Medicines Australia

Mr Simon Bell
Assistant Director
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra
ACT 2601

4 September 2020

Dear Mr Bell

Medicines Australia - Application for Authorisation

Medicines Australia (**MA**) provides this further submission in response to the further submissions of the NSW Ministry of Health (**NSW Health**) lodged with the ACCC on 1 September 2020 (**NSW Health Further Submission**).

NSW Health Further Submission

1. The NSW Health Further Submission asserts that:

   (a) it is critical for the taxpayers and health consumers in NSW that the outcomes of pharmaceutical tenders are as competitive as possible;

   (b) [redacted] NSW Health will continue to request "business as usual" tenders;

   (c) NSW Health contends that the Proposed Conduct under the authorisation would expressly immunise all the suppliers of medicines in Australia from the prohibitions of the *Competition and Consumer Act* in relation to NSW Health tenders and could result in a single joint response by all suppliers to a tender; and

   (d) either the NSW Health tender is excluded from the Proposed Conduct, or certain conditions of authorisation are necessary.

MA's response to NSW Health concerns

2. MA has addressed in its prior submissions in relation to the issues raised by NSW Health the public interest rationale for the inclusion of the ability of suppliers to co-ordinate - temporarily, in these unprecedented times - to ensure the un-interrupted supply of Critical Medicines and Devices for the benefit of patients who need those medicines.

3. MA does not consider that the NSW Health Further Submission provides a persuasive rationale which would lead the ACCC to conclude that it is in the public interest to prevent the continued operation of the authorisation in a form which has worked effectively for the benefit of the public for the past 6 months, and which gives effect to the stated wishes of Federal and State Governments nationally that suppliers co-ordinate to ensure continued supply of these medicines and which representatives of the Commonwealth TGA have worked hard to ensure has occurred.

4. In response to points 1(a) to (d) above, MA submits that:

(a) MA acknowledges and fully agrees with the proposition that it is critical for taxpayers and health consumers in NSW (*and, equally, other parts of Australia*) that the outcomes of pharmaceutical tenders let by public health authorities are as competitive as possible.

(b) However, in the context of the current exceptional circumstances of an ongoing global pandemic in which there is global competition for supplies of Critical Medicines and Devices, and constraints on specialist and general transport and logistics services, authorisation of the Proposed Conduct is necessary so that the public interest in ensuring public health takes temporary primacy to the economic concerns of NSW Health.

(c) Additionally, MA contends that there are already appropriate safeguards in place to protect the competitive tender process, including:

(i) the Proposed Conduct applies to medicines or devices which are identified "critical" as a result of COVID-19. In practice, only a very small proportion of medicines or devices have been designated as "critical" to date;

(ii) Suppliers are not "immunised" for any coordinated conduct in respect of pricing for tenders;

(iii) MA does not foresee any requirement for Suppliers to coordinate their conduct with respect to the supply of prescription-only medicines included in "business as usual" tenders. Suppliers **cannot** coordinate their conduct with respect to medicines or devices that are not Critical under the terms of the Proposed Conduct. The Proposed Conduct in relation to tenders is intended to apply only to tenders specifically dedicated to Critical Medicines and Devices as part of a coordinated strategy in relation to the supply of essential medicines and related supplies in response to COVID-19;

(iv) the Proposed Conduct is already subject to a reporting condition and, while not required under the terms of the authorisation, MA has voluntarily provided the ACCC with a written record of MA/GBMA Working Group meetings that have occurred to date pursuant to the Interim Authorisation; and

(v) discussions by Suppliers engaged in the Proposed Conduct are already subject to external oversight from a representative of the Commonwealth, the TGA, as well as an external competition advisor. This system has effectively addressed any competitive risks while the authorisation facilitates avoidance of temporary supply shortages of Critical Medicines or Devices.

5. The contention that, notwithstanding that these safeguards ensure transparency and operate only in respect of designated critical medicines for a temporary period under the supervision of the TGA, there could be collusive tender response to the NSW 2021 tender by a single supplier is fanciful and should be rejected.

