



# Draft Determination

Application for revocation of authorisation AA1000480 and the substitution of authorisation AA1000571

lodged by

National Pharmaceutical Services Association

in respect of

coordinating activities for the purpose of promoting continual, fair and equitable access to medicines and pharmacy products during the COVID-19 pandemic

Authorisation number: AA1000571

9 December 2021

Commissioners: Keogh  
Rickard  
Brakey  
Ridgeway

## Summary

The ACCC proposes to grant re-authorisation to the National Pharmaceutical Services Association (the NPSA), its current and future members and other Community Service Obligation Distributors (together the Participants) and certain manufacturers of Medicines and Pharmacy Products, to enable them to coordinate activities for the purpose of promoting continual, fair and equitable access to Medicines and Pharmacy Products to deal with issues arising out of the COVID-19 pandemic and to ensure the equitable and timely distribution of COVID-19 vaccines to community pharmacies.

Competitors sharing information and coordinating the supply of goods and/or services has the potential to lessen competition and result in consumer detriment by restricting supply and increasing prices, stifling innovation and preventing businesses from entering the market. However, in this case the ACCC considers that the proposed conduct is unlikely to significantly weaken competition because it does not enable the sharing of price information amongst competitors and is subject to a proposed condition that provides ACCC oversight of the conduct.

With the proposed condition, the ACCC considers that the proposed conduct is likely to result in public benefits by allowing the Participants to work together and where necessary, with relevant Government agencies, to address shortages in the supply of Medicines and Pharmacy Products that arise as a result of COVID-19 and to distribute COVID-19 vaccines to pharmacies.

The ACCC authorised substantially the same conduct on 17 September 2020. AA1000480 was due to end on 30 September 2021.

On 10 September 2021, the ACCC granted interim authorisation to enable the Participants to engage in the conduct including in relation to negotiations and coordination of the COVID-19 vaccine distribution. This interim authorisation, which includes a condition that NPSA provide fortnightly reports to the ACCC, remains in place. Granting interim authorisation suspended the operation of AA1000480.

Based on the available information, and subject to the proposed condition the ACCC considers that the likely public benefit from the proposed conduct would outweigh the likely public detriment.

The ACCC proposes to grant authorisation, with a reporting condition until 28 February 2023.

### Next steps

The ACCC invites submissions on this draft determination by 21 January 2022 before making its final determination.

NPSA and interested parties may also request the ACCC to hold a conference to allow oral submissions on the draft determination. Any party wishing to call a conference must notify the ACCC by 21 January 2022.

## 1. The application for authorisation revocation and substitution

- 1.1. On 6 September 2021, the National Pharmaceutical Services Association (**NPSA**), on behalf of itself, its current and future members and other Community Service Obligation (**CSO**) Distributors (together, the **Participants**<sup>1</sup>) lodged an application to revoke authorisation AA1000480 (the **Existing Authorisation**) and substitute authorisation AA1000571 for the one revoked (referred to as **re-authorisation**) with the Australian Competition and Consumer Commission (the **ACCC**). This application for re-authorisation was made under subsection 91C(1) of the *Competition and Consumer Act 2010* (Cth) (the **Act**).
- 1.2. The NPSA is seeking re-authorisation to enable the Participants and Other Participants (defined in paragraph 1.9) to continue to coordinate activities necessary for the purpose of providing equitable access to Medicines and Pharmacy Products for all Australians during supply shortages that may arise from the COVID-19 pandemic. The NPSA is also seeking re-authorisation to enable the NPSA, its current four members and any future members (the **Operating Participants**) and other CSO Distributors as required by the Department of Health (**DOH**) to work together to ensure the equitable and timely distribution of COVID-19 vaccines to pharmacies if directed to do so by the DOH, for a period of 12 months from the date of any final authorisation.
- 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.
- 1.4. The NPSA also requested interim authorisation given the Existing Authorisation was due to expire on 30 September 2021. On 10 September, the ACCC decided to suspend the operation of AA1000480 and grant conditional interim authorisation in substitution for the suspended authorisation. This interim authorisation was granted to enable the Participants to continue to engage in the conduct authorised in the Existing Authorisation and to work together to ensure the equitable and timely distribution of COVID-19 Vaccines if engaged by the Department of Health. The ACCC's interim authorisation decision is available on the [ACCC Public Register](#).

