Application for reauthorisation by revocation and substitution of Authorisation AA1000486

Lodged by Medicines Australia in respect of the supply of essential medicines, devices and related supplies in response to the COVID-19 pandemic

16 September 2021

Public version

The application for reauthorisation

1. This application is made on behalf of Medicines Australia (**MA**) and all named persons and entities in Annexure A, to revoke the authorisation granted to MA by the ACCC on 24 September 2020 (**Current Authorisation**) and to apply to substitute a new authorisation in its place (**Substitute Authorisation**).

2. MA represents the discovery-driven prescription medicines industry in Australia. MA works in partnership with government, the Australian innovative medicines industry, consumer groups and health professionals, to develop health and industry policy.

3. MA's mission is, in partnership with key stakeholders, to drive the creation and development of a predictable environment for the continued sustainable growth of innovative research based prescription medicines industry for the benefit of the Australian community.

4. Further information about MA, its members and it operations can be found on its website: https://medicinesaustralia.com.au/ and Annexure B.

5. This application for reauthorisation is also made on behalf of GBMA and its members. GBMA is the national representative body of generic and biosimilar medicines in Australia. Its members offer Australians high-quality generic and biosimilar medicines, whilst providing affordable community health outcomes that benefit all Australians.

6. GBMA 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.

7. The GBMA membership consists of two groups:

   (a) Manufacturers of generic and biosimilar medicines, including research-based prescription companies with biosimilar medicines

   (b) Companies that provide services to the pharmaceutical industry, or who are significantly engaged in the development, testing or registration of pharmaceutical products.

8. Further details of the GBMA can be found on its website: https://www.gbma.com.au/ and Annexure B.

9. The list of the members of the MA/GBMA Working Group who apply to be potential parties to the Proposed Conduct is set out in Annexure A. These members are the same as the members which were listed as potential parties under the Current Authorisation.

10. As is the case under the Current Authorisation, MA/GBMA considers that the mechanism for the addition of new MA/GBMA Working Group members to those in Annexure A, should be retained. Potential future members of the MA/GBMA Working Group may include parties that are neither members of MA nor GBMA but which perform a significant role in the continued delivery of essential medicines and related supplies to the Australian community.

Overview

11. The twelve month term of the Current Authorisation is set to expire on 30 September 2021. Broadly, it conditionally authorises MA/GBMA Working Group members to implement a coordinated strategy in relation to the supply of essential medicines, devices and related supplies in response to the COVID-19 pandemic.

12. By this application, MA seeks a Substitute Authorisation on terms which are substantially identical to the terms of the Current Authorisation, except that it does not seek reauthorisation of any conduct relating to tendering.

13. MA's application is made on the basis that the ongoing and escalating challenges arising from the Delta variant of COVID-19 in Australia are likely to require MA/GBMA Working Group members to engage (on short notice) in conduct requiring authorisation to ensure continuity of the supply of Critical Medicines and Critical Devices (as those terms are defined in the Current Authorisation).

14. MA recognises that the Substitute Authorisation should continue to be subject to a requirement for MA to provide regular reports to the ACCC on any meeting, discussions, developments and decisions in relation to the authorised conduct.

Section 1: Background

Rationale and grounds for the application for reauthorisation

15. When MA applied for authorisation on behalf of MA/GBMA Working Group members in March 2020, there was significant uncertainty in relation to the health and supply-chain effects of COVID-19. In particular, as regards to the impact of COVID-19 on the supply of Critical Medicines and Critical Devices, used to treat COVID-19 and other medical conditions.

16. In around early May 2021, the Delta variant of COVID-19 was detected in parts of New South Wales and Victoria, following a sustained period of low COVID-19 infections rates across Australia.

17. The Delta variant of COVID-19 is different to previous variants of the virus that were the cause of infections in Australia prior to this time:

- the Delta variant has significantly greater transmissibility compared with earlier variants. There is a high risk of transmission from even a short exposure to an infected person, and this has resulted in a much higher number of infections. Early data also appears to indicate that the risks of transmission in outdoor settings may be significantly higher than previous variants where generally, the risk of transmission is outdoor settings was considered low;[1] and

- the Delta variant has a shorter incubation time making it more difficult for contact tracers to identify and isolate potentially infectious people before they risk passing the virus on.

18. As a result of these characteristics of the Delta variant:

- since 26 June 2021, Greater Sydney has been in lockdown, with stay at home orders at certain times, encompassing the entire state of New South Wales, daily infection rates exceeding 1,000 per day and rising hospitalisations of persons infected with COVID-19. **Figure 1** illustrates the steadily increasing number of daily infections in the period between 15 August and 13 September 2021 in New South Wales:

[1] https://www.abc.net.au/news/2021-07-23/australia-covid-19-delta-spread-gives-experts-insight/100313568

Figure 1: Daily infection rate in New South Wales between 15 August 2021 and 13 September 2021[2]

- since around 16 July 2021 and again on 6 August 2021, parts of Victoria have been in lockdown;
- various other state and territories have been the subject of stay at home orders and/or lockdowns for various periods;
- in New South Wales (which presently reflects the national trend), the number of cases requiring hospitalisation since the beginning of August has increased, as shown in **Figure 2**:

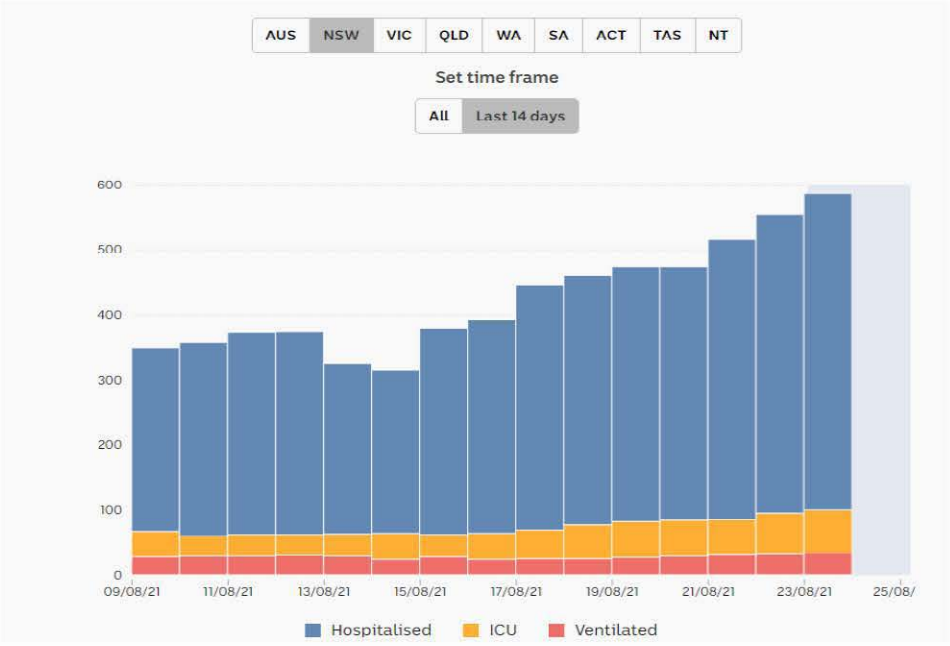

Figure 2: Number of COVID-19 cases requiring hospitalisation in NSW[3]

[2] Source: JHU CSSE COVID-19 Data

[3] https://www.abc.net.au/news/2020-03-17/coronavirus-cases-data-reveals-how-covid-19-spreads-in-australia/12060704#hospitalisation

- since the increase in the number of infections caused by the Delta variant, the number of deaths has increased, as shown in **Figure 3**, which presents national data over the period between 1 April 2020 and early August 2021:

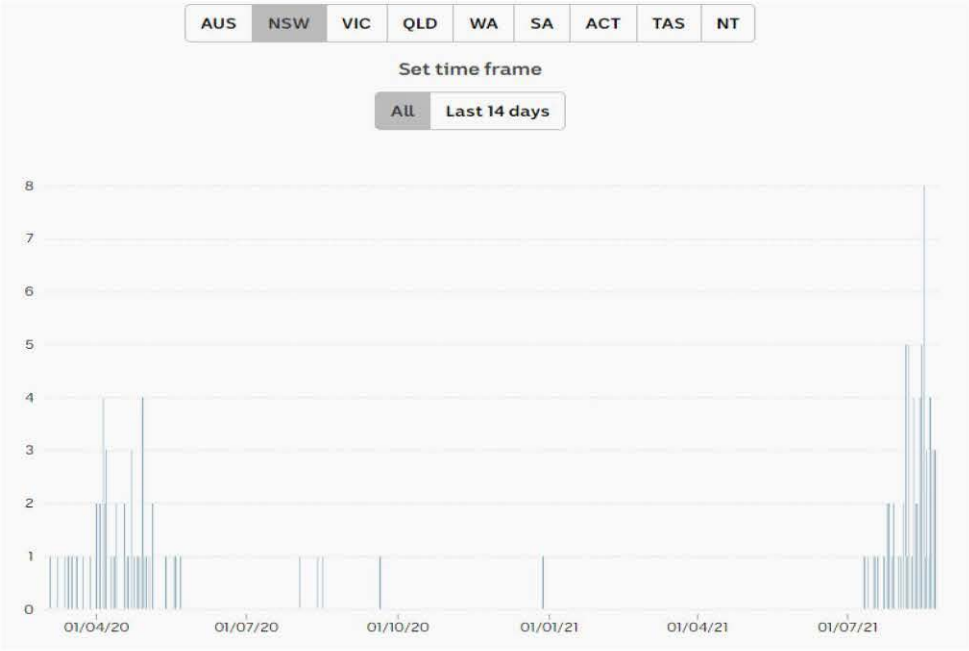

Figure 3: Number of deaths caused by COVID-19 in Australia

19. The data in **Figure 3** demonstrates that, because of the more highly infectious Delta variant of COVID-19, there is an increase in the number of overall infections, cases requiring hospitalisation and, unfortunately, deaths arising from COVID-19. **Figure 3** also illustrates that Australia is currently facing more acute levels of COVID-19 infections to that seen at the beginning of the pandemic, which placed pressure of Australia's supply of Critical Medicines and Critical Devices and resulted in the Current Authorisation. The situation is also escalating in Victoria with 423 new daily cases as at 14 September 2021.[4] MA submits that very similar or more unpredictable conditions exist now compared to when the Current Authorisation was applied for and granted, and this provides a strong public interest basis for the ACCC the grant the Substitute Authorisation.

20. As the number of infections increases, so too does the pressure on Australia's hospital system. One way in which the pressure on Australia's hospital system manifests is the difficulty obtaining Critical Medicines and Critical Devices to treat patients suffering from the symptoms of COVID-19. The uncertainty of supply not only affects patients suffering from COVID-19, but also affects patients suffering from other medical conditions that require treatment (or prevention) with Critical Medicines or Critical Devices.

21. Critical Medicines and Critical Devices that are currently being used to treat COVID-19 are not necessarily the same as the treatments that were used to treat COVID-19 at the beginning of the pandemic. By way of example, [redacted] has only recently been approved by the FDA in the United States for the treatment of COVID-19. Following the FDA's approval to use [redacted] in adults and children who had been hospitalised with COVID-19 in June 2021, an increase in global demand and inequitable distribution of the drug has resulted in a supply shortage of [redacted] in Australia. It is expected that supply of [redacted] to Australia will be constrained into 2022.