NSW Health's Proposed Conditions of Authorisation

6. Should NSW Health proceed with the 2021 tender notwithstanding that it is counterintuitive to do so [redacted] and that current

supply arrangements can simply be temporarily extended, NSW Health proposes that the Proposed Conduct should be subject to three conditions set out in the Further Submission.

MA's response to NSW Health's proposed conditions

7. MA opposes each of the conditions proposed by NSW Health for the following reasons:

(a) First and foremost, MA does not consider that the risks identified by NSW Health are likely to arise for reasons described in MA's previous submissions.

(b) NSW Health's proposed conditions add another layer of complexity and technicality that will undermine the practical effectiveness of a Final Authorisation.

(c) There are already appropriate safeguards in place to address NSW Health's concerns, in the unlikely event that they arise.

(d) MA considers that it is inappropriate to require Suppliers of a Critical Medicine or Device that is subject of a tender and may also be subject to a supply shortage to wait an arbitrary 14 day period and then to receive NSW Health consent to engage in urgent steps to resolve supply shortages. Such a condition would result in NSW Health effectively determining, what has already been determined by the Commonwealth (through the TGA) on behalf of patients in NSW and elsewhere, whether a shortage requires co-ordination to resolve.

The imposition of such a waiting period and consent requirement will plainly be to the potential detriment of the Australian public not only within NSW but also other areas of Australia that may require supply of the Critical Medicine or Device.

(e) The systems and procedures in place already provide for an external observer from the TGA (a Federal Government representative) to attend all discussions, including those that may involve a Critical Medicine or Device (as designated by the TGA) that is part of a tender.

MA submits that it is more appropriate that a representative of the TGA attend such meetings, as that person is more likely to have the relevant subject matter knowledge for each discussion and a national perspective. The TGA are able to request and collate supply information directly from manufacturers to understand the national supply levels of a medicine and to establish the need for such meetings. Further, any authorised discussions between Suppliers (whether under the Interim Authorisation or a Final Authorisation) has been and will continue to be attended by an external competition lawyer, who will act as a further safeguard against any coordination between Suppliers in relation to the pricing of tenders or any other conduct which extends beyond the authorised conduct.

MA's position

8. MA maintains the position that it is not appropriate that "business as usual" tenders be issued during this public health crisis and that it is in the public interest that the current terms on which medicines are being supplied to public health authorities should simply be temporarily extended.

9. However, notwithstanding MA's views that any Final Determination based on the current terms of the Draft Determination already include appropriate safeguards against the concerns raised by NSW Health, MA considers that the following conditions may be feasible (subject to drafting) in a Final Determination:

   (a) ***External Observer***: a condition that MA invite an external observer from the TGA to attend all discussions in relation to tenders.

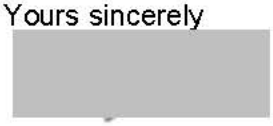
   (b) ***Notification to the relevant Federal or State tender agency***: a condition that MA notify the relevant agency responsible for issuing a request for tender of an upcoming discussion or other Proposed Conduct where the tender includes a Critical Medicine or Device previously outlined to Commission staff.

10. The MA/GBMA Working Group has established and given effect to a set of guidelines and protocol in relation to the Interim Authorisation that gives effect to the safeguards described above. The guidelines and protocol has been circulated to all participants in the Proposed Conduct. It is intended by MA that this protocol would be updated as required to reflect any Final Determination.

11. To date participants in the Proposed Conduct under the Interim Authorisation have followed the requirements of the guidelines and protocol, which has successfully operated to ensure that lawful co-ordination discussions between the TGA and Suppliers about potential shortages of Critical Medicines and Devices can take place efficiently and effectively.

12. The current parameters of the Proposed Conduct have been successful, and have achieved the purpose of the authorisation, for the past 6 months. The Proposed Conduct should be permitted to continue in the interests of patients for the period of the Final Determination and the theoretical concerns of NSW Health should not be permitted to override the efficacy of those supply safeguards.

Yours sincerely



Chief Executive Officer
Medicines Australia