Draft Determination

Application for authorisation
lodged by
Medicines Australia
in respect of
coordinating the supply of essential medicines and related supplies in response to the COVID-19 pandemic
Authorisation number: AA1000486

26 June 2020

Commissioners: Sims
Keogh
Rickard
Cifuentes
Court
Ridgeway

Summary

The ACCC proposes to grant conditional authorisation to Medicines Australia (MA) and its members, the Generic and Biosimilar Medicines Association (GBMA) and its members (the MA/GBMA Working Group), and future members of the MA/GBMA Working Group, to implement a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices in response to the COVID-19 pandemic.

On 3 April 2020, the ACCC granted conditional interim authorisation to enable the proposed arrangements to commence while the ACCC considers the substantive application for authorisation.

The ACCC received submissions from several interested parties, which were supportive of the proposed conduct. Based on feedback from the MA/GBMA Working Group members, conduct under the interim authorisation has been beneficial in identifying supply shortages of Critical Medicines and Critical Devices.

The ACCC considers that the proposed conduct is likely to result in public benefits by allowing the MA/GBMA Working Group to work together and where necessary, with relevant Government agencies, to address shortages in the supply of Critical Medicines and Critical Devices that arise as a result of COVID-19.

Competitors sharing information and coordinating supply of goods and/or services has the potential to lessen competition and result in consumer detriment by restricting supply and increasing prices, stifling innovation and preventing businesses from entering the market. However in this case, the proposed conduct is unlikely to significantly weaken competition beyond the short term.

Based on the available information, the likely public benefit will outweigh the likely public detriment including from any lessening of competition.

The ACCC proposes to grant conditional authorisation until 27 March 2021.

Next steps

The ACCC invites submissions on this draft determination by 17 July 2020 before making its final decision. The ACCC is particularly interested to understand the views of interested parties regarding the scope of the proposed conduct and the proposed duration of authorisation.

MA and interested parties may also request the ACCC to hold a conference to allow oral submissions on the draft determination.

1. The application for authorisation

1.1. On 27 March 2020, Medicines Australia (**MA**), on behalf of itself and its members and the Generic and Biosimilar Medicines Association (**GBMA**) and its members, (together the **MA/GBMA Working Group**) and future members of the MA/GBMA Working Group, lodged application for authorisation AA1000486 (the application) with the Australian Competition and Consumer Commission (the **ACCC**). MA is seeking authorisation to implement what it describes as a coordinated strategy in relation to the supply of essential medicines and related supplies in response to the COVID-19 pandemic.

1.2. MA sought authorisation for an initial period of six months from the date of final authorisation, but notes that the period may need to be extended, given the difficulties in predicting the duration and extent of the COVID-19 pandemic.

1.3. The application was made under subsection 88(1) of the *Competition and Consumer Act 2010* (Cth) (the **Act**).

1.4. The ACCC may grant authorisation which provides businesses with legal protection for arrangements that may otherwise risk breaching competition law but are not harmful to competition and/or are likely to result in overall public benefits.

1.5. MA also requested that the ACCC grant interim authorisation to commence engaging in the conduct while the ACCC considers the substantive application.

The Applicant

1.6. MA seeks authorisation on behalf of:

(a) itself and its members; and

(b) the Generic and Biosimilar Medicines Association (**GBMA**) and its members

(together, the **MA/GBMA Working Group**) to engage in the proposed conduct described below.

1.7. MA also seeks authorisation in respect of all potential future members of the MA/GBMA Working Group, namely:

(a) the National Pharmaceutical Services Association (NPSA) and its members; and

(b) other persons whose identity will be notified to the ACCC, being:

(i) new MA members;

(ii) persons who perform a significant role in the continued delivery of essential medicines and related supplies to the Australian community.

The Proposed Conduct

1.8. MA seeks authorisation for the MA/GBMA Working Group to implement a coordinated strategy in relation to the supply of:

(a) prescription-only medicines that are critical to patient health, including medicines used to treat patients suffering from the symptoms of COVID-19 (**Critical Medicines**)

(b) devices or services that are supplied or administered with Critical Medicines, and therefore essential to the efficacy and proper administration of Critical Medicines (**Critical Devices**)

to address shortages in the supply of Critical Medicines and Critical Devices that arise as a result of COVID-19.