22. Supply shortages of a Critical Medicine or Critical Device due to increased global demand and inequitable distribution have wider ramifications that their direct availability in treating COVID-

[4] https://www.coronavirus.vic.gov.au/victorian-coronavirus-covid-19-data

19. In the case of [redacted], Australian patients suffering from [redacted] are also affected, as they are unable to receive their usual treatment for that condition.

23. Further, because those patients cannot receive their usual treatment, there is a consequential increase in demand for alternative therapies used to treat that condition. By way of example, the sponsor in Australia for [redacted] an alternative therapy to [redacted], has reported to the TGA an increase in demand from a normal quantity of [redacted]. The sponsor is currently managing the increase in demand but has raised the possibility that it will not be able to do so, if demand continues to increase. The increase in demand of alternative therapies may also result in supply shortages. This is particularly so where the alternative therapy is used "off label" (that is, other than for the PBS approved indication). Suppliers of Critical Medicines and Critical Devices do not have the same visibility of use or anticipated demand where the medicine is used off label, which may result in an urgent and unexpected supply shortage.

24. The increase in repurposing existing therapies to treat COVID-19 may require coordination of supply to avoid shortages in Critical Medicines and Critical Devices in Australia. It is for this primary reason that MA reported to the ACCC potential activity within the Current Authorisation in relation to [redacted], on 3 September 2021.

25. 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.

26. Even if Australia's vaccination rates reach projected levels within the current contemplated timeframe (in NSW, mid-October) leading to a gradual 're-opening' of Australia's state and international borders, a significant proportion of the country will remain unvaccinated and there is a risk that this may result in continued increased pressure on the health care system as infections increase.

27. The 're-opening' that has been seen in other countries and the resulting increase in COVID-19 cases also places pressure on the supply of Critical Medicines and Critical Devices, where up to 90% of supplies are imported into Australia.

28. Similar challenges arose in the context of the original authorisation sought by MA, where the Current Authorisation has enabled MA/GBMA Working Group members in consultation with the TGA[5] to:

    (a) ensure adequate supplies of Critical Medicines and Critical Devices were able to meet increasing demand from infections across multiple State and Territories in Australia;

    (b) develop a modelling tool to successfully identify demand and project supply requirements;

    (c) ensure communication was made with related entities overseas to access supply for Australia; and

    (d) allocate supply priorities to ensure continued supply of Critical Medicines and Critical Devices.

29. MA acknowledges that following an initial period of interim authorisation it has largely avoided the need to engage in conduct authorised under the Current Authorisation (see paragraphs 38 to 43 below). This, of course, should be seen as a positive, as the public health issues that the

[5] In practice, the "in consultation with the TGA" requirement has been interpreted and applied by MA/GBMA and the TGA to mean "at the request of the TGA". MA considers that this is appropriate in circumstances where it will only engage in the authorised conduct on an "as necessary" basis.

proposed conduct sought to address arose early in the response to COVID-19. Yet, the limited recourse to, or reliance on, the Current Authorisation should not provide the ACCC a reason to refuse a further narrower authorisation for a limited period, in the form of the Substitute Authorisation. Granting the Substitute 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 TGA.

30. Until recently, Australia has successfully avoided many of the health and societal effects of the pandemic. The reality that Australia is now facing is the prospect of rapidly increasing infections across a number of jurisdictions caused by the Delta variant. Even with a robust uptake in vaccinations, this risk is at least as acute as when interim authorisation was granted in March 2020 and the Current Authorisation was made in September 2020.

31. Until vaccination rates among the eligible population are above 70-80%, the Federal Government's vaccination rollout plan continues to contemplate further restrictions and lockdowns to manage the pandemic. There is also no certainty that Australia will meet these targets based on percentage vaccination rates in other countries, where reports from the UK and US indicate that vaccination rates show a trend of plateauing as those within the population wanting to be vaccinated have done so.[6] In MA's view it is possible that the current restrictions and lockdowns (or a form of them) will continue to be used to manage the risk of COVID-19 until some time in 2022. Whilst ever these restrictions are in place, the risk of supply chain pressures is more acute.

32. MA submits that the conduct set out in the Substitute Authorisation will enable suppliers of Critical Medicines and Critical Devices to have the best opportunity to avoid supply shortages and manage increasing demand of Critical Medicines and Critical Devices as well as assist Federal, State and Territory Governments in responding to the threat of the Delta variant of COVID-19.

Section 2: Current Authorisation

The authorised conduct

33. On 30 March 2020, MA applied for authorisation of certain conduct on behalf of:

(a) MA and each of its members; and

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

(**together, the MA/GBMA Working Group**) as well as potential future members of the MA/GBMA Working Group which included:

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

(d) other persons notified to the ACCC, being new MA members or other persons who perform a significant role in the continued delivery of essential medicines and related supplies to the Australian community.

34. On 24 September 2020, MA obtained authorisation (AA1000486) on behalf of MA/GBMA Working Group members to implement a coordinated strategy in relation to the supply of:

[6] https://www.cnbc.com/2021/04/30/covid-vaccinations-in-us-are-slowing-as-supply-outstrips-demand.html; see also: https://www.bbc.com/news/health-55274833

(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 service 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 Devices that arise as a result of COVID-19.