### The Applicants and Participants

- 1.5. The NPSA is a peak industry body representing pharmaceutical wholesalers in Australia. The NPSA's members distribute medicines and pharmacy products to pharmacies and major hospitals in Australia.
- 1.6. The NPSA's current members are:
  - **Australian Pharmaceutical Industries Limited** - the parent company of Priceline Pharmacy, Soul Pattinson Chemist and Pharmacist Advice; services include wholesale product delivery, retail services, marketing programs and business advisory services.
  - **Sigma Healthcare Limited** – owns Amcal, Guardian, Discount Drug Store, PharmaSave and Chemist King, has strategic partnerships with independent pharmacy support groups Pharmacy Alliance, Reform, and SmarterPharm and distributes products to hospitals and health facilities.

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<sup>1</sup> In its application for re-authorisation, NPSA refers to the entities seeking authorisation as the 'Applicants'. In this draft determination, these entities are called the Participants. The Applicant is NPSA.

- **Symbion Pty Ltd** - a national wholesaler of healthcare services and products with over 4000 retail pharmacy customers and 1300 hospital customers and also offers retail support to major groups, brands, and independent pharmacies.
  - **Friendly Society Medical Association Limited trading as National Pharmacies.**
- 1.7. CSO Distributors are entities that have entered into a deed with the Commonwealth in relation to the CSO Funding Pool and the National Diabetes Services Scheme (**NDSS**). The CSO Funding Pool and the NDSS were introduced by the Federal Government to assist with the additional costs faced by some pharmaceutical wholesalers in providing the full range of Pharmaceutical Benefits Scheme (**PBS**) medicines and NDSS products to pharmacies. The CSO Funding Pool financially supports pharmaceutical wholesalers to supply the full range of PBS medicines to pharmacies across Australia, regardless of pharmacy location and the relative cost of supply.
- 1.8. CSO Distributors currently eligible under the CSO Funding Pool are:
- NPSA members
  - Barrett Distributors Pty. Ltd.
  - Clifford Hallam Healthcare Pty Limited.
- 1.9. The NPSA submits that re-authorisation should also apply to the following parties (collectively, the **Other Participants**) on an 'as needed' basis:
- Medicines Australia (MA) (and its members); and/or
  - the Generic and Biosimilar Medicines Association (GBMA) (and its members); and/or
  - other manufacturers of Medicines and Pharmacy Products.

## The Proposed Conduct

- 1.10. The NPSA is seeking re-authorisation to enable the Participants to discuss, including to share information, agree, enter into, and give effect to, any contract, arrangement or understanding between them, or engage in conduct (excluding the sharing of any price information except in relation to the NPSA's negotiations with the Government in respect of the Participants' proposed distribution of the COVID-19 Vaccines (including booster shots and directly related consumables)) that has the purpose of facilitating the supply of, and access to, Medicines and Pharmacy Products, including co-operating in relation to any conduct which has been recommended by the Government and/or Working Groups.
- 1.11. In particular, in seeking to maintain the integrity of the supply chain, the Participants propose to, if necessary, engage in activities relating to:
- (a) sustainable coordinated stock acquisition and determination of appropriate supply restrictions among themselves, as well as liaising with, Other Participants and/or relevant industry peak bodies regarding purchasing arrangements, importing logistics and the imposition of appropriate supply restrictions;
  - (b) coordinating inventory management strategies, such as stock reservation, including allocation of supplies of Medicines and Pharmacy Products to Customers;

