

# Determination

Application for authorisation 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: AA1000480

17 September 2020

Commissioners: Sims

Keogh Rickard Court Ridgeway

## **Summary**

The ACCC has decided to grant conditional authorisation to the National Pharmaceutical Services Association and its current and future members and other Community Service Obligation Distributors (together **the Participants**), to enable them to coordinate activities for the purpose of promoting continual, fair and equitable access to Medicines and Pharmacy Products during the COVID-19 pandemic.

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

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 the COVID-19 pandemic. Interested parties generally supported the proposed conduct and likely public benefits.

Based on the available information, and subject to the conditions of authorisation, the ACCC considers that the likely public benefit will outweigh the likely public detriment.

The ACCC has decided to grant conditional authorisation until 30 September 2021.

This determination is made on 17 September 2020. If no application for review of the determination is made to the Australian Competition Tribunal, the authorisation will come into effect on 9 October 2020.

# 1. The application for authorisation

- 1.1. On 27 March 2020, the National Pharmaceutical Services Association (NPSA), on behalf of itself and its current and future members and other Community Service Obligation (CSO) Distributors (together the Participants¹), lodged application for authorisation AA1000480 (the Application) with the Australian Competition and Consumer Commission (the ACCC). NPSA sought authorisation to enable the Participants to coordinate activities necessary for the purpose of providing continued and equitable access to Medicines and Pharmacy Products for all Australians during supply shortages that may arise from the COVID-19 pandemic.
- 1.2. The NPSA sought authorisation to engage in the Proposed Conduct for a period of 12 months from the date of a final determination by the ACCC. However, if the supply chain recovers from COVID-19 disruptions earlier than expected, the NPSA intends to cease the Proposed Conduct at that time and will notify the ACCC accordingly.<sup>2</sup>
- 1.3. The application was made under subsection 88(1) of the *Competition and Consumer Act 2010* (Cth) (the **Act**).
- 1.4. The ACCC may grant authorisation, which provides businesses with legal protection for arrangements that may otherwise risk breaching competition law but are not harmful to competition and/or are likely to result in overall public benefits.
- 1.5. The NPSA also requested that the ACCC grant interim authorisation to commence engaging in the conduct while the ACCC considers the substantive application.

## The Applicant

1.6. 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.

#### 1.7. The NPSA's 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.
- **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
- 1.8. 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

In its application for authorisation, NPSA refers to the entities seeking authorisation as the 'Applicants'. In this determination, these entities are called the Participants. The Applicant is NPSA.

National Pharmaceutical Services Association (NPSA), Application for authorisation, 27 March 2020, p.8, Public register for NPSA

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.

- 1.9. CSO Distributors currently eligible under the CSO Funding Pool are:
  - NPSA members
  - Barrett Distributors Pty. Ltd.
  - Clifford Hallam Healthcare Pty Limited.

## The Proposed Conduct

- 1.10. The NPSA sought authorisation so that the Participants can have discussions, enter into or give effect to arrangements between them, or engage in conduct (excluding the sharing of any price information):
  - that have the purpose of facilitating the supply of, and access to, Medicines and Pharmacy Products; and/or
  - that have 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 Australian Government and/or Working Groups.<sup>3</sup>
- 1.11. In seeking to maintain the integrity of the supply chain, the NPSA proposed, if necessary, to engage in activities relating to:
  - sustainable coordinated stock acquisition, including liaising with manufacturers/suppliers of Medicines and Pharmacy Products and/or relevant industry peak bodies regarding purchasing arrangements and importing logistics:
  - coordinate inventory management strategies, such as stock reservation, including allocation of supplies of Medicines and Pharmacy Products to Customers; and
  - 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 them 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.

(together, paragraphs 1.10 and 1.11 form the **Proposed Conduct**).4

- 1.12. The following definitions apply:<sup>5</sup>
  - Medicines includes all therapeutic goods (both prescription and non-prescription medicines, medical devices and biologicals);
  - Pharmacy Products includes all other goods available for sale at community pharmacies (such as personal protective equipment, face masks, gloves, hand sanitisers and toilet paper);

<sup>&</sup>lt;sup>3</sup> 'Working Groups' includes the Therapeutic Goods Administration coordinated Medicines Shortages Working Group and the Department of Health's Medicine Shortages Working Party.

<sup>&</sup>lt;sup>4</sup> NPSA, Application for authorisation, 27 March 2020, pp. 6-7, Public register for NPSA

<sup>&</sup>lt;sup>5</sup> NPSA, Application for authorisation, 27 March 2020, pp. 2-3, Public register for NPSA

- Customers means purchasers of the Participants' products, including pharmacies and hospitals; and
- Consumers means end users of the Participants' products, such as patients and individuals.