35. The Current Authorisation permits MA/GBMA Working Group members, in consultation with the Federal Government and / or Federal Government Agencies, such as the Therapeutic Goods Administration (**TGA**), to:

(a) share 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) coordinate and allocate the fulfilment of orders and supply requests for Critical Medicines and Critical Devices between MA/GBMA Working Group members as suppliers;

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

(d) work together to respond to current or future tenders or requests for supply of Critical Medicines or Critical Devices:

(i) by Federal or State Governments;

(ii) including sharing information or joint tenders; but

(iii) excluding making or giving effect to agreements and arrangements or exchanging information between MA/GBMA Working Group members, on the pricing aspects of such tenders or requests for supply.[7]

36. Significantly, none of the conduct authorised by the Current Authorisation concerns price.

37. MA is subject to two conditions under the Current Authorisation:

Condition 1: Providing the ACCC with fortnightly reports

Summary: MA is required to report to the ACCC, on a fortnightly basis, any material recommendations made to the Federal Government or its agencies following a meeting or discussion between MA/GBMA Working Group members under the Current Authorisation as

[7] see paragraph 1.8, 1.9 and paragraph 5.6 of the Final Determination.

well as the details of those meetings, including any material decision between MA/GBMA Working Group members.

The Final Determination provides that MA must:

(a) *provide fortnightly reports to the ACCC 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 **Fortnightly Report**). The Fortnightly Report must report on any meetings, discussions, developments and decisions in relation to the Proposed Conduct. The Fortnightly Report must include, insofar as the following information has not already been provided in a previous Fortnightly Report:*

  (i) *material recommendations, if any, made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct;*

  (ii) *information regarding any meeting or discussion between two or more of the MA/GBMA Working Group members relating to the Proposed Conduct, including:*

    A. *the attendees at the meeting or discussion;*

    B. *the agenda items of the meeting or discussion that are related to the Proposed Conduct;*

    C. *any minutes of the meeting or discussion relating to the Proposed Conduct; and*

    D. *an overview of topics discussed and any material decisions made that related to the Proposed Conduct;*

  (iii) *any changes to the MA/GBMA Working Group;*

(b) *provide the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct; and*

(c) *meet with the ACCC to provide regular updates in relation to the Proposed Conduct, requested by the ACCC.*[8]

Condition 2: Engaging in the Proposed Conduct in relation to government health agency tendering

Summary: MA is also required to report to the ACCC the details of any proposal by MA/GBMA Working Group members to engage in the coordinated conduct in response to a State or Government tender, including the relevant participants and the Critical Medicines or Devices the subject of the tender.

The Final Determination provides:

*Where a state or territory government health agency commences any tender process during the period of authorisation, and any MA/GBMA Working Group Members intend to engage in the Proposed Conduct in relation to such a tender (**Intended Conduct**), MA must provide*

[8] See paragraph 5.12 of the Final Determination.

notice to the relevant state or territory government health agency and the ACCC of the Intended Conduct. In particular, MA must:

(a) *provide written notice no less than 5 business days prior to engaging in any Intended Conduct to:*

(i) *the relevant state or territory government health agency and*

(ii) *the ACCC*

such notice to identify:

(iii) *the Critical Medicines and Critical Devices that will be the subject of the Intended Conduct and*

(iv) *MA/GBMA Working Group members who intend to engage in the Intended Conduct.*

(b) *invite an external observer from each of the TGA and the ACCC to attend all discussions by MA/GBMA Working Group members in relation to the Intended Conduct (such meeting not to occur before the expiry of notice given under clause (a) above[9])*

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 authorisation on its behalf.[10]

Conduct that has taken place under the interim authorisation or Current Authorisation

38. Following the lodgement of its application on 30 March 2020, MA was granted interim authorisation by the ACCC on 3 April 2020. Interim authorisation was granted to MA in recognition of the unpredictable and urgent circumstances arising from COVID-19 infections.

39. During the period of the interim authorisation, the MA/GBMA Working Group engaged in the following conduct reported under the interim authorisation:

(a) 23 April 2020 - discussion between TGA and suppliers of [redacted] and [redacted];

(b) 28 April 2020 - discussion between TGA and suppliers of [redacted];

(c) 8 May 2020 - second discussion between TGA and suppliers of [redacted];

(d) 14 May 2020 - discussion between TGA and suppliers of [redacted] and

(e) 8 July 2020 - discussion between TGA and suppliers of [redacted].

40. Discussions under the interim authorisation concerned the supply of those medicines following identification of potential interruptions to the supply chain and /or shortages by the TGA. Issues that were raised during these discussions included:

(a) identification of supply issues concerning the Critical Medicines;

[9] Reference to clause 5.14.1 in the Final Determination.

[10] See paragraphs 5.13 and 5.14 of the Final Determination.

(b) current stock supply of the Critical Medicines and the ability to meet current demands to supply by sponsors;

(c) gaps or areas of potential permitted coordination to resolve supply shortages of Critical Medicines; and

(d) next steps to resolving any identified issues concerning the supply of Critical Medicines.

41. MA was granted conditional authorisation on 24 September 2020. As is shown in **Figure 4**, the number of COVID-19 infections in Australia declined significantly by the end of August 2020, following restrictions being put in place by the various state and territory governments, which successfully mitigated the effect of COVID variants that were not the Delta variant. At the date of the Final Determination, Australia recorded 10 new cases of COVID-19 infections with a 7 day average of 24 cases.