- (c) facilitating relevant coordinated logistical arrangements to assist in the equitable distribution of Medicines and Pharmacy Products, such as the Participants may need to consider coordinating stock transfers between themselves to pharmacies, using pharmacies as a central delivery point and sharing of distribution centre resources, and when appropriate, collaborating with Customers and other haulage providers; and
- (d) jointly negotiating, via the NPSA on behalf of the Operating Participants, the terms and conditions with the Government, and/or specific third parties if directed to do so by the Government, such third parties being logistics service providers or transport companies/freight forwarders that are currently distributing the Covid-19 Vaccines, to arrange for the distribution of the COVID-19 Vaccines (including, if needed, booster shots and directly related consumables) to Customers, particularly community pharmacies, including remuneration for the supply of such services.

(the **Proposed Conduct**)

- 1.12. In respect of paragraph 1.11(d), NPSA submits that this will involve only the NPSA and the Operating Participants and may be extended to other CSO Distributors as required by the Government. It does not involve any of the Other Participants as defined in paragraph 1.9.
- 1.13. The NPSA submits that to the extent that there is a need as part of the negotiations in respect of the proposed distribution of COVID-19 Vaccines to share competitively sensitive information including costs, each NPSA member will provide this information on a confidential basis directly to the NPSA. The parties will not share the competitively sensitive information with each other.
- 1.14. The following definitions apply:
  - **Medicines** includes all therapeutic goods (both prescription and non-prescription medicines, medical devices and biologicals, as well as COVID-19 Vaccines, booster shots, and other vaccination consumables (including needles, syringes, alcohol wipes, labels etc.).
  - **Pharmacy Products** includes all other goods available for sale at community pharmacies (including, but not limited to products such as personal protective equipment (**PPE**), face masks, gloves, hand sanitisers and toilet paper).
  - **Customers** means purchasers of the Participants' products, including community pharmacies and hospitals.
  - **Consumers** means end users of the Participants' products, such as patients and other individuals.

## 2. Background

- 2.1. When the ACCC granted the Existing Authorisation on 17 September 2020, it recognised that there were significant challenges arising from the COVID-19 pandemic, including a risk to the availability of sufficient supplies of certain Medicines and Pharmacy Products.
- 2.2. The NPSA submits that the impacts of the COVID-19 pandemic that led the ACCC to grant the Existing Authorisation are highly unlikely to entirely abate before the end of the period for which re-authorisation is sought. During the past year, the continued

global prevalence of COVID-19 and the emergence of new variants of the virus have exacerbated the challenges that necessitated the grant of the Existing Authorisation.

- 2.3. The NPSA submits that the Participants have collaboratively addressed significant COVID-19 related supply challenges (and will continue to need to do so), including:
  - (a) interruption of supply chains, either due to a COVID-19 outbreak overseas or domestically, and
  - (b) abnormal ordering patterns and 'panic buying' behaviour by Consumers of Medicines and Pharmacy Products, often in anticipation of lockdowns/at the start of lockdowns due to fears of potential supply chain shortages as well as a desire to 'stock up' so as to reduce the frequency of relevant shopping trips and external exposure.
- 2.4. The NPSA submits that given the urgency of encouraging as many Australians as possible to take up the COVID-19 Vaccines as well as the significant opportunity that exists for the Operating Participants to assist the Government to further increase the effectiveness and efficiency of its COVID-19 vaccination program, the ability for the NPSA (on behalf of the Operating Participants) to collectively negotiate a timely and efficient COVID-19 Vaccine distribution model through various locations, including community pharmacies, will benefit Australians.
- 2.5. The NPSA and the Operating Participants understand that there is potential to significantly improve the speed, volume and logistical effectiveness of the distribution of COVID-19 Vaccines, particularly in respect of its roll out to community pharmacies.