1.9. This includes, in consultation with the Federal Government and/or Federal Government Agencies such as the Therapeutic Goods Administration:

(a) sharing information regarding:

(i) available stock and inventory levels;

(ii) likely quantities that can be obtained through existing supply channels,

(iii) new sources of supply and potential quantities; and

(iv) opportunities to increase domestic manufacturing,

for Critical Medicines and Critical Devices,

(b) coordinating and allocating the fulfilment of orders and supply requests for Critical Medicines and Critical Devices between MA/GBMA Working Group members as suppliers;

(c) prioritising certain requests for supply for Critical Medicines and Critical Devices as nominated by the Federal Government, State and Territory Governments and relevant health authorities, and

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

(together paragraphs 1.8 and 1.9 form the **Proposed Conduct**).[1]

1.10. MA has clarified that the Proposed Conduct contemplated by paragraph 1.9(d) is conduct:[2]

(a) concerning tenders let, or to be let, by Federal or State Governments; and

(b) 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.

The ACCC considers that the Proposed Conduct is broad in nature and is seeking submissions on the breadth of the Proposed Conduct prior to releasing its final determination. In making its final determination the ACCC will seek to ensure that the Proposed Conduct is no broader than necessary to address supply issues arising from the COVID-19 pandemic.

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1 The Proposed Conduct was set out in Medicines Australia's application for authorisation and clarified in subsequent correspondence published under the Applications section on the ACCC Public Register.

2 Email from Medicines Australia, 2 April 2020.

Interim authorisation

1.11. MA requested interim authorisation so that the MA/GBMA Working Group members could engage in the Proposed Conduct while the ACCC is considering the substantive application.

1.12. On 3 April 2020, the ACCC granted conditional interim authorisation in respect of the application.[3]

1.13. Interim authorisation was granted for the Proposed Conduct subject to the following conditions:[4]

The Applicants will regularly update the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including by:

1. *notifying the ACCC of:*
    a. *material recommendations made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct;*
    b. *material decisions or arrangements made by the MA/GBMA Working Group or members of the MA/GBMA Working Group which involve the Proposed Conduct, including arrangements made to:*
        i. *allocate supply between MA/GBMA Working Group members;*
        ii. *prioritise requests for supply; or*
        iii. *respond to tenders or requests for supply;*
    c. *any changes to the membership of the MA/GBMA Working Group and the identity of any new members;*
2. *providing to the ACCC, within a reasonable timeframe, all information reasonably requested by the ACCC in relation to the Proposed Conduct; and*
3. *meeting with the ACCC to provide regular updates in relation to the Proposed Conduct, as agreed by the Applicants and the ACCC*.

1.14. The interim authorisation remains in place until the ACCC final determination comes into force, it is revoked by the ACCC or the application is withdrawn by MA.

2. Background

2.1. On 11 March 2020, the World Health Organisation announced that COVID-19 is a pandemic.

2.2. The ACCC recognises the significant challenges occurring as a result of the COVID-19 pandemic. The pandemic has caused a major disruption to society and the economy, with social distancing measures and travel bans affecting various sectors across the economy. In that context, the ACCC has received a large number of applications for authorisation, including interim authorisation, aimed at providing financial relief to businesses and individuals, facilitating the supply of goods and services (including medical products and services) and managing the financial impact of a significant economic shock. In the early stages of the pandemic, there was a significant risk of Australia's health services being put under significant stress, including through the

[3] ACCC, Medicines Australia – Interim Authorisation Decision Statement of Reasons, 3 April 2020.

[4] ACCC, Medicines Australia – Interim Authorisation Decision Statement of Reasons, 3 April 2020, pp. 3-4.

unavailability of sufficient supplies of certain medicines. The identification of this risk and the need for collective and coordinated action by competitors gave rise to the need for applications for authorisation such as the one from MA.

2.3. In its application, MA submits that as COVID-19 increasingly impacts on Australia's health system and supply chains globally, it is expected that the ongoing supply of essential medicines and associated supplies may become severely constrained.

2.4. MA submits that due to the impact of COVID-19, it is assisting the Department of Health (**DOH**) to identify any potential issues relating to the supply of Critical Medicines and Critical Devices necessary for the treatment of COVID-19 patients, and to ensure measures are in place to mitigate any medicines shortages or supply chain issues in the near future.

2.5. MA submits that in order to respond to the Federal Government's requests, coordination among the MA/GBMA Working Group will be necessary to identify current stock levels, likely quantities that can be obtained through existing supply channels, new sources of supply and potential quantities, as well as opportunities to increase domestic manufacturing and sharing of resources between (some or all) members of the MA/GBMA Working Group.

