

Email

27 March 2020

Mr Daniel McCracken-Hewson
General Manager, Adjudication
Australian Competition and Consumer Commission
23 Marcus Clarke Street
Canberra ACT 2601
adjudication@acc.gov.au

Dear Mr McCracken-Hewson

Medicines Australia: urgent application for interim authorisation

We act for Medicines Australia (**MA**).

This application is made on behalf of:

- MA and each of its members; and
- the Generic and Biosimilar Medicines Association (**GBMA**) and each of its members.

MA represents the discovery-driven pharmaceutical industry in Australia. Its members include companies that invent, manufacture and supply innovative medicines and vaccines to the Australian community. On behalf of its members, MA engages with government, the industry, consumer groups and health professionals, including for the purpose of ensuring the continuation of a viable medicines industry and supply to consumers in Australia. The MA secretariat and its member companies contribute experience and expertise through participation in a wide range of activities, including membership of advisory committees and participation in health and industry policy development.

MA members are differentiated into four classes:

- Research based Prescription Pharmaceutical Companies (Class 1);
- Non-research based Prescription Pharmaceutical Companies or being a related body corporate of Class 1 members (Class 2);
- Companies significantly engaged in research into potential pharmaceutical products but which have not yet commenced commercial production (Class 3); and
- Companies ineligible for other classes of membership, which are significantly engaged in the development, testing or registration of prescription pharmaceutical products or which are in the opinion of the MA Board, engaged with the research-based pharmaceutical industry for a significant part of their business (Class 4).

The GBMA is the national association representing generic and biosimilar medicine suppliers in Australia. Its members ensure that all Australians are offered high-quality generic and biosimilar medicines, whilst providing affordable community health outcomes that benefit all Australians.

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.

The GBMA membership consists of two groups:

1. Manufacturers of generic and biosimilar medicines, including research-based prescription companies with a biosimilar portfolio
2. Companies that provide consultation services to the pharmaceutical industry, or who are significantly engaged in the development, testing or registration of pharmaceutical products.

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. We are instructed that, due to the impact of COVID-19, MA is assisting the Department of Health (**DOH**) to identify any potential issues relating to the supply of essential medicines and associated supplies 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.

A confidential letter from the DOH requesting MA's assistance to address the impact of COVID-19 is enclosed.

MA seeks by this application to have the ability, in the national interest, to coordinate discussions between:

- its members (**MA Members**); and
- the GBMA and its members (**GBMA Members**),

(together, the **Working Group**),

to develop and implement strategies to ensure the continued supply of essential medicines and associated supplies to Australians, including those needed in the treatment of COVID-19. In order to respond to the Federal Government's requests, coordination among the 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 Working Group.

MA seeks an urgent authorisation on behalf of the Working Group to make and effect the arrangements described below in **Schedule 1** to implement a coordinated strategy in relation to the supply of essential medicines and related supplies in response to the current COVID-19 crisis (**Proposed Conduct**). In light of the current demands on the health system, and in order to provide timely responses and assistance to relevant government bodies, MA seeks urgent interim authorisation for the Proposed Conduct in the period before the ACCC delivers its decision on MA's authorisation application.

Further details in relation to the Proposed Conduct to assist the ACCC's review of this application are set out in Schedule 1.

We will arrange the payment of the prescribed filing fees as soon as practicable.

Please let us know if you have any questions.

Daniel McCracken-Hewson, Australian Competition and Consumer Commission

27 March 2020

Yours sincerely



Bruce Lloyd, Partner



Mihkel Wilding, Special Counsel



Our ref 219/14594

Schedule 1 - Further information regarding authorisation application

The Applicants

1. 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.
2. 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.
3. Further details about the Applicant is set out below:

Name	Medicines Australia
ACN	126 990 001
Registered Office	17 Denison Street Deakin ACT 2600
Telephone	+612 6147 6500
Contact person(s)	Elizabeth de Somer, Chief Executive Officer Phone: [REDACTED] Email address: [REDACTED] Dr Anna Lavelle, Independent Chair, Medicines Australia Phone: [REDACTED] Email address: [REDACTED] with a copy to: Bruce Lloyd, Partner Clayton Utz Phone: [REDACTED] Email address: [REDACTED]
Email address for service	Bruce Lloyd, [REDACTED]

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

5. The application 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 ensure that all Australians are offered 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. Further details about GBMA are set out below:

Name	Generic and Biosimilar Medicines Association
ABN	19 096 009 540
Registered Office	PO Box 87 Deakin West ACT 2600
Telephone	+61 2 5104 0196
Contact person(s)	Marnie Peterson, Chief Executive Officer Phone: [REDACTED] Email address: [REDACTED] Sylvain Vigneault, Country Manager - Australia and Head of ANZ Commercial, Chair GBMA Phone: [REDACTED] Email address: [REDACTED]
Email address for service	[REDACTED]

8. Further details of the GBMA can be found on its website: <https://www.gbma.com.au/> .
9. The list of the members of the Working Group who are currently expected to be party to the Proposed Conduct is set out in **Schedule 2**.
10. Authorisation is requested on behalf of MA and all named persons and entities in Schedule 2 together with all other persons and entities concerned in the supply of medical supplies who agree to participate in the conduct described below for which authorisation is sought and whose identity will be provided to the ACCC.
11. MA anticipates that new Working Group members may be added to the list in Schedule 2 by notice to the ACCC, as the response to the crisis evolves and the supply of essential

medicines and supplies become prioritised. MA notes that potential future members of the Working Group may include parties that are neither members of MA nor members of GBMA but perform a significant role in the continued delivery of essential medicines and related supplies to the Australian community.