### 3. Consultation

- 3.1. A public consultation process informs the ACCC's assessment of the likely public benefits and detriments from the Proposed Conduct.
- 3.2. The ACCC invited submissions from a range of potentially interested parties, including state and federal government and relevant regulatory bodies, the Participants and other medical/pharmaceutical associations/businesses.
- 3.3. The ACCC received three submissions in relation to the application.
- 3.4. Public submissions are available on the [ACCC Public Register for NPSA](#).
- 3.5. The DOH supports the application for re-authorisation noting that the Proposed Conduct will support the desired outcomes of facilitating supply of and access to Medicines and Pharmacy Products. The DOH supports the reporting condition and permitting the Proposed Conduct only as necessary for the purposes of addressing supply shortages arising as a result of the COVID-19 pandemic. The DOH also submits that the definition of Pharmacy Products may be too broad, and that any re-authorisation could also apply to non-NPSA members. These final two issues are explored in the Public Detriment section below.
- 3.6. The Pharmacy Guild of Australia does not oppose re-authorisation.
- 3.7. The Therapeutic Goods Administration (**TGA**) submits that during the Existing Authorisation period, the NPSA has provided the TGA with updates on a coordinated approach to managing demand spikes. Demand fluctuates and as the States and Territories open, more frequent demand spikes may occur. The TGA considers that the Proposed Conduct is a useful tool for the TGA to work with stakeholders to respond to supply issues that arise. The TGA also submits that it is not concerned



about the broad definition of pharmacy products under the Proposed Conduct, and if the definition is too narrow this may lead to unintended shortages of clinical products like devices (such as syringes and nebulisers) or PPE.

#### *NPSA response to interested party submissions and ACCC information request*

- 3.8. The NPSA responded to the submission made by DOH (see the Public Detriments section).
- 3.9. In responding to an ACCC information request<sup>2</sup>, the NPSA submits that it has provided fortnightly reports to the ACCC, as required by the condition of authorisation for the Existing Authorisation. These reports have included information on the nature of supply chain restrictions imposed by the Participants and the sequence of events that led to such restrictions being imposed. The NPSA submits that the ACCC and key Government stakeholders such as the DOH and the TGA will continue to maintain close oversight of the Proposed Conduct if it is re-authorised.

## 4. ACCC assessment

- 4.1. The ACCC's assessment of the Proposed Conduct is carried out in accordance with the relevant authorisation test contained in the Act.
- 4.2. The NPSA is seeking authorisation for Proposed Conduct that would or might constitute a cartel provision within the meaning of Division 1 of Part IV of the Act, may substantially lessen competition within the meaning of section 45 of the Act and may contravene section 46 (1) and section 47(1) of the Act.<sup>3</sup>
- 4.3. Subsections 90(7) and 90(8) of the Act provide that the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (authorisation test).

## Relevant areas of Competition

- 4.4. To assess the likely effect of the Proposed Conduct, the ACCC identifies the relevant areas of competition likely to be impacted.
- 4.5. The NPSA submits that the Participants compete in the acquisition and wholesale and retail supply of, all Medicines and Pharmacy Products and associated logistics services.
- 4.6. The ACCC considers that the relevant areas of competition are the supply of medicines and pharmacy products to Customers and the provision of associated logistics services. The ACCC does not consider that a precise definition of the relevant areas of competition is necessary for assessment of the Proposed Conduct.

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<sup>2</sup> See response to ACCC information request [ACCC Public Register - NPSA](#)

<sup>3</sup> NPSA 6 September 2021, *Application for revocation and Substitution of Authorisation AA1000480-1*, section 5.4, available: [ACCC Public Register - NPSA](#)