#### Interim authorisation

- 1.13. The NPSA also sought urgent interim authorisation so that the Participants could engage in the Proposed Conduct while the ACCC is considering the substantive application.
- 1.14. On 31 March 2020, the ACCC granted conditional interim authorisation to the NPSA for the Proposed Conduct subject to the following conditions:<sup>6</sup>

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

- any material recommendations made by the Working Groups;
- key operational and supply arrangements and material conduct in parallel with, or to enable the optimal implementation of, Government decisions; and
- any changes to the Applicant group.
- 1.15. Since being granted conditional interim authorisation, the NPSA has been providing the ACCC with regular updates on developments in relation to the Proposed Conduct. The Participants have formed a working group to enable them to share trends or concerns regarding the supply of, or supply chain issues associated with, Medicines and/or Pharmacy Products and make decisions about supply arrangements based on the information available to the working group. The Participants also continue to engage with the TGA to reduce shortages of Medicines.
- 1.16. The conditional interim authorisation granted on 31 March 2020 remains in place until it is revoked or until the date the ACCC's final determination comes into effect.

# 2. Background

- 2.1. The ACCC recognises that there are significant challenges arising from the COVID-19 pandemic. The pandemic has caused a major disruption to society and the economy, with social distancing measures and travel bans affecting various sectors across the economy. In that context, the ACCC has received a large number of applications for authorisation, including requests for interim authorisation, aimed at providing financial relief to businesses and individuals, facilitating the supply of goods and services (including medical products and services) and managing the financial impact of a significant economic shock. At some stages of the pandemic there has been a risk of Australia's health services being put under significant stress, including through the unavailability of sufficient supplies of certain medicines and equipment. The identification of this risk and the need for collective and coordinated action by competitors gave rise to applications for authorisation such as the application from the NPSA.
- 2.2. The NPSA submitted:7

<sup>&</sup>lt;sup>6</sup> ACCC, 31 March 2020, NPSA Interim Authorisation Decision - Statement of Reasons

<sup>&</sup>lt;sup>7</sup> NPSA, 27 March 2020, Application for authorisation, pp. 5-6, Public register for NPSA

- The rapid escalation of issues relating to COVID-19 have resulted in unprecedented demand from Consumers of Medicines and Pharmacy Products, as well as unusual ordering patterns from some Customers, placing significant pressure on all participants of the Medicines and Pharmacy Products supply chain.
- These logistical challenges and proposed solutions are not unique. Other suppliers, both of medical equipment and grocery and household goods have also formed the view that coordinated action between suppliers is essential to stabilise the relevant supply chains.
- As a part of formulating a proportionate and practical response to COVID-19, the
  Participants have been engaging with the Government in a proactive and
  consultative manner. These discussions have resulted in Government directives
  that the Participants impose appropriate supply restrictions as a part of delivering a
  responsible and evolving emergency management strategy during COVID-19. In
  parallel, there are various existing regulatory and industry working groups seeking
  to relevantly address COVID-19 developments, including the Therapeutic Goods
  Administration (TGA) coordinated Medicines Shortages Working Group and the
  Australian Government Department of Health's (DOH) Medicine Shortages
  Working Party (which the NPSA is a contributor to) (Working Groups).
- Imports account for a significant portion of the Participants' supply chains. The
  global nature of COVID-19 developments also has significant ramifications for the
  domestic supply of Medicines and Pharmacy Products. This means that closer
  coordination regarding the acquisition and/or sourcing of Medicines and Pharmacy
  Products will also be an important part of supporting the continued and equitable
  distribution of these products to all Australians.
- The Proposed Conduct would enable the Participants to seek to address these outstanding concerns in an expeditious manner, in urgent circumstances, in parallel with, or to enable the optimal implementation of, Government decisions. It would allow the Participants to optimise their supply chains to better meet the CSO objectives of providing broad access to essential Medicines for all Australians, in the context of the pandemic's unprecedented challenges.
- 2.3. The NPSA submitted that urgent coordinated action in respect of issues affecting the acquisition and distribution of Medicines and Pharmacy Products is the most effective way to promote a stable and workable supply chain which is being significantly disrupted as a result of the COVID-19 pandemic.<sup>8</sup>

#### 3. Consultation

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

#### Consultation on the application and request for interim authorisation

- 3.2. Due to the urgent need to ensure the continued supply of Medicines and Pharmacy Products, including those needed for the treatment of COVID-19, and the compelling nature of the public benefits likely to result from interim authorisation, the ACCC did not conduct public consultation before it decided to grant conditional interim authorisation.
- 3.3. Prior to issuing its draft determination, the ACCC invited submissions on both the decision to grant interim authorisation and the substantive application for authorisation

<sup>8</sup> NPSA, Application for authorisation, 27 March 2020, p. 2, Public register for NPSA

from a range of potentially interested parties, including state and federal government and relevant regulatory bodies, the Participants and other medical/pharmaceutical associations/businesses.