3. Consultation

3.1. A public consultation process informs the ACCC's assessment of the likely public benefits and detriments from the Proposed Conduct.

3.2. Due to the urgent need to ensure the continued supply of essential medicines and associated supplies, including those needed for the treatment of COVID-19 to Australians, and the compelling nature of the public benefits likely to result from the request for interim authorisation, the ACCC did not conduct public consultation in respect of the request for interim authorisation.

3.3. The ACCC invited submissions on both the decision to grant interim authorisation and the substantive application for authorisation from a range of potentially interested parties, including state and federal government and relevant regulatory bodies, members of the MA/GBMA Working Group, and other medical/pharmaceutical associations and businesses.

3.4. The ACCC received four submissions from interested third parties in relation to the application.

3.5. The ACCC also wrote to members of the MA/GBMA Working Group, requesting an update on activities under the interim authorisation. Twelve members of the working group responded.

3.6. Public submissions by interested parties and MA/GBMA Working Group members are on the Public Register for Medicines Australia.

Interested party submissions

3.7. The Department of Industry, Science, Energy and Resources (**DISER**) submits that coordination through the MA/GBMA Working Group will ensure measures are in place to mitigate any medicines shortages or supply chain issues in the near future and will help address the increased demands on the health system during the COVID-19 pandemic. DISER submits that these benefits outweigh the short-term risks of sharing

information and coordinating supply. It was submitted that a six-month authorisation period reduces these risks.[5]

3.8. The Pharmacy Guild of Australia (the **Pharmacy Guild**) supports the Proposed Conduct. The Pharmacy Guild submits that:[6]

- the MA/GBMA Working Group members have important information regarding both local and global supply of prescription medicines that is of value in planning and managing problems associated with the supply and distribution of medicines, and
- enabling the MA/GBMA Working Group to engage with other key stakeholder groups is essential to effective and expeditious management of medicine supply problems at both a national and regional level.

3.9. NSW Ministry of Health (**NSW Health**) submits that it is premature to make a detailed submission on the process because the impact of COVID-19 on the availability of medicines is evolving and the effectiveness of the Proposed Conduct in mitigating the impact of COVID-19 is not yet clear.[7] NSW Health made additional comments that are considered in the section on public detriments.

3.10. The Victorian Department of Health and Human Services submits that:[8]

- The COVID-19 pandemic has increased global demand for essential medicines, pathology supplies, personal protective equipment and medical devices used in the management of patients with COVID-19.
- Supply chains for critical medicines used to treat other medical conditions have also been impacted. Securing sufficient supplies for healthcare workers and patients has been a major focus of the Victorian Government.
- Given the current global supply chain issues and a rapidly evolving public health emergency, effective collaboration and sharing of knowledge and intelligence within the healthcare industry is critical and necessary during these unprecedented times to support the work led by all State/Territory and Commonwealth Governments in responding to the pandemic.

Medicines Australia response to submissions

3.11. MA responded to the submissions stating that MA's application for authorisation to permit members of the MA/GBMA Working Group to engage in the Proposed Conduct is made in response to extraordinary circumstances. Its focus is on ensuring that there is a continuity of supply to the Australian public of Critical Medicines and Critical Devices at this time.[9]

3.12. MA submits that since the interim authorisation was granted on 3 April 2020, the relevant Federal Government bodies, in particular the Therapeutic Goods Administration (TGA) and DOH, have been centrally involved in discussions of the MA/GBMA Working Group. Any material decisions or actions arising from those discussions are at the request, or with the express involvement and endorsement, of those government bodies. MA has also performed an important role, separate but

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5 Department of Industry, Science, Energy and Resources 27 April 2020, Submission, Available: Public register for Medicines Australia

6 The Pharmacy Guild of Australia, Submission, 28 April 2020, Available: Public register for Medicines Australia

7 NSW Ministry of Health, 30 April 2020, Submission, available: Public register for Medicines Australia

8 Department of Health and Human Services, 12 May 2020, Submission on the Medicines Australia and Medical Technology Association of Australia, Available, Public register for Medicines Australia

9 Medicines Australia, Response to submissions from ACCC's public consultation process, 11 May 2020 Available: Public register for Medicines Australia

related to that under the authorisation, of informing these government bodies of any anticipated supply issues advised to it by members. MA intends for any discussions between the MA/GBMA Working Group to continue to occur in the same manner.[10]