## Future with and without the Proposed Conduct

- 4.7. In applying the authorisation test, the ACCC compares the likely future with the Proposed Conduct that is the subject of the authorisation to the likely future in which the Proposed Conduct does not occur.<sup>4</sup>
- 4.8. The ACCC considers that in the future with the Proposed Conduct, the participants will coordinate activities for the purpose of providing continued, equitable access to Medicines and Pharmacy Products in response to issues arising from COVID-19, including negotiating the distribution of the COVID-19 Vaccines to Customers, particularly to community pharmacies as is currently occurring under the interim authorisation.
- 4.9. The NPSA submits that without the Proposed Conduct, the Participants may act to address shortages individually and this will be less effective, timely and efficient compared to taking a coordinated approach. Further, without the Proposed Conduct, concerns remain regarding the supply chain issues including logistics, distribution and importation of Medicines and Pharmacy Products in Australia.
- 4.10. The ACCC considers that in the future without the Proposed Conduct, the Participants may be less able to quickly and effectively cooperate to respond to Federal Government and/or Federal Government agencies to address any shortages in the supply of Medicines and Pharmacy Products as a consequence of the COVID-19 pandemic, or to contribute to an effective COVID-19 vaccination program in Australia by coordinating the distribution of COVID-19 vaccines, including booster shots, to pharmacies.

## Public benefits

- 4.11. 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.*<sup>5</sup>

### *The NPSA submission*

- 4.12. The NPSA submits that the key public benefits arising from the Proposed Conduct are:
- facilitating and promoting a sustainable and strong supply chain to respond to Customers' demand in a responsible manner (especially for critical life-saving Medicines, as well as Pharmacy Products which are in short supply),
  - amplifying the effectiveness of existing and proposed Government and regulatory bodies responses to COVID-19 in attempting to smooth any supply chain strain,
  - facilitating a safe and orderly environment for Medicines and Pharmacy Products supply chain employees, such as distribution centres, pharmacies and hospital

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

<sup>5</sup> 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



staff to work in; this can in turn facilitate the enforcement of social distancing rules, limiting further outbreaks of COVID-19 and employment opportunities for the relevant supply chain staff,

- promoting continued equitable access to Medicines and Pharmacy Products for all Australians, and
- maximising the rate of uptake of COVID-19 vaccination by Australians and ensuring all Australians receive equitable and timely access to COVID-19 Vaccines (and if needed, booster shots) and reduce adverse economic impacts.

#### *The ACCC's view*

- 4.13. 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 continue to 're-open', there is likely to be continued pressure on the healthcare system. In these circumstances, while the extent to which the Proposed Conduct will be engaged in is uncertain, there remains a risk of supply shortages for Medicines and Pharmacy Products in Australia.
- 4.14. The ACCC accepts the NPSA's submission regarding the likely public benefits that will arise from the proposed conduct, outlined above at paragraph 4.12.
- 4.15. These public benefits arise to the extent to which there are, or there are risks of, significant numbers of COVID-19 infections in Australia and/or overseas, which disrupt supply chains and create shortages of Medicines and Pharmacy Products. The risk of increased infection rates both in Australia and overseas remains and therefore there remains a threat to the supply of Medicines and Pharmacy Products.
- 4.16. The ACCC acknowledges that to the extent infection rates in Australia remain relatively low, and there are no associated critical issues in the supply and/or demand of Medicines and Pharmacy Products, the actual reliance on the Proposed Conduct may be limited. However, given the uncertain environment in which delays and inefficiencies may have significant public health consequences, the Proposed Conduct is likely to ensure the Participants are able to respond to risks to supply by enabling urgent action if the need arises and this in itself is a public benefit.
- 4.17. In addition, the ACCC acknowledges that, since interim authorisation on 10 September 2021, the rates of single and first-dose vaccination rates in Australia have increased substantially. The ACCC nevertheless considers that the Proposed Conduct will continue to support maximising the rate of uptake of COVID-19 vaccination, including booster shots and vaccination of children, as well as to respond to any future vaccines released in response to new COVID-19 variations and strains.

### Public detriments

- 4.18. 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.<sup>6</sup>*

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<sup>6</sup> Re 7-Eleven Stores (1994) ATPR 41-357 at 42,683.