- 3.4. The ACCC received three submissions from interested third parties in relation to the application.
- 3.5. Public submissions are on the Public Register for NPSA.

#### Interested party submissions

- 3.6. The Pharmacy Guild of Australia (the **Pharmacy Guild**), the national peak body representing community pharmacy, supports the Proposed Conduct. The Pharmacy Guild submitted that:<sup>9</sup>
  - While medicines shortages have been a long-term problem in Australia, particularly for prescription medicines, COVID-19 has had a significant impact on medicine accessibility due to a combination of factors, including but not limited to:
    - panic stockpiling of medicines by consumers
    - stockpiling by pharmacies
    - prescriber behaviour providing prescriptions for patients for quantities in excess of standard use
    - local supply and distribution disruptions
    - global supply and distribution disruptions
    - manufacturing problems.
  - CSO Distributors have information not associated with pricing that is of value in
    planning and managing problems associated with the supply and distribution of
    medicines; enabling these distributors to share information through the NPSA and
    with other key stakeholders is essential to effective and expeditious management
    of medicine supply problems at both a national and regional level.
- 3.7. The Australian Healthcare and Hospitals Association (**AHHA**) strongly supports the Proposed Conduct. The AHHA submitted that the impact of COVID-19 on the availability of medicines and pharmacy products has been significant. This impact will have a major and long-lasting impact on the health of all Australians, not only for those experiencing COVID-19, but also for the many Australians who are now unable to access regular health care.<sup>10</sup>
- 3.8. NSW Ministry of Health (**NSW Health**) considered that it was premature for it to make a detailed submission on the process because the impact of COVID-19 on the availability of medicines is evolving and the effectiveness of the Proposed Conduct in mitigating the impact of COVID-19 on supply chains is not yet clear.<sup>11</sup>

#### Consultation on the draft determination

3.9. On 24 July 2020, the ACCC issued a draft determination proposing to grant conditional authorisation until 27 September 2020. A pre-decision conference was not requested following the draft determination.

<sup>&</sup>lt;sup>9</sup> The Pharmacy Guild of Australia, Submission, 24 April 2020, Available: Public register for NPSA

Australian Healthcare and Hospitals Association, 23 April 2020, Submission, available: Public register for NPSA

NSW Ministry of Health, 30 April 2020, Submission, available: Public register for NPSA

- 3.10. The DOH notes 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 submitted that the definition of Pharmacy Products is broad and the ACCC should consider whether conditional authorisation could be extended to non-CSO wholesalers and distributors.<sup>12</sup>
- 3.11. NPSA proposed amendments to the reporting conditions included in the draft determination. This is discussed in paragraphs 4.35 to 4.40.
- 3.12. NPSA also responded to the DOH submission. NPSA's specific responses are summarised in the assessment section.

#### 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 and may substantially lessen competition within the meaning of section 45 of the Act. Subsections 90(7) and 90(8) of the Act provide that the ACCC must not grant authorisation unless it is satisfied, in all the circumstances, that the conduct would result or be likely to result in a benefit to the public, and the benefit would outweigh the detriment to the public that would be likely to result (authorisation test).

## Relevant areas of competition

- 4.3. To assess the likely effect of the Proposed Conduct, the ACCC identifies the relevant areas of competition likely to be impacted.
- 4.4. The application did not specifically describe the relevant areas of competition.
- 4.5. The ACCC considers that the relevant areas of competition are likely to be for the supply of medicines and pharmacy products to pharmacies and hospitals. The ACCC does not consider that a precise definition of the market is necessary for the assessment of the Proposed Conduct.

## Future with and without the Proposed Conduct

- 4.6. In applying the authorisation test, the ACCC compares the likely future with the Proposed Conduct that is the subject of the authorisation to the likely future in which the Proposed Conduct does not occur.<sup>13</sup>
- 4.7. The rationale for Proposed Conduct is linked with the impacts of COVID-19 in Australia and overseas. The future likelihood and severity of those impacts is largely unknown at this point in time.
- 4.8. The ACCC notes that COVID-19 infection rates in Australia have been relatively low and the demand for Medicines and Pharmacy Products has largely stabilised since

Department of Health, 6 August 2020, Submission, Available: <u>Public register for NPSA</u>

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.

peaks in March and April 2020. However, the continued increase of infection rates internationally and the recent increases in some Australian states may influence the availability of the supply of Medicines and some Pharmacy Products in Australia.