3.13. MA submits that the risks to supply faced by pharmacies, large and small, which play a critical role in facilitating the supply of Critical Medicines and Critical Devices to Australian consumers, may be magnified at this time. Should meetings of the MA/GBMA working group need to address specific issues in the supply chain that may affect supply to pharmacies, MA is confident that the involvement of the TGA, DOH and relevant government bodies in those meetings will seek to facilitate fair supply without any undue preferencing of MA/GBMA customers, whilst at the same time balancing any particular areas of public need.[11]

3.14. MA also submits:[12]

- Following identification of a potential supply shortage of a Critical Medicine or Critical Device, only those suppliers of the Critical Medicine or Critical Device have been invited to participate in discussions with the TGA/DoH and members of the MA and GBMA executive. This has been strictly observed to date, and MA has provided the ACCC and the public with transparency by means of weekly reports where a meeting has occurred (or has notified where no meeting has occurred). This is in recognition of the highly unusual nature of the potential co-ordination among suppliers of Critical Medicines and Devices and the need to provide confidence to stakeholders that the collaboration, where necessary for it to occur in the context of the authorisation, is conducted within the strict parameters set by and for the purpose described in the application for authorisation.
- Where a discussion has occurred, its sole purpose has been to seek to identify the source or cause of the potential supply shortage and to establish whether future conduct between the relevant parties to the discussion requires coordination to ensure that any supply shortage of the Critical Medicine or Device is averted or managed appropriately in the public interest.
- The discussions which have occurred concern only supply issues (including for example, stockpile orders and supply logistics). No aspect of price or cost information of any of the parties has been discussed. All meetings have also been attended by a competition law observer.
- To date, the potential supply shortages identified, and resulting discussions, have involved information sharing of a kind which might raise concerns under Part IV in the absence of Interim Authorisation, but have not required the relevant parties to engage in any coordinated conduct to resolve those potential supply issues, and it has been sufficient that the relevant parties have been able to unilaterally undertake certain actions to avoid or resolve those issues.

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[10] Medicines Australia, Response to submissions from ACCC's public consultation process, 11 May 2020 Available: Public register for Medicines Australia

[11] Medicines Australia, Response to submissions from ACCC's public consultation process, 11 May 2020 Available: Public register for Medicines Australia

[12] Medicines Australia, Further response to submissions from ACCC's public consultation process, 10 June 2020 Available: Public register for Medicines Australia

Submissions about the effect of interim authorisation

3.15. Many of the 12 MA/GBMA Working Group members that responded to the ACCC's request for an update on activities under the interim authorisation submit that they have not needed to engage in the Proposed Conduct to date. Participant comments include:

- One participant noted that it was able to have discussions with other suppliers in consultation with the TGA and MA to address a national shortage of a Critical Medicine.
- The supply of Critical Medicines and Critical 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.
- Interim authorisation supports management of the supply chain by increasing visibility of demand for medicines.
- While we (the participant) have not engaged in the Proposed Conduct, having the interim authorisation available is a good measure. If the situation had been worse having this facility available would have been extremely helpful in working to ensure patients were able to receive treatment.
- It is important to get insight into the supply and demand situation for the entire country beyond an individual company's situation to identify (potential) gaps and to adjust accordingly. It was therefore very valuable to understand the situation across all market players.
- MA and GBMA have issued clear guidance on the specific rules to help companies understand what is permitted when engaging with any other member of the MA/GBMA Working Group.

3.16. MA/GBMA Working Group member submissions are available on the Public Register for Medicines Australia.

4. ACCC assessment

4.1. The ACCC's assessment of the Proposed Conduct is carried out in accordance with the relevant authorisation test contained in the Act.

4.2. MA is seeking authorisation for Proposed Conduct that would or might constitute a cartel provision within the meaning of Division 1 of Part IV of the Act and may substantially lessen competition within the meaning of section 45 of the Act. Subsections 90(7) and 90(8) of the Act provide that the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (**authorisation test**).

Relevant areas of Competition

4.3. To assess the likely effect of the Proposed Conduct, the ACCC identifies the relevant areas of competition likely to be impacted.

4.4. The application did not specifically describe the relevant areas of competition.

4.5. The ACCC considers that the relevant areas of competition are likely to be for the supply of Critical Medicines and Critical Devices as defined in paragraph 1.8 above.

The ACCC does not consider that a precise definition of the market is necessary for the assessment of the Proposed Conduct.

