Draft Determination

Application for revocation of AA1000486 and the substitution of authorisation AA1000579
lodged by
Medicines Australia
in respect of
coordinating the supply of essential medicines and related devices in response to the COVID-19 pandemic
Authorisation number: AA1000579

11 November 2021

Commissioners: Keogh
Rickard
Brakey
Ridgeway

Summary

The ACCC proposes to grant re-authorisation with a condition to enable Medicines Australia (MA) and its members, the Generic and Biosimilar Medicines Association (GBMA) and its members, and potential future members that will be notified to the ACCC (the MA/GBMA Working Group), to continue to implement a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices in response to the COVID-19 pandemic.

This conduct has been previously authorised since April 2020. The conduct the subject of the current application is narrower in scope than that previously authorised. Specifically, MA/GBMA Working Group members would engage in the conduct only at the request of the Federal Government and/or a Federal Government Agency, and MA does not seek re-authorisation for any conduct related to tendering.

The application for revocation and substitution was lodged because the previous authorisation was due to expire on 30 September 2021. On 29 September 2021, the ACCC granted interim authorisation with a condition to enable the arrangements to continue while the ACCC considers the substantive application.

Based on information provided by MA, including regular reporting required as a condition of the previous authorisation, and feedback from the Therapeutic Goods Administration (TGA), the ACCC considers that the coordinated strategy has been beneficial in identifying and responding to supply shortages.

The ACCC considers that the conduct is likely to continue to result in public benefits by allowing the MA/GBMA Working Group, at the request of relevant Government agencies, to work together 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. In this case, however, the conduct is unlikely to significantly weaken competition beyond the short term.

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

Re-authorisation is proposed to be subject to a condition that MA report any meetings, discussions, developments or decisions between MA/GBMA Working Group members to the ACCC.

The ACCC proposes to grant re-authorisation until 30 September 2022.

The ACCC invites submissions in response to this draft determination by 25 November 2021 before making its final decision.

1. The application for authorisation revocation and substitution

1.1. On 17 September 2021, Medicines Australia (**MA**) lodged an application on behalf of the MA/GBMA Working Group to revoke authorisation AA1000486 and substitute authorisation AA1000579 for the one revoked (referred to as re-authorisation) with the Australian Competition and Consumer Commission (the **ACCC**).

1.2. This application for re-authorisation AA1000579 was made under subsection 91C(1) of the *Competition and Consumer Act 2010* (Cth) (the **Act**).

1.3. The ACCC may grant authorisation, which provides businesses with protection from legal action under the competition provisions in Part IV of the Act, for arrangements that may otherwise risk breaching those provisions in the Act but are not harmful to competition and/or are likely to result in overall public benefits.

The Applicant

1.4. MA is the applicant for re-authorisation. MA seeks re-authorisation on behalf of itself and its members, and the Generic and Biosimilar Medicines Association (**GBMA**) and its members (the **MA/GBMA Working Group**). MA also seeks re-authorisation in respect potential future members of the MA/GBMA Working Group. MA will notify the ACCC of any new member to be covered by the re-authorisation.

1.5. MA states that it represents the discovery-driven pharmaceutical industry in Australia. MA submits that it works in partnership with government, the Australian innovative medicines industry, consumer groups and health professionals to develop health and industry policy.

1.6. The GBMA is a national association representing generic and biosimilar medicine suppliers in Australia. Its members consist of companies that manufacture, supply and market pharmaceutical products in Australia. Its associate members provide consultation and services to the pharmaceutical and pharmacy industries.

The Conduct

1.7. MA seeks re-authorisation to allow the MA/GBMA Working Group, at the request of the Federal Government and/or a Federal Government Agency, to continue 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**), and

(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 supply of Critical Medicines and Critical Devices that arise as a result of COVID-19.

1.8. The specific conduct for which re-authorisation is sought includes:

(a) sharing information about Critical Medicines and Critical Devices 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

iv. opportunities to increase domestic manufacturing

(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 of Critical Medicines and Critical Devices as nominated by the Federal Government, State and Territory Governments and relevant health authorities.

(Together, paragraphs 1.7 and 1.8 form the **Conduct**).