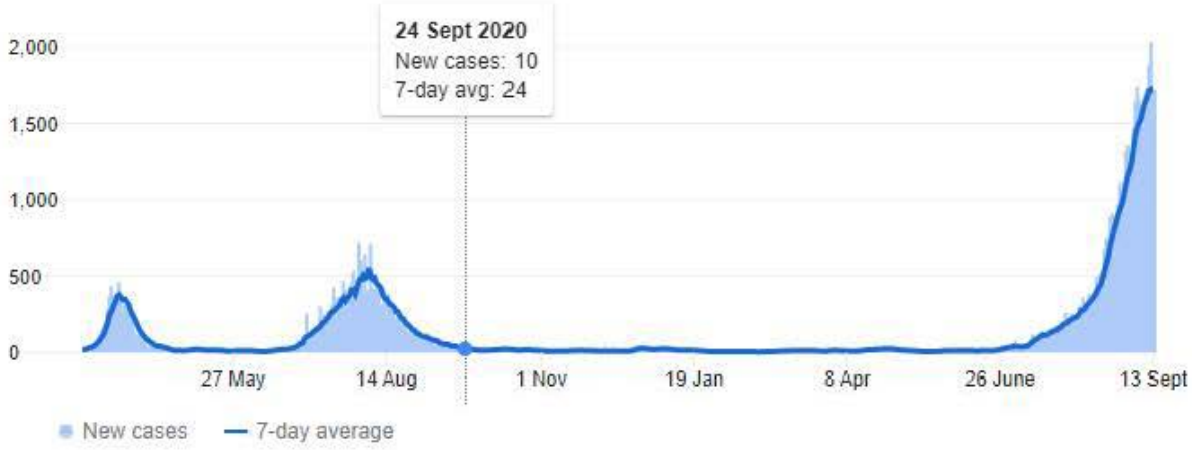

Figure 4: COVID-19 infections across Australia between 10 March 2020 and 13 September 2021

42. As a result of the low and stabilised rates of COVID-19 infections, the requirement to engage in conduct that was the subject of the Current Authorisation did not arise, which was intended to be engaged in only on an 'as needed' basis. MA has continued to report to the ACCC even though those reports did not record any instances of conduct arising under the Current Authorisation.

43. However, MA submits that the current situation presented by the Delta variant is significantly more difficult and unpredictable than the circumstances that existed when the ACCC granted the first interim authorisation. Compared to the last 12 months, the number and rate of COVID-19 infections gives rise to a material change which increases the likelihood that MA/GBMA Working Group members will need to engage in coordinated conduct to ensure continuity of supply of Critical Medicines and Critical Devices. As **Figure 4** shows, the number of infections as at September 2021 far exceeds the number of infections during the period at which the ACCC granted the interim authorisation in March 2020 and issued its Final Determination in September 2020.

Section 3: Application for interim authorisation and Substitute Authorisation

MA application for interim Authorisation

44. MA seeks interim authorisation to ensure the protection afforded to the MA/GBMA Working Group under the Current Authorisation is not interrupted and that the supply of Critical Medicines and Critical Devices can continue in response to the Delta variant of COVID-19.

45. MA seeks interim authorisation to enable MA/GBMA Working Group members, at the request of the Federal Government and / or a Federal Government Agency, 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.

46. The specific conduct includes:

(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; and

(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.

(together paragraphs 45 and 46 form the **Proposed Conduct**).

47. MA submits that the Interim Authorisation (and any subsequent Substitute Authorisation) be subject to the following condition:

(a) 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 under the Substitute Authorisation 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 Proposed Conduct. The Monthly Report must include, insofar as the following information has not already been provided in a previous Monthly Report:

(i) material recommendations, if any, made to the Federal Government or a Federal Government Agency by the MA/GBMA Working Group in relation to the Proposed Conduct;

(ii) information regarding any meeting or discussion between two or more of the MA/GBMA Working Group members relating to the Proposed Conduct, including:

A. the attendees at the meeting or discussion;

B. the agenda items of the meeting or discussion that are related to the Proposed Conduct;

C. any minutes of the meeting or discussion relating to the Proposed Conduct; and

D. an overview of topics discussed and any material decisions made that related to the Proposed Conduct;

(iii) any changes to the MA/GBMA Working Group,

(b) provide the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct; and

(c) meet with the ACCC to provide regular updates in relation to the Proposed Conduct, requested by the ACCC.

48. None of the conduct which MA proposes for interim authorisation relates to price.

49. MA requests that the interim authorisation be given on the terms set out in paragraphs 45 to 47 above. If however, the ACCC's preference is for MA to commit to the terms of the Current Authorisation, in any period during which an interim authorisation is in effect, then MA would comply with that requirement.

MA's application for Substitute Authorisation

MA's proposed changes to narrow the scope of the Current Authorisation

50. MA wishes to revoke the Current Authorisation and apply for Substitute Authorisation for conduct which is narrower in scope but otherwise on terms which are substantially identical to the terms of the Current Authorisation.

51. MA proposes two changes to narrow the scope of conduct in the Current Authorisation:

(a) any conduct will only be engaged in by MA/GBMA Working Group members at the request of, rather than in consultation with, the Federal Government and / or a Federal Government Agency;

(b) MA/GBMA Working Group members will not engage in any coordinated conduct to respond to current or future tenders or requests for supply of Critical Medicines or Critical Devices by Federal or State Governments.

52. As is the case under the Current Authorisation, none of the conduct in the Substitute Authorisation concerns price.

53. MA also proposes two refinements to the conditions of authorisation:

(a) a change to the frequency of ACCC reporting condition so that MA would report to the ACCC (on the same terms) on a monthly basis or no later than 5 business days following a meeting of MA/GBMA Working Group members under the Substitute Authorisation. This change is being proposed so that reporting remains regular on a monthly basis whilst recognising the principle that the ACCC requires timely reporting of any meeting of MA/GBMA Working Group members;

(b) a consequential change to remove the current government health agency tendering condition because no conduct would be authorised in relation to those tenders, thereby reducing any potential detriment and simplifying the authorisation materially;

Set out in Annexure C is a mark-up of these proposed changes to the Current Authorisation.