Future with and without the Proposed Conduct

4.6. In applying the authorisation test, the ACCC compares the likely future with the Proposed Conduct that is the subject of the authorisation to the likely future in which the Proposed Conduct does not occur.[13]

4.7. As the Proposed Conduct is currently occurring subject to interim authorisation the ACCC has the benefit of observing how the Proposed Conduct is operating in practice and this is likely to be of relevance to a view of how the likely future with the Proposed Conduct would look if authorisation is granted in a final determination.

4.8. The rationale for Proposed Conduct is closely linked with the impacts of COVID-19 in Australia. The future likelihood and severity of those impacts is largely unknown at this point in time.

4.9. The ACCC notes that, currently, COVID-19 infection rates in Australia are low and the demand for Critical Medicines and Critical Devices has largely stabilised since peaks in March and April 2020. However, the continued increase of infection rates internationally is likely to influence the availability of supply of Critical Medicines and Critical Devices in Australia. Accordingly the future with and without the Proposed Conduct is more difficult to predict compared to applications for authorisation that are not related to the COVID-19 pandemic, or those where the Australian circumstances are more insulated from global factors.

4.10. The ACCC considers that in the future with the Proposed Conduct, the participants will continue to share information and coordinate and allocate the fulfilment of orders and supply requests for Critical Medicines and Critical Devices amongst themselves, as is occurring under the interim authorisation. The MA/GBMA Working Group will continue to discuss shortages of Critical Medicines and Critical Devices with DOH and TGA and where required to do so by these government bodies take action to alleviate shortages. In doing so, the MA/GBMA Working Group members and Federal Government and/or Federal Government Agencies can respond quickly to an increase in demand for Critical Medicines and Critical Devices.

4.11. The ACCC considers that in the future without the Proposed Conduct the MA/GBMA Working Group and Federal Government and/or Federal Government agencies may be less able to quickly and effectively respond to any increase in the rate of COVID-19 infection in Australia or globally and so the supply of Critical Medicines and Critical Devices may not meet demand.

Public benefits

4.12. The Act does not define what constitutes a public benefit. The ACCC adopts a broad approach. This is consistent with the Australian Competition Tribunal (the **Tribunal**) which has stated that the term should be given its widest possible meaning, and includes:

> *…anything of value to the community generally, any contribution to the aims pursued by society including as one of its principal elements … the achievement of the economic goals of efficiency and progress.* [14]

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[13] Re Queensland Independent Wholesalers Ltd (1995) 132 ALR 225; Re Qantas Airways Ltd [2004] ACompT 9;; Re VFF Chicken Meat Growers Boycott Authorisation [2006] ACompT 2; Re Application by Medicines Australia Inc [2007] ACompT 4; Re Macquarie Generation and AGL Energy Ltd [2014] ACompT 1.

Medicines Australia submission

4.13. MA submits that the Interim Authorisation has allowed efficient and necessary engagement between the parties to identify the relevant supply issues and deploy appropriate actions to resolve those issues. MA also submits that absent the rapid ability to have such coordinated communications and information sharing with Government stakeholders and among members, the response to potential shortages would not have been as effective.[15]

4.14. MA submits that the Proposed Conduct will allow:[16]

- MA/GBMA Working Group members to coordinate, in the national interest, their manufacturing and supply activities and exchange information so that areas of supply shortage and constraint can be addressed more quickly and effectively to assist State and Federal Governments to respond more effectively to COVID-19.
- The Working Group, where necessary or desired, to more effectively advise Federal, State and Territory Governments and relevant health agencies in relation to the supply of essential medicines and associated supplies, which is necessary to ensuring a coordinated and effective response to this unprecedented international public health crisis.

4.15. While the discussions that have taken place to date under the Interim Authorisation have not required coordinated conduct or any material decisions or actions, MA considers there is a need for the mechanisms in place under the Interim Authorisation to remain in place for a period of six months after the final determination is issued, as the threat of COVID-19 persists and the need for information sharing and communications continues. In particular: [17]

- MA submits that while social distancing restrictions are starting to ease, MA and its members (like the governments and the public) are cautious that the challenges arising from COVID-19 are not over. MA recognises that further potential supply shortages of Critical Medicines and Critical Devices may arise as a result of further outbreaks of COVID-19 as restrictions are eased in each State and Territory and travel resumes in the coming months (thereby increasing the potential for the virus to spread again and a possible second wave). This is particularly so as Australia moves into the winter months.
- The supply chain will likely continue to be impacted by events outside Australia, and as the ordering and supply of Critical Medicines and Critical Devices can occur many months in advance of supply to a patient, those effects may continue to be felt notwithstanding the positive results of the public health protection measures to date in Australia.