#### *The NPSA submission*

- 4.19. The NPSA submits that any public detriment that may arise from the Proposed Conduct (including from the sharing of limited information between competitors for a short period of time and for a defined purpose) is limited and are significantly outweighed by the public benefits.
- 4.20. The NPSA submits that in granting the Existing Authorisation, the ACCC found that the Proposed Conduct was unlikely to significantly impact competition beyond the short term (and consequently would have minimal public detriments). The NPSA submits these findings continue to apply to the Proposed Conduct for re-authorisation.
- 4.21. In relation to negotiating the distribution of the COVID-19 Vaccines to Customers, the NPSA submits any public detriment will be limited as:
- to the extent that there is a need by the Operating Participants, in responding to any requests by the DOH, as part of the negotiations in respect of the proposed distribution of COVID-19 Vaccines (including, if needed, booster shots and directly related consumables) to share competitively sensitive information, including costs, each Operating Applicant will provide their competitively sensitive information on a confidential basis directly to the NPSA; and
  - no Operating Participant will share competitively sensitive information with other Operating Participants or have visibility of other Operating Participants' competitively sensitive information.

#### *Department of Health submission*

- 4.22. The DOH submitted that the definition of Pharmacy Products is broad and the ACCC could consider narrowing the scope of the current definition. The DOH submitted that if amendments to the definition of Pharmacy Products are not possible due to practical difficulties in narrowing the scope of the definition, DOH encourages the ACCC to give additional consideration to how the reporting condition (and any associated monitoring arrangements) may best be utilised during the authorisation period to ensure that the Proposed Conduct is being applied to only address relevant shortages due to the COVID-19 pandemic.
- 4.23. The DOH submits that while a significant volume of Medicines and Pharmacy Products are supplied through appointed CSO Distributors (some of whom are NPSA members), there are a number of other non-CSO pharmaceutical wholesalers and distributors which supply essential Medicines and Pharmacy Products. The DOH would welcome the opportunity for current, future and non-NPSA members to participate in the Proposed Conduct.

#### *NPSA response to Department of Health submission*

- 4.24. The NPSA submits that the inclusion of Pharmacy Products in the Proposed Conduct is necessary having regard to the fact that there is an integrated supply chain for the delivery of both Pharmacy and Medicines (such that COVID-19 related impacts could affect all such products) to community pharmacies. In addition, the Participants have responsibly applied the broad scope of Pharmacy Products to date (and will continue to do so).
- 4.25. The NPSA submits that in respect of the identity of the proposed participants, in the absence of further information or consultation regarding the need or interest to broaden the scope of the Participants in the manner suggested by the DOH, the

Participants cannot make a considered decision on whether such expansion is necessary.

*ACCC view*

- 4.26. Competitors sharing information and coordinating in the supply of products may reduce competition and result in public detriment. Detriment may extend beyond the short term because the Participants may have a better understanding of each other's pricing and stocking strategies. The Proposed Conduct could also give rise to opportunities to discuss and coordinate the supply of Medicines and Pharmacy Products that are not necessary to address shortages due to COVID-19. Such conduct could reduce competition in relation to these products.
- 4.27. The ACCC notes that the definition of Pharmacy Products is broad however it accepts NPSA's submissions that the scope of the Proposed Conduct is necessary to ensure timely and equitable distribution of Pharmacy Products where shortages due to COVID-19 are likely. The ACCC also notes the TGA's concern that too narrow a definition of Pharmacy Products may lead to unintended shortages of clinical products like devices (such as syringes and nebulisers) or PPE. The TGA also pointed to the fact that there had been no inappropriate supply restrictions imposed under the previous authorisation. The ACCC considers the proposed condition of authorisation will ensure the ACCC maintains an appropriate level of oversight of the authorised conduct, including in relation to Pharmacy Products, during the period of authorisation.
- 4.28. The ACCC notes that the NPSA has not requested non-CSO wholesalers and distributors join the authorisation and these parties have not sought to be included as participants to the Proposed Conduct for re-authorisation. Other parties that wish to participate in the Proposed Conduct should make submissions on this draft determination.
- 4.29. The ACCC considers that there are a number of factors that mean it is unlikely that the Proposed Conduct will significantly impact competition:
- The Proposed Conduct is a temporary measure to optimise the Medicines and Pharmacy Products supply chain during the COVID-19 pandemic.
  - The Proposed Conduct only applies to arrangements and conduct for the purposes set out in paragraphs 1.10 and 1.11, which are broadly to assist the Participants to address the supply chain issues arising from unprecedented consumer demand and to enable timely distribution of COVID-19 vaccines to pharmacies. This will assist Customers and Consumers to equitably access Medicines, including COVID-19 vaccines, and Pharmacy Products.
  - The Proposed Conduct excludes any price coordination behaviour in respect of the sourcing, or arrangements relating to the supply, of Medicines and Pharmacy Products.
  - It is not compulsory for the Participants to engage in the Proposed Conduct. Any Participant can opt out of the Proposed Conduct at any time, and any future NPSA members and other CSO Distributors can 'opt in' to participate in the Proposed Conduct.
- 4.30. The Proposed Conduct, in relation to Medicines, will be subject to relevant oversight from Government and other regulatory bodies, such as the TGA coordinated Medicines Shortages Working Group and the Department of Health's Medicine Shortages Working Party.