Reasons for the changes to scope of conduct proposed by MA

54. (**Substitute Authorisation only to apply to conduct at the request of the Federal Government or its agencies**) MA's experience of the Current Authorisation has demonstrated that MA/GBMA Working Group members only engaged in conduct at the request of the TGA. At all times, a competition law observer has also been present at meetings convened by the TGA under the Current Authorisation.

55. MA anticipates that the TGA or another Government health agency will continue to be the body to request MA/GBMA Working Group members to convene to engage in the relevant conduct under the Substitute Authorisation. As has occurred to date, MA anticipates that only those MA/GBMA Working Group members that are relevant to the supply of a Critical Medicine or Critical Device which a Government health agencies has raised concerns will engage in the relevant conduct.

56. (**Substitute Authorisation will not apply to any coordinated conduct related to tenders**) This application for Substitute Authorisation seeks an authorisation for a period of 12 months. During this period, MA considers that it is unlikely that MA/GBMA Working Group members will be required to respond to any Federal, State or Territory tenders or requests for supply such that MA/GBMA Working Group members will not be required to make or give effect to any agreements or arrangements including the sharing of information in response to tenders. As a result, MA considers that it is appropriate that the Substitute Authorisation removes any conduct related to tendering. The tendering condition should also be removed because it is not necessary.

57. (**Period of Authorisation**) As stated above, MA seeks Substitute Authorisation for a limited period of 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.[11]

58. The National Plan consists of four phases:

(a) **Phase A:** being the current phase which is directed to suppressing the virus for the purpose of minimising community transmission;

(b) **Phase B:** seeks to minimise serious illness, hospitalisation and fatality results of COVID-19 with low level restrictions. The Australian Government has indicated that Phase B commences when approximately 70% of the eligible population are fully vaccinated against COVID-19. The Prime Minister has publicly stated that the target of 70% of the population being fully vaccinated in Australia could be reached before the end of the year;[12]

(c) **Phase C:** seeks to minimise serious illness, hospitalisations and fatalities as a result of COVID-19 with baseline restrictions. The Australian Government has indicated that Phase C commences when 80% or more of the eligible population are fully vaccinated against COVID-19. It is inferred that this Phase is unlikely to commence before the end of the year and most likely to commence in early 2022; and

(d) **Phase D:** manages COVID-19 consistent with public health management of other infectious diseases. The Australian Government has not indicated what level of the population above 80% is required to be fully vaccinated for Phase D to commence.

[11] https://www.pm.gov.au/media/national-cabinet-statement-10

[12] https://www.abc.net.au/news/2021-07-30/national-cabinet-four-phase-plan-out-of-covid-pandemic/100339314

59. It is anticipated that, within the timeframes set out above, and as vaccination levels of the Australian population (and those overseas) increase, supply chains should stabilise and the likelihood for supply shortages or disruptions arising from COVID-19 should decrease or no longer occur (in the best case scenario). In these circumstances, MA's position is that Substitute Authorisation is necessary to ensure that suppliers are able to engage in conduct that mitigates or eliminates any shortages or disruptions to the supply chain of Critical Medicines or Critical Devices until that time.

60. Absent authorisation, to engage in the conduct the subject of this application may risk giving rise to potential contraventions of the following provisions of the CCA:

(a) making and or giving effect to a contract arrangement or understanding that may include a cartel provision (Division 1 of Part IV);

(b) making and or giving effect to a contract, arrangement or understanding that have a purpose or effect, or likely effect, of substantially lessening competition (section 45(1)(a) and(b)); and

(c) engaging in a concerted practice that has a purpose or effect or likely effect of substantially lessening competition (section 45(1)(c)).

Reasons for refinements to the conditions of the Substitute Authorisation

61. (**Reporting in respect of tenders not relevant**) The application for Substitute Authorisation seeks authorisation for a narrower scope of conduct which does not include engaging in conduct in response to tenders or requests for supply from Government agencies. In the absence of this conduct, the condition that requires MA to report to the ACCC in respect of engaging in conduct in relation to government health agency tendering is no longer relevant and is not necessary.

62. (**Reporting should be fit for purpose**) The experience of the Current Authorisation has demonstrated that during periods of stability in the supply of Critical Medicines and Critical Devices, as occurred in late 2020 when COVID-19 infections across Australia were low, the requirement to report fortnightly was unduly burdensome and administrative on both the ACCC and MA. In almost all cases these reports were 'nil' reports, as there was a limited number of meetings between MA/GBMA Working Group members and on each of these occasions, no material recommendations or decisions regarding any Critical Medicine or Critical Device were made.

63. However, since early 2021, the number of COVID-19 infections and cases requiring ICU treatment have greatly increased and commensurate supply chain pressures and interruptions are expected (see paragraphs 20 - 25 above). As mentioned at paragraph 21 above, the [redacted] treatment, [redacted] is currently facing shortage in Australia due to its use as a treatment of COVID-19 patients overseas. It is anticipated that this shortage will continue into 2022, affecting its availability to assist patients in Australia suffering from the symptoms of COVID-19 as well as [redacted]. MA is aware that there are other treatments that the TGA are also actively monitoring due to potential risks of shortages caused from increased demand arising from the Delta variant of COVID-19.

64. MA submits that a monthly report will provide the ACCC with appropriate and timely oversight of any conduct engaged in by MA/GBMA Working Group members under the terms of the Substitute Authorisation. By reporting on a monthly basis, or within 5 business days of any authorised conduct, the condition balances the need for regular reports to be submitted to the ACCC with the adaptability of reporting that corresponds with the frequency and need of the MA/GBMA Working Group member meetings. Should more frequent meetings be required during the period of authorisation, the ACCC will be provided with reports of each meeting during that time. However, if the circumstances concerning the supply of Critical Medicines and Critical Devices becomes or remains stable and does not require MA/GBMA Working Group members to engage in the relevant conduct, the terms of the condition reduces the administrative burden on ACCC and MA staff where 'nil' reports would be lodged.