Interested party submissions

4.16. The Victorian Department of Health and Human Services, the Pharmacy Guild and DISER support the Proposed Conduct as a means to mitigate the risk of shortages of supply of Critical Medicines and Critical Devices during the COVID-19 pandemic.

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[14] Queensland Co-operative Milling Association Ltd (1976) ATPR 40-012 at 17,242; cited with approval in Re 7-Eleven Stores (1994) ATPR 41-357 at 42,677.

[15] Medicines Australia, Further response to submissions from ACCC's public consultation process, 10 June 2020 Available: Public register for Medicines Australia

[16] Medicines Australia, Application for authorisation 27 March 2020 Available: Public register for Medicines Australia

[17] Medicines Australia, Further response to submissions from ACCC's public consultation process, 10 June 2020 Available: Public register for Medicines Australia

4.17. DISER submits that public benefits are likely to be enhanced if the MA/GBMA Working Group collaborates with all members of the pharmaceutical sector, including businesses who are not members and businesses who are in supply chains not normally part of the pharmaceutical sector such as chemical manufacturers and medical device and technology manufacturers.

The ACCC's view

4.18. Subject to its ongoing assessment, including submissions made in response to this draft determination, the ACCC considers that there are likely to be significant public benefits of permitting the MA/GBMA Working Group to engage in the Proposed Conduct, including enabling MA/GBMA Working Group members to:

- coordinate discussions within the medicines supply chain to develop and implement strategies to ensure the continued supply of essential medicines and supplies to Australians,
- provide more effective advice to governments and relevant health agencies regarding the supply of essential medicines and associated supplies including by identifying and addressing supply shortages and constraints, and
- maximise the efficient use of supply channels.

4.19. Those public benefits arise to the extent to which there are, or there are risks of, significant numbers of COVID-19 infections in Australia and/or overseas. The ACCC notes that COVID-19 infection rates in Australia have not been as high as initially projected and therefore the demand for Critical Medicines and Critical Devices (and in turn, the need for the Proposed Conduct) has not been as great as may have been anticipated. However, the risk of increased infection rates both in Australia and overseas remains and therefore there remains a threat to the supply of Critical Medicines and Critical Devices in Australia.

4.20. The ACCC accepts MA's view that, absent the ability to rapidly communicate with the MA/GBMA Working Group and share information with Government stakeholders and among working group members, the response to potential shortages to date would not have been as effective.

4.21. The ACCC acknowledges that to the extent infection rates in Australia remain low, and there are no associated critical issues in the supply and/or demand of Critical Medicines and Critical Devices, the actual reliance on the Proposed Conduct may be limited. However, given the uncertain environment in which delays and inefficiencies may have significant public health consequences, the Proposed Conduct is likely to mitigate these risks to a significant extent by enabling urgent action if the need arises and this is a public benefit.

Public detriments

4.22. The Act does not define what constitutes a public detriment. The ACCC adopts a broad approach. This is consistent with the Tribunal which has defined it as:

> *…any impairment to the community generally, any harm or damage to the aims pursued by the society including as one of its principal elements the achievement of the goal of economic efficiency.*[18]

[18] Re 7-Eleven Stores (1994) ATPR 41-357 at 42,683.

4.23. Competitors sharing information and coordinating supply of goods and/or services has the potential to lessen competition and result in consumer detriment by restricting supply and increasing prices, stifling innovation and preventing businesses from entering the market.

Potential to reduce competition for the supply of critical medicines and critical devices

Medicines Australia submission

4.24. MA submits that the Proposed Conduct:[19]

- Is a temporary measure in response to a national crisis, and seeks to maximise the efficient use of existing supply channels in a time of peak demand, in situations where demand is difficult to forecast and where there is limited time to scale and prepare for such demand. Any public detriments identified by the ACCC will only arise temporarily and, in any event, are significantly outweighed by the public benefits arising from the Proposed Conduct.
- Will not materially alter the competitive dynamics in any market, and markets will be able to substantially return to their current state once the emergency circumstances subside.
- Includes the exchanging of information around pricing and quantities, and the coordination of supply, but does not extend to setting or agreeing prices (which will remain at the discretion of each supplier in accordance with relevant legislation).
- Is not compulsory for its members to engage in, and any participant can opt out of any information sharing arrangements or other elements of the Proposed Conduct.