12. MA also understands that the National Pharmaceutical Services Association (**NPSA**) has lodged an application seeking authorisation with the ACCC to collectively engage with industry peak bodies. To the extent that the NPSA application, if granted, does not authorise the conduct sought to be authorised under this application, MA anticipates that there is a potential for NPSA and its members to become members of the Working Group in the future. MA has therefore listed the NPSA members in Schedule 2 on a contingent basis. MA will promptly notify the ACCC of any new Working Group members that are, or are expected to become, involved in the Proposed Conduct, including the NPSA and its members.

Proposed conduct to be authorised

13. The Proposed Conduct includes making and giving effect to agreements and arrangements, and exchanging information between Working Group members for the purposes of:
- (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 a range of essential medicines and supplies.
 - (b) coordinating and allocating the fulfilment of orders and supply requests between Working Group members as suppliers;
 - (c) prioritising certain requests for supply as nominated by the Federal Government, State and Territory Governments and relevant health authorities;
 - (d) working together to respond to tenders or requests for supply (including sharing information or joint tenders) for the purchase of products to treat COVID-19 and other patients.
14. MA anticipates that State and Federal health authorities will determine the manner in which they require supplies of necessary medical equipment to be made by Working Group members rather than those matters being determined or agreed among those members. However given the fluidity and uncertainty of the current situation and the need to implement any further measures quickly, MA is also seeking authorisation for the conduct set out above, to allow for arrangements to be made between Working Group members to the extent they become necessary in order to respond to the demands of the Australian health system.
15. MA seeks authorisation for the Proposed Conduct for an initial period of 6 months. At this stage 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.
16. The relevant provisions of the CCA which may apply to the Proposed Conduct include:
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- (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)).

Interim authorisation

- 17. The COVID-19 crisis has been declared a pandemic by the World Health Organisation and the Australian health system is already suffering from a shortage of essential medicines and supplies which may hamper Australia's response to this unprecedented public health crisis.
- 18. In light of the current crisis and projected increase in the spread of COVID-19, the Applicants request the ACCC grant interim authorisation for the Proposed Conduct on an urgent basis so that Working Group members can start working together as necessary to address supply shortages for critical medicines and associated supplies, and where necessary, provide information and advice to the Federal, State and Territory Governments and relevant health agencies in relation to supply of medicines and associated supplies, including areas of current or anticipated shortage and supply constraints.

Public benefits significant outweigh any competitive detriments

- 19. As noted in paragraphs 18 and 19 above, the Australian health system is currently under significant pressure to ensure that the supply of essential medicines and related supplies continue to meet the increased demand, particularly with respect to those medicines needed in the treatment of COVID-19. An insufficient supply essential medicines and supplies would result in increased and accelerated COVID-19 infection rates and higher death rates in the Australian community.
- 20. The Proposed Conduct will allow 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 the COVID-19 crisis.
- 21. The Proposed Conduct will also allow 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.
- 22. MA submits that the public benefits of the Proposed Conduct will significantly outweigh any competitive detriments. While the Proposed Conduct would include the exchanging of information around pricing and quantities, and the coordination of supply, it does not extend to setting or agreeing prices (which will remain at the discretion of each supplier in accordance with relevant legislation). Accordingly it is submitted that there are not any significant public detriments associated with the Proposed Conduct.
- 23. The Proposed Conduct 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.

24. If the ACCC were to form the view that the Proposed Conduct gave rise to any public detriments, MA submit that those public detriments will only arise temporarily and, in any event, are significantly outweighed by the public benefits arising from the Proposed Conduct.
25. The interim and final authorisation 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. In particular it is not clear at the time of submission that the Proposed Conduct will impact market share or profitability of market participants.
26. Importantly, the Proposed Conduct is not compulsory and any participant can opt out of any information sharing arrangements or other conduct that is the subject of this application.

Schedule 2 - 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
- Symbion Pty Ltd

GBMA Members

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

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- Southern Cross Pharma Pty Ltd

GBMA Associate Members

- Commercial Eyes Pty Ltd
- IQVIA
- Sinapse Pty Ltd

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 below) in response to the crisis as it evolves and information relating to new medicines and suppliers are required.

NPSA Members (included on a contingent basis)

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

MA will notify the ACCC of any new Working Group member to be covered by the terms of the authorisation.

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

Office held

Elizabeth de Somer

(Print) Name of authorised person

This ...27..... day of March 2020

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.