from COVID-19 . Benefits arise as a result of the disclosure or exchange of limited supply information between suppliers and State and Territory health authorities, which ameliorates the risk of supply shortages of Critical Medicines arising as a result of COVID-19;

(c) the definition of Proposed Conduct in the Interim Authorisation/Draft Determination which directly addresses the issue of tenders (see paragraphs 1.9(d) and 1.10 of the Draft Determination). The introductory words to paragraph 1.9 ensure that no coordination on potential supply shortages of any kind (including, relevantly, a tender request) can occur without the involvement of the Federal Government or Federal Government Agencies such as the TGA. This is an effective and material protection against the concern NSW Health has raised about potential coordination affecting its NSW Health 2021 Tender;

(d) the definition of the Proposed Conduct specifically excludes any discussion of price of any Critical Medicine or Device among MA/GBMA Working Group members, including in relation to tender requests. This is clear from paragraph 1.10(b) of the Draft Determination. To the extent that NSW Health's concern about a reduction in competitive tension between suppliers is about price, this concern does not arise as any authorisation would not provide legal protection for coordination on price and Part IV of the Competition and Consumer Act 2010 will apply to any such conduct;

(e) as a practical matter, the TGA has facilitated and lead all MA/GBMA Working Group meetings, and has only convened meetings where, in its expert view, there a risk of a supply shortage of a Critical Medicine or Device. Meetings have been kept to a minimum and no material decisions requiring MA to report to the ACCC have been made at any MA/GBMA Working Group meeting. Despite this, MA has reported continuously to the ACCC to ensure that the Proposed Conduct is transparent and that the ACCC maintains oversight of all MA/GBMA Working Group meetings. This practice will continue and mitigates the concerns raised by NSW Health;

(f) the public interest purpose of the authorisation is to address a public health need in the event there is a supply shortage of a Critical Medicine or Device arising from COVID-19. It is important for the authorisation to remain in place to guard against potential supply shortages that may arise from a second wave or rapid further spike, such as that being experienced in Victoria, in other parts of Australia underlining the virulence of the disease. In the event that travel restrictions nationally or internationally are relaxed, there may be a need to deal with a further resurgence of COVID-19-related issues at short notice by means of the authorised conduct. If the availability of medicines to Australia is reduced, there may be greater need for coordination of supplies into the country and across States and Territories as well as to pharmacies and hospitals. Because the threat

posed by COVID-19 is continuing, the potential for supply shortages to arise in the future remains a real possibility. There continues to be a sound foundation in the public interest as to why the authorisation in its current terms is necessary and desirable.

MA's approach since the Interim Authorisation

6. MA has adopted a prudent and risk averse approach to ensure that MA and GBMA Working Group members comply with the terms of the Interim Authorisation. MA will continue to take this approach during the period of authorisation (which also will coincide with when the NSW Health 2021 Tender is planned).

7. While MA acknowledges the concerns raised by NSW Health, those concerns are already addressed by the terms of the Interim Authorisation itself, and in the Draft Determination. As the ACCC is aware from MA's regular and transparent contact about the conduct of MA/GBMA Working Group meetings, MA has been cautious to remind all participants invited by the TGA to participate in such meetings, and therefore engaged in the Proposed Conduct, that any coordinated conduct must only occur within the strict parameters of the Interim Authorisation. MA has also issued guidelines to MA and GBMA members to reiterate this point.

The Draft Determination

8. MA considers that it is in the public interest that necessary measures are implemented to ensure that the Australian public continues to receive supply of Critical Medicines and Devices during the COVID-19 pandemic. The NSW Health Tender should not disturb the clear public benefit of ensuring continuity of supply across all affected areas of Australia, especially where the terms of the authorisation itself, and implementation in practice, provide appropriate safeguards against any concern. It is also compelling that the Federal Government and other State/Territory Governments support the authorisation as being in the public interest.