Interested party submissions

4.25. DISER submits that collaboration across the pharmaceutical sector including both members and non-members of the Working Group is an essential factor in mitigating possible competitive detriments that could arise from the authorisation.

4.26. The Pharmacy Guild submits that arrangements should be in place to ensure that the work done under this authorisation is not used to preferentially advantage any of the participants' customers.

4.27. NSW Health submits that the conduct to be authorised, including conduct in relation to tenders, and any collaboration with wholesalers/distributors should be limited to conduct which is for a purpose requested by the Commonwealth or one or more State or Territory governments.

ACCC view

4.28. The ACCC notes the submissions made by DISER, the Pharmacy Guild and NSW Health.

4.29. The TGA, a government body, coordinates the national Medicines Shortages Working Group, which includes Medicines Australia, the GBMA, and some sections of the pharmaceutical sector which is likely to facilitate broad collaboration, engagement and

[19] Medicines Australia, Response to submissions from ACCC's public consultation process, 11 May 2020 Available: Public register for Medicines Australia

fair supply to pharmacies. Further, members of the National Pharmaceutical Services Association are now members of the MA/GBMA Working Group.

4.30. The ACCC is aware that under the interim authorisation, relevant Federal Government bodies, in particular the TGA and DOH, have been involved in discussions with the MA/GBMA Working Group. It is likely to be important for MA/GBMA Working Group members to share information and collaborate to identify potential supply shortages of Critical Medicines and Critical Devices and then discuss this with relevant Government bodies.

4.31. Although the long-term effects of the COVID-19 pandemic are somewhat uncertain, the ACCC considers that there are a number of factors that mean it is unlikely that the Proposed Conduct will significantly impact competition beyond the short term. The Proposed Conduct:

- only applies to arrangements and conduct for the purposes of coordinating the supply of Critical Medicines and Critical Devices in the circumstances of the current COVID-19 pandemic;
- does not extend to setting or agreeing prices;
- is a temporary measure in response to the COVID-19 pandemic;
- will be undertaken in the context of broader coordination and communication by the MA/GBMA Working Group with relevant Government and regulatory bodies, including the TGA; and
- is not compulsory and any participant can opt out of any information sharing arrangements or other authorised conduct.

4.32. The ACCC notes that the Proposed Conduct contemplated by paragraph 1.9(d) above is conduct (a) concerning tenders let, or to be let, by Federal or State Governments and (b) 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.

4.33. Nevertheless, competitors sharing information and coordinating the supply of products may reduce competition and result in public detriment in the short term. Detriment may extend beyond the short term because the participants may have a better understanding of each other's pricing and stocking strategies.

4.34. Accordingly the ACCC considers that the Proposed Conduct is likely to result in some public detriment in the short term.

Potential to facilitate unauthorised information sharing and coordination

4.35. Agreements among competitors increase the potential for anticompetitive coordination beyond the scope of the application. While the Proposed Conduct is limited to coordination in relation to the supply of Critical Medicines and Critical Devices in response to the COVID-19 pandemic, these discussions may give rise to opportunities to discuss other matters. This could lead, either explicitly or tacitly, to agreements in relation to the supply of medicines, devices and other products not relevant to the COVID-19 pandemic. Such conduct could significantly reduce competition in relation to these products.

4.36. Agreements in relation to the supply of medicines, devices and other products not relevant to the COVID-19 pandemic would not be protected under the proposed authorisation. Any such agreements would be subject to investigation by the ACCC

and, as appropriate, prosecution under the Act. On this basis, the ACCC considers that the risk of coordination more broadly is limited.

Balance of public benefit and detriment

4.37. The ACCC considers that the Proposed Conduct is likely to result in significant public benefits by facilitating the supply of Critical Medicines and Critical Devices, particularly in the event of an increase in COVID-19 infection rates in Australia or worldwide. In the event that infection rates remain low, public benefits – while still likely to accrue – may be less significant. In any event the ACCC considers that there are public benefits in maintaining readiness for possible outbreaks.

4.38. The ACCC considers that the Proposed Conduct is likely to result in some public detriment over the short term because it is likely to reduce competition.

4.39. Overall, the ACCC considers that the Proposed Conduct is likely to result in a public benefit and that this public benefit would outweigh any likely detriment to the public from the Proposed Conduct.

4.40. As noted above, the significant uncertainty around COVID-19 infection rates means the future with and without the Proposed Conduct is difficult to predict. Accordingly, the ACCC's view of the likely public benefits and detriments of the Proposed Conduct may change prior to making a final determination.