1.9. MA is seeking re-authorisation for conduct that is similar but narrower in scope than the arrangements that were in place under authorisation AA1000486, which was due to expire on 30 September 2021 (the **Previous Authorisation**).

1.10. Specifically, re-authorisation is only sought for MA/GBMA Working Group members to engage in the Conduct at the request of, rather than in consultation with, the Federal Government and/or a Federal Government Agency. Further, the application for re-authorisation does not seek re-authorisation for any conduct related to tendering.

1.11. MA is seeking to retain a similar reporting condition that was imposed by the ACCC in relation to interim authorisation and the Previous Authorisation. In particular, that MA must regularly report to the ACCC regarding any meetings, discussions, developments or decisions in relation to the Conduct.

1.12. MA seeks re-authorisation for 12 months. It does so having regard to the Australian Government's National Plan to transition Australia's National COVID-19 Response (**National Plan**) published on 31 July 2021.

Interim authorisation

1.13. MA requested interim authorisation so that the MA/GBMA Working Group members could engage in the Conduct while the ACCC is considering the substantive application. Interim authorisation was requested because the Previous Authorisation was due to expire before the ACCC made a final determination about the application for re-authorisation.

1.14. On 29 September 2021, the ACCC suspended the operation of the Previous Authorisation and granted interim authorisation in its place. The interim authorisation is subject to a condition as summarised at paragraph 1.11. For more detail, see the Interim Authorisation Decision on the ACCC's public register.

1.15. The interim authorisation remains in place until the ACCC's final determination comes into effect, the application for re-authorisation is withdrawn, or the ACCC decides to revoke interim authorisation.

2. Background

2.1. MA submits that the ongoing and escalating challenges arising from COVID-19 are likely to require MA/GBMA Working Group members to engage in the Conduct to ensure continuity of supply of Critical Medicines and Critical Devices.

2.2. MA considers that the risk of supply chain pressures is more acute now than it has been previously, particularly as a result of the highly infectious Delta variant of COVID-19 which is causing an increase in the number of overall infections and cases requiring hospitalisation. One way in which the pressure on Australia's hospital system manifests is difficulty in obtaining Critical Medicines and Critical Devices to treat patients suffering from the symptoms of COVID-19 as well as patients suffering from other medical conditions that can be treated by Critical Medicines and Critical Devices. This may also lead to an increase in demand for alternative therapies to Critical Medicines for patients suffering from other medical conditions.

2.3. In circumstances of rapidly increasing infections caused by the Delta variant of COVID-19, difficulties in ensuring supply of Critical Medicines and Critical Devices may be further exacerbated by import and quarantine delays, stockpiling by State Purchasing Authorities and interstate transport limitations.

2.4. MA submits that re-authorisation of the Conduct will enable suppliers of Critical Medicines and Critical Devices to have the best opportunity to avoid supply shortages and assist Federal, State and Territory Governments in responding to the threat of the Delta variant of COVID-19.

3. Consultation

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

3.2. Due to the need to provide ongoing authorisation for the Conduct, with a view to ensuring the continued supply of Critical Medicines and Critical Devices, the ACCC did not seek public submissions prior to granting interim authorisation.

3.3. The ACCC subsequently invited submissions on both the decision to grant interim authorisation and the substantive application for re-authorisation from a range of potentially interested parties, including State, Territory and Federal Government agencies, relevant regulatory bodies and medical/pharmaceutical associations.

3.4. The ACCC received one written submission from the Pharmacy Guild of Australia and one oral submission from the TGA, both of which are on the public register.

3.5. The TGA explained that while the Previous Authorisation was used sparingly, it has been useful in dealing with spikes in demand for certain medicines related to COVID-19. The TGA submits that the main benefit has been the ability for MA/GBMA Working Group members and the TGA to discuss stock levels, plan for anticipated demand and therefore avoid supply shortages. As COVID-19 restrictions ease across Australia, the TGA expects that it will need to convene more meetings with MA/GBMA Working Group members to discuss potential supply issues, for example in relation to ICU medicines.

3.6. The Pharmacy Guild of Australia submitted that it does not oppose re-authorisation.

3.7. Public submissions by MA and interested parties are on the public register for this matter.[1]

4. ACCC assessment

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

4.2. MA is seeking re-authorisation for 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. Consistent with subsection 90(7) and 90(8) of the Act,[2] the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to

[1] www.accc.gov.au/authorisationsregister.