9. The Proposed Conduct is framed to allow suppliers to take limited and necessary steps to manage or avoid potential supply shortages of Critical Medicines and Devices that arise as a result of COVID-19. The objective of the authorisation is to keep the public safe, by ensuring that access to life-saving treatments is not compromised. By ensuring access to Critical Medicines and Devices, the Proposed Conduct also enables the public to maintain confidence in the Australian health system and indirectly support Australia's economic recovery.

10. Any potential risks to competition are significantly outweighed by the clear public benefit arising from the Proposed Conduct. The public benefits of the Proposed Conduct are recognised in the Draft Determination (see paragraphs 4.18 to 4.21) as are the limited detriments (see paragraphs 4.28 to 4.34). The ACCC's analysis of overriding benefit is unchanged by NSW Health's Submission.

11. As MA has submitted previously, any risks that may arise from the Proposed Conduct are mitigated by the implementation of a number of safeguards. Those safeguards include the presence of an external competition lawyer to give a competition law compliance statement, and to ensure that discussions at MA/GBMA Working Group Meetings do not venture outside the permitted scope of the Interim Authorisation (in particular that there is no discussion of

any pricing matter relating to the Critical Medicine or Device which is under discussion at the Meeting or otherwise).

12. The Draft Determination specifically addresses the possibility of tender requests being issued. Paragraphs 1.9(d) and 1.10 of the Draft Determination provide that the Proposed Conduct includes, in consultation with the Federal Government and/or Federal Government Agencies such as the TGA:

(d) working together to respond to tenders or requests for supply (including sharing information or joint tenders) of Critical Medicines and Critical Devices.

and that this conduct:

- *concerns tenders let, or to be let, by Federal or State Governments; and*
- *will not encompass making or giving effect to agreements and arrangements, or exchanging information between MA/GBMA Working Group members, on the pricing aspects of such tenders.*

13. As noted above, the Draft Determination expressly excludes in its definition of the Proposed Conduct, any discussions relating to price, including the pricing aspect of such tenders. As a result, it is not immediately apparent that specific concerns will arise from the Proposed Conduct in relation to NSW Health 2021 Tender. The Proposed Conduct will not prevent price competition between competing tenderers under the terms of the NSW Health 2021 Tender.

Operation of the Reporting Condition under the Interim Authorisation and Draft Determination

14. MA infers that NSW Health are of the view that the concerns they have identified may arise where participants of the MA/GBMA Working Group engage in coordinated action to address supply shortages of Critical Medicines or Devices such as:

(a) allocating supply between MA/GBMA Working Group Members;
(b) prioritising requests for supply; or more relevantly,
(c) responding to tenders or requests for supply.

15. Coordinated conduct such as that described in above (and as outlined in paragraph 22 of the Draft Determination) involve a decision, arrangement or recommendation that would trigger MA's reporting obligation to the ACCC under the terms of the Interim Authorisation/Draft Determination. To date, no such conduct has taken place.

16. Participating MA and GBMA members consider coordinated action to be of 'last resort', with a preference to unilaterally resolve any potential supply shortages. MA does not consider that this approach adopted by its and GBMA's members will change.

17. It should be noted that the discussions between MA/GBMA Working Group members and the TGA (who have taken the role of coordinating such discussions) have taken place in relation to five medicines or classes of medicines, demonstrating the cautious (but necessary) approach that is being adopted by all parties involved under the Interim Authorisation. It is not the case that suppliers are engaged in discussions on a frequent basis in respect of a broad range of medicines or devices relevant to a broad tender request by a State or Territory health authority.

Prescription only medicines

18. Finally, the NSW Health Submission appears to state that Critical Medicines are likely to be all or almost all prescription-only medicines, and are not limited to medicines to treat patients suffering from symptoms of COVID-19. It is appropriate that the authorisation applies to prescription only medicines generally, and is capable of being applied to those prescription only medicines where there is a potential supply shortage (as is the case presently) arising from COVID-19. The practical commercial reality remains that many of these prescription-only medicines are sourced from overseas, and these supply chains continue to be disrupted by COVID-19.

Please do not hesitate to contact me should any questions arise from this submission.

Yours sincerely,

Chief Executive Officer
Medicines Australia

Medicines Australia

Confidential Annexure A

[redacted]

[redacted]