4.31. Nevertheless, the ACCC considers that the Proposed Conduct is likely to result in some public detriment in the short-term resulting from competitors sharing information and working together in relation to the supply of Medicines and Pharmacy Product relative to a situation where each Participant individually makes its own decisions.

### **Proposed reporting condition**

4.32. The ACCC considers the Proposed Conduct is broad, particularly in relation to Pharmacy Products. Further, future COVID-19 infection rates and the demand for Medicines and Pharmacy Products are uncertain.

4.33. A reporting condition would allow the ACCC to maintain oversight of the conduct for the duration of the authorised period.

4.34. Accordingly, the ACCC proposes to include a reporting condition, which would be largely based on the reporting condition imposed in the Existing Authorisation.

4.35. The ACCC notes that the Medicines Shortages CSOD Supply Restriction (MSSR) Working Group meets monthly. The ACCC proposes that the NPSA provide a monthly report to the ACCC, or a report within five business days of engaging in reportable activity, rather than a fortnightly report as required under the Existing Authorisation.

4.36. The proposed reporting condition is set out in paragraph 5.7.

### **Balance of public benefit and detriment**

4.37. The ACCC considers that the Proposed Conduct is likely to result in significant public benefits by facilitating the supply of Medicines, including supply of vaccines to pharmacies, and Pharmacy Products, particularly in circumstances where the Delta variant of COVID-19 is present in Australia, alongside the ongoing easing of COVID-19 restrictions, which may lead to a rise in overall infections. 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.

4.38. The ACCC considers that the Proposed Conduct is likely to result in some public detriment over the short term because it is likely to reduce competition between Participants in the supply of Medicines and Pharmacy Products. The proposed reporting condition provides some transparency on coordination undertaken under the protection of authorisation.

4.39. Therefore, for the reasons outlined in this draft determination, the ACCC is satisfied that the Proposed 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 Proposed Conduct.

### **Length of authorisation**

4.40. The Act allows the ACCC to grant authorisation for a limited period.<sup>7</sup> This enables the ACCC to be in a position to be satisfied that the likely public benefit will outweigh the detriment for the period of authorisation. It also enables the ACCC to review the authorisation, and the public benefit and detriment that have resulted, after an appropriate period.

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<sup>7</sup> Subsection 91(1)

- 4.41. In this instance, the NPSA seeks re-authorisation for 12 months from the date of any Final Determination made by the ACCC.
- 4.42. The TGA submits that it has no concerns about the proposed 12-month re-authorisation period.
- 4.43. While it is difficult to predict how long these measures will be necessary, for the reasons outlined in this draft determination, the ACCC considers a re-authorisation period of 12 months from any final determination is appropriate.
- 4.44. The ACCC proposes to grant re-authorisation until 28 February 2023.<sup>8</sup>

## 5. Draft determination

### The application

- 5.1. On 6 September 2021, the NPSA lodged an application to revoke authorisation AA1000480 and substitute authorisation AA1000571 for the one revoked (referred to as re-authorisation). This application for re-authorisation was made under subsection 91C(1) of the Act.
- 5.2. The NPSA is seeking re-authorisation to enable the Participants and Other Participants (as defined in paragraph 1.9) to continue to coordinate activities necessary for the purpose of providing equitable access to Medicines and Pharmacy Products for all Australians during supply shortages that may arise from the COVID-19 pandemic.
- 5.3. Subsection 90A(1) of the Act requires that before determining an application for authorisation, the ACCC shall prepare a draft determination.