Public Benefits

65. There continues to be significant public benefits in authorising the conduct proposed under the Substitute Authorisation. As set out in the ACCC's Final Determination in respect of the Current Authorisation, enabling MA/GBMA Working Group members to engage in the narrowed conduct proposed under the Substitute Authorisation will allow suppliers of Critical Medicines and Critical Devices to:

(a) rapidly respond to increasing demands of Critical Medicines or Critical Devices;[13]

(b) develop and implement strategies with government health agencies to ensure the continued supply of Critical Medicines and Critical Devices including by identifying and addressing supply shortages and constraints;[14]

(c) mitigate or avoid an increase in demand of Critical Medicines or Critical Devices impacting the supply of medicines that are used to treat other (non-COVID-19 related) medical conditions;[15]

(d) coordinate and allocate the fulfilment of orders and supply requests quickly and effectively;[16]

(e) maximise the efficient use of supply channels for Critical Medicines and Critical Devices;[17] and

(f) provide more effective advice to Federal, State and Territory Governments and their health agencies to manage the equitable supply of Critical Medicines and Critical Devices appropriately and to mitigate stockpiling.[18]

66. MA submits that the above public benefits are equally relevant to the Substitute Authorisation as they were in respect of the Current Authorisation and that the ACCC should reauthorise the (narrower) range of conduct proposed, even if the need to engage in the propose conduct may be limited. As it did in respect of the Current Authorisation, the ACCC similarly concluded that, given the uncertain environment in which delays and inefficiencies may have significant public health consequences, permitting MA to engage in the narrower range of conduct proposed is of material public benefit because "it is likely to mitigate health risks to a significant extent by enabling urgent action if the need arises"[19].

Public detriments

67. MA considers that the Current Authorisation did not give rise to any material public detriments because the scope of the coordinated conduct was limited and temporary in response to a national crisis, and did not materially alter the competitive dynamics of any market.[20] MA maintains this submission in this application for Substitute Authorisation, and submits that in

[13] Determination, paragraphs 4.19.

[14] Determination, paragraph 4.17.

[15] Determination, paragraph 4.20.

[16] Determination, paragraph 4.10.

[17] Determination, paragraph 4.17.

[18] ibid.

[19] Determination, paragraph 4.20.

[20] Determination, paragraph 4.23.

the remote chance that any public detriments were to arise under the Substitute Authorisation, these would be temporary, limited in scope and far outweighed by the public benefits of the conduct proposed.

68. MA also submits that any potential detriment which arose from including tenders in the scope of the proposed conduct under the Current Authorisation, will not arise under any Substitute Authorisation as this conduct has been excluded from the scope of the conduct for which MA seeks reauthorisation. This specific exclusion of tenders weighs further in favour of greater net public benefits arising from the Substitute Authorisation, by further limiting any potential for public detriment to arise.

Safeguards

69. MA's proposed terms for the Substitute Authorisation maintain appropriate safeguards to mitigate the risk of any public detriment.

70. These include:

(a) the proposed conduct under the Substitute Authorisation 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;

(b) MA would continue to report to the ACCC following any meetings under the terms of the Substitute Authorisation (and by no later than 5 days after the end of each month, if no meetings occur) of any material decisions or recommendations. The reporting obligation on MA provides appropriate transparency and oversight to the ACCC;

(c) the proposed conduct under the Substitute Authorisation does not involve any coordinated conduct between MA/GBMA Working Group members in relation to pricing;

(d) the proposed conduct under the Substitute Authorisation removes the potential for any coordinated conduct in responding to current or future tenders or requests for supply of Critical Medicines or Critical Devices by Federal or State Governments; and

(e) the proposed term of the Substitute Authorisation is 12 months, and this term corresponds to the period within which State and Federal Governments intend to have vaccinated the Australian population and mitigated the potential for supply disruptions arising from COVID-19.

Annexure A - List of Working Group members

MA Members

- A. Menarini Australia Pty Ltd
- AbbVie Pty Ltd
- Amgen Australia Pty Ltd
- Astellas Pharma Australia Pty Ltd
- AstraZeneca Pty Ltd
- Bayer Australia Limited
- Biogen Australia Pty Ltd
- Boehringer Ingelheim Pty Ltd
- Bristol-Myers Squibb Australia Pty Ltd
- Celgene Pty Limited
- Eisai Australia
- Eli Lilly Australia Pty Ltd
- Gilead Sciences Pty Ltd
- GlaxoSmithKline Australia Pty Ltd
- Ipsen Pty Ltd
- Janssen Pty Ltd
- Merck Healthcare Pty Ltd
- Merck Sharp & Dohme (Australia) Pty Ltd
- Novartis Pharmaceuticals
- Novo Nordisk Pharmaceuticals Pty Ltd-Australia
- Pfizer Australia Pty Ltd
- Roche Products Pty Limited
- Sanofi
- Shire Australia Pty Ltd
- Takeda Pharmaceuticals Australia Pty Ltd
- UCB Australia Pty Ltd
- Vifor Pharma
- Besins Healthcare Australia Pty Ltd
- Norgine Pty Ltd
- FIT-BioCeuticals Ltd
- Medlab Clinical Limited
- Direct Cold (A Direct Couriers Company)
- Commercial Eyes Pty Ltd
- Covance Pty Ltd
- Biointelect
- Hahn Healthcare Pty Ltd
- IQnovate (Farmaforce, Clinical Rsearch Corporation)
- Princeton Health
- Prospection Pty Ltd
- IQVIA
- Smartways
- Health Technology Analysts
- BeiGene