Length of authorisation

4.41. The Act allows the ACCC to grant authorisation for a limited period of time.[20] This enables the ACCC to be in a position to be satisfied that the likely public benefits will outweigh the detriment for the period of authorisation. It also enables the ACCC to review the authorisation, and the public benefits and detriments that have resulted, after an appropriate period.

4.42. In this instance, MA sought authorisation for six months from the date of the final determination. MA notes that it is difficult to predict the duration or extent of the COVID-19 crisis and therefore the period in which authorisation for the Proposed Conduct may need to be extended.

4.43. Two interested parties made submissions on the length of authorisation:

- Amgen submits that a six month authorisation period is sufficiently confined to ensure any coordinated conduct does not extend beyond potential supply shortages that arise as a result of COVID-19.
- DISER submits that limiting the initial authorisation period to six months substantially reduces the possible competition risks.

4.44. The ACCC proposes to grant authorisation until 27 March 2021.

[20] Subsection 91(1)

5. Draft determination

The application

5.1. On 27 March 2020, MA lodged application AA1000486 with the ACCC, seeking authorisation under subsection 88(1) of the Act.

5.2. MA seeks authorisation for the Proposed Conduct on behalf of current and future members of the MA/GBMA Working Group.

5.3. Subsection 90A(1) of the Act requires that before determining an application for authorisation, the ACCC shall prepare a draft determination.

The authorisation test

5.4. Under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Proposed Conduct is likely to result in a benefit to the public and the benefit would outweigh the detriment to the public that would be likely to result from the Proposed Conduct.

5.5. For the reasons outlined in this draft determination, the ACCC considers, in all the circumstances, that the Proposed Conduct would be likely to result in a benefit to the public and the benefit to the public would outweigh the detriment to the public that would result or be likely to result from the Proposed Conduct.

Proposed condition of authorisation

5.6. The ACCC may specify conditions in an authorisation.[21] The legal protection provided by the authorisation does not apply if any of the conditions are not complied with.[22]

5.7. The ACCC may specify conditions in circumstances where, although the relevant public benefit test is met, without the conditions the ACCC would not be prepared to exercise its discretion in favour of authorisation.[23]

5.8. In this instance, the ACCC is conscious that where future COVID-19 infection rates and the demand for Critical Medicines and Critical Devices are uncertain, the extent of the benefits and detriments of authorisation may also be uncertain. However there are benefits in any event from maintaining readiness in the face of remaining risks of outbreak. Nonetheless, the ACCC considers it appropriate to specify a reporting condition so that it can maintain an appropriate level of oversight in the current dynamic environment.

5.9. The ACCC proposes to include the following reporting condition, which is similar to that included in the interim authorisation:

MA will update the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including by:

1. notifying the ACCC of:

[21] Section 88(3) of the Act.

[22] Section 88(3) of the Act.

[23] Application by Medicines Australia Inc (2007) ATPR 42-164 at [133].

a. material recommendations made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct;

b. material decisions or arrangements made by the MA/GBMA Working Group or members of the MA/GBMA Working Group which involve the Proposed Conduct, including arrangements made to:

ii. allocate supply between MA/GBMA Working Group members;

iii. prioritise requests for supply; or

iv. respond to tenders or requests for supply;

c. any changes to the membership of the MA/GBMA Working Group and the identity of any new members;

2. providing to the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct; and

3. meeting with the ACCC to provide regular updates in relation to the Proposed Conduct, as agreed by MA and the ACCC.

Conduct which the ACCC proposes to authorise

5.10. The ACCC proposes to grant conditional authorisation AA1000486 to enable the MA/GBMA Working Group to engage in the Proposed Conduct. However the ACCC proposes to grant conditional authorisation for the Proposed Conduct only insofar as it is for the sole purpose of ensuring the supply of Critical Medicines and Critical Devices in response to the COVID-19 pandemic.

5.11. The ACCC proposes to grant conditional authorisation AA1000486 until 27 March 2021.

5.12. This draft determination is made on 26 June 2020.

6. Next steps

6.1. The ACCC now invites submissions in response to this draft determination by 17 July 2020. The ACCC is particularly interested to understand the views of interested parties regarding the scope of the proposed conduct and the proposed duration of authorisation. In particular, the ACCC seeks submissions on the scope of the Proposed Conduct and whether, given the rate of COVID-19 infections, the scope may be too broad.

6.2. In addition, consistent with section 90A of the Act, the applicant or an interested party may request that the ACCC hold a conference to discuss the draft determination.