### The authorisation test

- 5.4. Under subsections 90(7) and 90(8) of the Act, the ACCC must not grant authorisation unless it is satisfied in all the circumstances that the Proposed Conduct is likely to result in a benefit to the public and the benefit would outweigh the detriment to the public that would be likely to result from the Proposed Conduct.
- 5.5. For the reasons outlined in this draft determination, and with the proposed condition, the ACCC is satisfied, in all the circumstances, that the Proposed Conduct would be likely to result in a benefit to the public and the benefit to the public would outweigh the detriment to the public that would result or be likely to result from the Proposed Conduct, including any lessening of competition.
- 5.6. Accordingly, the ACCC proposes to grant re-authorisation.

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<sup>8</sup> Assuming the ACCC makes a final determination granting authorisation on 28 February 2022. This date is subject to change.

## Proposed condition of authorisation

5.7. The ACCC proposes to grant re-authorisation with the following condition (which is similar to that imposed in the Existing Authorisation and the interim authorisation granted on 10 September 2021, noting that previously, the NPSA was required to report to the ACCC fortnightly):

(a) The NPSA will provide a report to the ACCC at the end of each month or within 5 business days of any material recommendation, meetings, discussions, developments or decisions, which will be published on the ACCC's public register (subject to the ACCC deciding to exclude material from the public register, as requested by the NPSA) (the **Monthly Report**). The Monthly Report shall 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:

- any material recommendations made by the Medicines Shortages CSOD Supply Restriction (**MSSR**) Working Group;
- information regarding any meeting or discussion between two or more of the Participants relating to the Proposed Conduct, including:
  - the attendees at the meeting or discussion;
  - the agenda items of the meeting or discussion that are related to the Proposed Conduct;
  - any minutes of the meeting or discussion relating to the Proposed Conduct; and
  - an overview of topics discussed that related to the Proposed Conduct;
- any changes to the Participant group including to the extent that Other Participants or any other specified third parties as directed by the DOH (in respect of the COVID-19 Vaccine distribution, including if needed, booster shots and directly related consumables) become involved in discussions with the Participants in respect of any relevant aspects of the Proposed Conduct.

(b) The NPSA will provide to the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct.

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.

5.9. The legal protection provided by the authorisation does not apply if any of the conditions are not complied with.<sup>9</sup>

## Conduct which the ACCC proposes to authorise

5.10. The ACCC proposes to revoke authorisation AA1000480 and grant authorisation AA1000571 in substitution. Authorisation AA1000571 is to enable the Participants and the Other Parties defined in paragraph 1.9 to engage in the Proposed Conduct as described in paragraphs 1.10 and 1.11.

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<sup>9</sup> Section 88(3) of the Act.



- 5.11. The ACCC proposes to grant authorisation AA1000571 with the proposed condition as described at paragraph 5.8.
- 5.12. The ACCC proposes to grant re-authorisation for the Proposed Conduct only insofar as it is necessary to address shortages in the supply of Medicines and Pharmacy Products that may arise from COVID-19 and to enable the NPSA and Operating Participants (and other CSO Distributors as required by DOH) to work together to ensure the equitable and timely distribution of COVID-19 Vaccines if engaged by the DOH.
- 5.13. 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.
- 5.14. The ACCC proposes to grant authorisation AA1000571 until 28 February 2023.
- 5.15. This draft determination is made on 9 December 2021.

## 6. Next steps

- 6.1. The ACCC now invites submissions in response to this draft determination by 21 January 2022. 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.