[2] See subsection 91C(7)

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 Conduct, the ACCC identifies the relevant areas of competition likely to be impacted.

4.4. 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 1.7 above. The ACCC does not consider that a precise definition of the market is necessary for the assessment of the Conduct.

Future with and without the Conduct

4.5. In applying the authorisation test, the ACCC compares the likely future with the Conduct that is the subject of the authorisation to the likely future in which the Conduct does not occur.

4.6. The ACCC considers that in the future with the Conduct, MA/GBMA Working Group members will continue to share information and coordinate and allocate the fulfilment of orders and supply requests for Critical Medicines and Critical Devices amongst themselves at the request and instruction of the Federal Government and/or a Federal Government Agency, as is occurring under the interim authorisation.

4.7. The ACCC considers that in the future without the Conduct, MA/GBMA Working Group members will not be able to work collectively to respond to Federal Government/and or Agencies to anticipate or respond to any medicine shortages or supply chain issues, to the extent that doing so will contravene the CCA. In this case, MA/GBMA Working Group members may need to work individually with the Federal Government and/or Agencies in a series of bilateral discussions. This could potentially increase cost and delay and result in harm to those who rely on consistent supply of Critical Medicines and Critical Devices.

Public benefits

4.8. 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 in considering public benefits:

> *we would not wish to rule out of consideration any argument coming within the widest possible conception of public benefit. This we see as 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.* [3]

4.9. MA submits that very similar or more unpredictable conditions exist now compared to when the Previous Authorisation was granted. MA submits that while there was limited need to engage in the conduct under the Previous Authorisation, granting re-authorisation is of clear public benefit as it will preserve the ability for MA/GBMA Working Group members to swiftly respond to shortages of Critical Medicines and Critical Devices by engaging in coordinated conduct if required, and only at the request of the of the Federal Government and/or a Federal Government Agency.

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3 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.

4.10. MA submits the Conduct will allow suppliers to take various actions to respond to increasing demands and ensure adequate supply of Critical Medicines and Critical Devices for the treatment of COVID-19 and other medical conditions. It will also allow them to develop strategies and provide advice to government health agencies to ensure continuity of supply, coordinate on the fulfilment of supply requests and maximise the efficient use of supply channels.

4.11. The TGA supports re-authorisation of the Conduct as a means to mitigate the risk of supply shortages of Critical Medicines and Critical Devices. The TGA expects it will convene more meetings with MA/GBMA Working Group members compared to under the Previous Authorisation. This is due to the expectation that as states ease COVID-19 restrictions and open up, there may be a need to meet to discuss ICU medicines in response to an increase in patients and any potential supply issues.

The ACCC's view

4.12. The ACCC recognises the significant challenges that are continuing to occur as a result of COVID-19. While the Australian Government's National Plan is rolled out and Australia's state and international borders begin to 're-open', there is likely to be continued pressure on the healthcare system. In these circumstances, while the extent to which the Conduct will be engaged in is uncertain, there remains a risk of supply shortages for Critical Medicines and Critical Devices in Australia.

4.13. The ACCC considers that there are likely to be significant public benefits that result from the Conduct in the current circumstances. The Conduct will allow MA/GBMA Working Group members to continue to, at the request of the Federal Government and/or a Federal Government Agency:

(a) coordinate discussions within the medicines supply chain to develop and implement strategies to ensure the continued supply of Critical Medicines and Critical Devices to Australians

(b) provide more effective advice to governments and relevant health agencies regarding the supply of Critical Medicines and Critical Devices including by identifying and addressing supply shortages and constraints, and

(c) maximise the efficient use of Critical Medicines and Critical Devices and supply channels in times of peak demand, including by more effectively prioritising requests for supply of Critical Medicines and Critical Devices as nominated by the Federal Government, State and Territory Governments and relevant health authorities.

4.14. The ACCC considers that the Conduct is likely to mitigate the risks associated with supply shortages and increased pressure on the health system as a result of COVID-19 by enabling urgent action if the need arises.