GBMA Members

- Arrotex Pharmaceuticals Pty Ltd
- Celltrion Healthcare Australia Pty Ltd
- Fresenius Kabi Australia Pty Limited
- Juno Pharmaceuticals Pty Ltd
- Viatris (Mylan) Australia
- Sandoz Pty Ltd

- Southern Cross Pharma Pty Ltd

GBMA Associate Members

- Commercial Eyes Pty Ltd
- Sinapse Pty Ltd

NPSA Members

- SigmaHealthcare
- Symbion
- NPD (National Pharmacies)
- Australian Pharmaceutical Industries

Other members previously notified to the ACCC

- Mundipharma Pty Limited
- STADA Australia
- B. Braun Australia Pty Ltd
- Pharamco (N.Z.) Ltd & Pharmaco (Australia) Ltd
- Baxter Healthcare
- Accord Healthcare
- Lundbeck Australia Pty Ltd
- Aspen Australia
- iNova Pharmaceuticals
- Sun Pharma ANZ
- Generic Health Australia
- Mayne Pharma

New Working Group members

MA anticipates that the list of Working Group members may be expanded to add non-members and new MA Members, GBMA Members or, potentially, NPSA Members (as listed above) in response to the crisis as it evolves and information relating to new medicines and suppliers are required. MA will notify the ACCC of any new Working Group member to be covered by the terms of the authorisation.

Annexure B - Further details of applicants

Name	Medicines Australia
ACN	126 990 001
Registered Office	17 Denison Street Deakin ACT 2600
Telephone	[redacted]
Contact person(s)	Elizabeth de Somer, Chief Executive Officer [redacted] Anne-Maree Englund, Head of Strategic Policy Implementation, Medicines Australia [redacted] with a copy to: Mihkel Wilding, Partner Clayton Utz [redacted]
Email address for service	[redacted]

Name	Generic and Biosimilar Medicines Association
ABN	19 096 009 540
Registered Office	PO Box 87 Deakin West ACT 2600
Telephone	[redacted]
Contact person(s)	Marnie Peterson, Chief Executive Officer [redacted] Jane Halton AO PSM, GBMA Independent Chair [redacted]

	[redacted]
Email address for service	[redacted]

Annexure C - Comparison of the proposed terms of the Interim and Substitute Authorisation

The Proposed Conduct

1.8. MA sought authorisation for the MA/GBMA Working Group, at the request of the Federal Government and/or a Federal Government Agency, 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:~~ The specific conduct includes:

(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**).

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

~~i. concerning tenders let, or to be let, by Federal or State Governments; and~~

~~ii. 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.~~

Conditions of authorisation

Condition 1: Providing the ACCC with fortnightly reports

5.12. MA must:

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 under the Substitute Authorisation ~~fortnightly reports to the ACCC~~ 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 **Fortnightly Report**)~~ (the **Monthly Report**). The ~~Fortnightly~~ Monthly Report must report on any meetings, discussions, developments and decisions in relation to the Proposed Conduct. The ~~Fortnightly~~ Monthly Report must include, insofar as the following information has not already been provided in a previous ~~Fortnightly~~ 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 Proposed Conduct;

    b. information regarding any meeting or discussion between two or more of the MA/GBMA Working Group members relating to the Proposed Conduct, including:

        i. the attendees at the meeting or discussion;

        ii. the agenda items of the meeting or discussion that are related to the Proposed Conduct;

        iii. any minutes of the meeting or discussion relating to the Proposed Conduct; and

        iv. an overview of topics discussed and any material decisions made that related to the Proposed 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 Proposed Conduct; and

3. meet with the ACCC to provide regular updates in relation to the Proposed Conduct, requested by the ACCC.

~~**Condition 2: Engaging in the Proposed Conduct in relation to government health agency tendering**~~

~~5.13. Where a state or territory government health agency commences any tender process during the period of authorisation, and any MA/GBMA Working Group Members intend to engage in the Proposed Conduct in relation to such a tender (**Intended Conduct**), MA must provide notice to the relevant state or territory government health agency and the ACCC of the Intended Conduct. In particular, MA must:~~

~~1. provide written notice no less than 5 business days prior to engaging in any Intended Conduct to:~~

a) the relevant state or territory government health agency and

b) the ACCC,

such notice to identify:

c) the Critical Medicines and Critical Devices that will be the subject of the Intended Conduct and

d) MA/GBMA Working Group members who intend to engage in the Intended Conduct.

2. invite an external observer from each of the TGA and the ACCC to attend all discussions by MA/GBMA Working Group members in relation to the Intended Conduct (such meeting not to occur before the expiry of notice given under clause 5.14.1).5.14. 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 authorisation on its behalf.

Declaration by Applicant(s)

Authorised persons of the applicant(s) must complete the following declaration. Where there are multiple applicants, a separate declaration should be completed by each applicant.

The undersigned declare that, to the best of their knowledge and belief, the information given in response to questions in this form is true, correct and complete, that complete copies of documents required by this form have been supplied, that all estimates are identified as such and are their best estimates of the underlying facts, and that all the opinions expressed are sincere.

The undersigned undertake(s) to advise the ACCC immediately of any material change in circumstances relating to the application.

The undersigned are aware that giving false or misleading information is a serious offence and are aware of the provisions of sections 137.1 and 149.1 of the *Criminal Code* (Cth).

Signature of authorised person

Chief Executive Officer, Medicines Australia

Office held

Elizabeth de Somer

(Print) Name of authorised person

This 16th day of September 2021

Note: If the Applicant is a corporation, state the position occupied in the corporation by the person signing. If signed by a solicitor on behalf of the Applicant, this fact must be stated.