Public detriments

4.15. 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.*[4]

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

4.16. MA submits that the Conduct will not give rise to any material public detriments because it is limited in scope and temporary in response to a national crisis and will not materially alter the competitive dynamics of any market.

4.17. MA submits that safeguards would be in place that mitigate the risk of any public detriment arising as a result of the Conduct, in particular that the Conduct would only be engaged in by MA/GBMA Working Group members at the request and instruction of the Federal Government and/or a Federal Government Agency.

The ACCC's view

4.18. The ACCC considers that the Conduct is likely to result in some public detriment in the short term as it reduces the potential for competition between suppliers of Critical Medicines and Critical Devices. 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 stocking strategies.

4.19. There is also the potential for anticompetitive coordination beyond the scope of the Conduct. While the 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.

4.20. To address the potential for public detriment the ACCC proposes to impose a reporting condition. The condition requires MA to provide a report to the ACCC at the end of each month or within 5 business days of any meeting, discussion, development or decision between MA/GBMA Working Group members to be published on the ACCC's public register (the **Monthly Report**). The Monthly Report must report on any meetings, discussions, developments and decisions in relation to the Conduct. See paragraph 5.7 for detail.

4.21. MA was required to provide similar reports on a fortnightly basis under the Previous Authorisation. However, in the majority of cases these reports did not record instances of the conduct occurring due to relatively low COVID-19 infection numbers and stability in the supply of Critical Medicines and Critical Devices. More recently, in September 2021, MA reported to the ACCC that the TGA convened a meeting with certain MA/GBMA Working Group members to facilitate discussions about current demand and future supply outlook for a particular medicine.[5] More generally, the reports provided to the ACCC over the course of the Previous Authorisation and the current interim authorisation suggests that the collaboration between MA/GBMA Working Group members and relevant government agencies has occurred only as necessary and in accordance with the terms of the authorisation.

4.22. Therefore, with the proposed condition, the ACCC considers the detriments are likely to be limited because:

(a) the Conduct will only be engaged in by MA/GBMA Working Group members at the request of the Federal Government and/or a Federal Government Agency,

(b) the Conduct is a temporary measure in response to the COVID-19 pandemic,

[5] The reports are published on the ACCC's public register.

(c) the Conduct only applies to arrangements and conduct for the purposes of implementing a coordinated strategy in relation to the supply of Critical Medicines and Critical Devices in the circumstances of the COVID-19 pandemic. Any arrangements or agreements not relevant to the COVID-19 pandemic would not be protected under the proposed re-authorisation. Any such agreements would be subject to investigation by the ACCC and, as appropriate, prosecution under the Act,

(d) the Conduct is not compulsory and any participant can opt out of any information sharing arrangements or other authorised conduct,

(e) the Conduct 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,

(f) the Conduct does not involve any coordinated conduct between MA/GBMA Working Group members relating to pricing, and

(g) there will be transparency around the Conduct as a result of the involvement of Government Agencies and the reporting condition that the ACCC proposes to continue as part of the re-authorisation.

Balance of public benefit and detriment

4.23. The ACCC considers that the Conduct is likely to result in significant public benefits by facilitating the continuity of supply of Critical Medicines and Critical Devices, particularly in circumstances where the Delta variant of COVID-19 in Australia alongside the gradual easing of COVID-19 restrictions has caused a rise in overall infections and cases requiring hospitalisation. As vaccination rates across Australia increase, pressure on the health system and the potential for associated supply chain pressures may ease. As a result, public benefits – while still likely to accrue – may be less significant.

4.24. The ACCC also considers that the Conduct will result in some public detriment in the short term because it is likely to reduce competition. However, the detriment is limited by the fact that the Conduct will only be engaged in at the request and instruction of the Federal Government and/or a Federal Government Agency and that the proposed reporting condition provides further transparency.

4.25. Overall, the ACCC considers that the Conduct with the proposed condition is likely to result in a public benefit and that this public benefit would outweigh any likely detriment to the public from the Conduct.

Length of authorisation

4.26. The Act allows the ACCC to grant authorisation for a limited period of time.[6] 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.

4.27. In this instance, MA is seeking re-authorisation for 12 months, having regard to the Australian Government's National Plan and projected vaccination levels. MA submits that as vaccination levels of the Australian population (and those overseas) increase,

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6 Subsection 91(1)

supply chains should stabilise and the likelihood of supply shortages or disruptions from COVID-19 should decrease. MA submits that until then it is necessary to ensure that suppliers are able to engage in conduct to mitigate or respond to issues in the supply of Critical Medicines and Critical Devices.

4.28. The TGA submits that main use of the authorisation will be to work alongside the states' plans for re-opening. The TGA submits that it is not clear how far into 2022 that will continue to be a big issue and considers that it is difficult to say what the appropriate period of re-authorisation is.

4.29. While it is difficult to predict how long these measures will be necessary, for the reasons outlined in this draft determination, including the fact that the Conduct will only be engaged in by MA/GBMA Working Group members at the request of the Federal Government and/or a Federal Government Agency, the ACCC considers a re-authorisation period of 12 months from when the Previous Authorisation expired to be appropriate.

4.30. The ACCC proposes to grant re-authorisation until 30 September 2022.

5. Draft determination

The application

5.1. On 17 September 2021, MA lodged an application to revoke authorisation AA1000486 and substitute authorisation AA1000579 for the one revoked (referred to as re-authorisation). This application for re-authorisation AA1000579 was made under subsection 91C(1) of the Act.

5.2. MA seeks re-authorisation to allow the MA/GBMA Working Group to continue to implement a coordinated strategy at the request of the Federal Government and/or a Federal Government Agency to address shortages in the supply Critical Medicines and Critical Devices.

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 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 Conduct.

5.5. For the reasons outlined in this draft determination, the ACCC is satisfied, in all the circumstances, that the 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 Conduct, including any lessening of competition.

Proposed condition of authorisation

5.6. The ACCC may specify conditions in an authorisation. The legal protection provided by the authorisation does not apply if any of the conditions are not complied with.[7]

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

5.7. The ACCC proposes to grant re-authorisation with the following condition (which is identical to that imposed in the interim authorisation granted on 29 September 2021):

MA must:[8]

1. provide a report to the ACCC at the end of each month or within 5 business days of any meeting, discussion, development or decision between MA/GBMA Working Group members in relation to the Conduct, to be published on the ACCC's public register (subject to the ACCC deciding to exclude material from the register, as requested by MA) (the **Monthly Report**). The Monthly Report must report on any meetings, discussions, developments and decisions in relation to the Conduct. The Monthly Report must include, insofar as the following information has not already been provided in a previous Monthly Report:
    a. material recommendations, if any, made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Conduct
    b. information regarding any meeting or discussion between two or more of the MA/GBMA Working Group members relating to the Conduct, including:
        i. the attendees at the meeting or discussion
        ii. the agenda items of the meeting or discussion that are related to the Conduct
        iii. any minutes of the meeting or discussion relating to the Conduct
        iv. an overview of topics discussed and any material decisions made that related to the Conduct
    c. any changes to the MA/GBMA Working Group
2. provide the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Conduct
3. meet with the ACCC to provide regular updates in relation to the Conduct, as requested by the ACCC.

5.8. Under the condition, the ACCC may authorise a Committee or Division of the ACCC, a member of the ACCC or a member of the ACCC staff, to exercise a decision-making function under the conditions of this re-authorisation on its behalf.

Conduct which the ACCC proposes to authorise

5.9. The ACCC proposes to revoke authorisation AA1000486 and grant authorisation AA1000579 in substitution to enable the MA/GBMA Working Group to continue to engage in the Conduct as described in paragraphs 1.7 and 1.8.

5.10. The ACCC proposes to grant authorisation AA1000579 with the proposed condition as described at paragraph 5.7.

5.11. The ACCC proposes to grant re-authorisation for the 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.

5.12. The Conduct may involve a cartel provision within the meaning of Division 1 of Part IV of the Act or may have the purpose or effect of substantially lessening competition within the meaning of section 45 of the Act.

[8] ACCC, Medicines Australia – Interim Authorisation Decision, 29 September 2021

5.13. The ACCC proposes to grant authorisation AA1000579 until 30 September 2022.

5.14. This draft determination is made on 11 November 2021.

6. Next steps

6.1. The ACCC now invites submissions in response to this draft determination by 25 November 2021. 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.