#### Future with the Proposed Conduct

4.9. The ACCC considers that in the future with the Proposed Conduct, the participants will continue to coordinate activities for the purpose of providing continued, equitable access to Medicines and Pharmacy Products during the COVID-19 pandemic, as is occurring under the interim authorisation. This includes coordination by Participants in parallel with Government and regulatory body decisions, in relation to the supply of Medicines and Pharmacy Products. During periods where the impacts of the COVID-19 pandemic are not significant, the Participants will maintain a readiness to respond to possible supply problems should outbreaks occur.

#### Future without the Proposed Conduct

- 4.10. Without the Proposed Conduct, the Participants will need to continue to address COVID-19 challenges but without coordination. The NPSA submitted that the Australian Government has directed Participants to impose supply restrictions to address surges in demand for Medicines and Pharmacy Products. Despite the current measures and actions taken by each Participant individually, there remain concerns regarding supply chain issues including logistics, distribution and import of Medicines and Pharmacy Products in Australia.<sup>14</sup>
- 4.11. The ACCC considers that in the future without the Proposed Conduct, the Participants and Federal Government and/or Federal Government agencies may be less able to quickly and effectively respond in a coordinated fashion to any shortages in the supply of Medicines and Pharmacy Products due to an increase in the rate of COVID-19 infection in Australia or globally.

#### Public benefits

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

...anything of value to the community generally, any contribution to the aims pursued by society including as one of its principal elements ... the achievement of the economic goals of efficiency and progress. <sup>15</sup>

#### The NPSA submission

- 4.13. The NPSA submitted that the Proposed Conduct is expected to generate significant public benefits by positioning the Participants to adopt a proactive approach to address current supply chain challenges and alleviate heightened levels of consumer anxiety regarding the availability of Medicines and Pharmacy Products, particularly for those most in need.
- 4.14. The NPSA submitted that the key public benefits arising from the Proposed Conduct are that it will:<sup>16</sup>

<sup>&</sup>lt;sup>14</sup> NPSA, 27 March 2020, Application for authorisation, p. 9, available: Public register for NPSA

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.

NPSA, 27 March 2020, Application for authorisation, p. 9, available: Public register for NPSA

- facilitate and promote 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);
- amplify the effectiveness of existing and proposed Government and regulatory bodies responses to COVID-19 in attempting to smooth any supply chain strain;
- facilitate a safe and orderly environment for Medicines and Pharmacy Products supply chain employees, such as distribution centres, pharmacies and hospital 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;
- promote continual equitable access to Medicines and Pharmacy Products for all Australians; and
- alleviate heightened levels of consumer anxiety regarding the availability of Medicines and Pharmacy Products, particularly for those most in need.

#### Interested party submissions

- 4.15. The Pharmacy Guild submitted that enabling CSO distributors to share information through the NPSA and with other key stakeholders is essential to effective and expeditious management of medicine supply problems at both a national and regional level.<sup>17</sup>
- 4.16. The AHHA submitted that every effort needs to be made to ensure the stability of the supply chain for medicines and pharmacy products, including the coordination of activities by the pharmaceutical services sector.<sup>18</sup>

#### The ACCC's view

- 4.17. The ACCC considers that the Proposed Conduct is likely to result in public benefits including:
  - 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 strain on the supply chain;
  - facilitating a safe and orderly environment for employees of the Medicines and Pharmacy Products supply chain, such as distribution centres, pharmacies and hospitals, 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; and
  - promoting continued equitable access to Medicines and Pharmacy Products for all Australians.
- 4.18. Those public benefits arise to the extent to which there are, or there are risks of, significant numbers of COVID-19 infections in Australia and/or overseas, which disrupt supply chains and create shortages of Medicines and Pharmacy Products. The ACCC notes that COVID-19 infection rates in Australia have not been as high as initially

<sup>&</sup>lt;sup>17</sup> The Pharmacy Guild of Australia, 24 April 2020, Submission, Available; Public register for NPSA

<sup>&</sup>lt;sup>18</sup> Australian Healthcare and Hospitals Association, 23 April 2020, Submission, available: Public register for NPSA

projected and therefore the disruption to the supply chains for Medicines and Pharmacy Products (and in turn, the need for the Proposed Conduct) has not been as great as may have been anticipated. However, the risk of increased infection rates both in Australia and overseas remains and therefore there remains a threat to the supply of Medicines and Pharmacy Products.

4.19. The ACCC acknowledges that to the extent infection rates in Australia remain low, and there are no associated critical issues in the supply and/or demand of 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.

#### Public detriments

- 4.20. 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>19</sup>
- 4.21. The benefits of competition generally include increased efficiency, innovation, efficient prices and greater consumer choice. Competitors sharing information and coordinating supply of goods and/or services has the potential to lessen competition and result in consumer detriment by restricting supply and increasing prices, stifling innovation and preventing businesses from entering the market.

#### The NPSA submission

- 4.22. The NPSA submitted that the public benefits of the Proposed Conduct will outweigh any detriments because:<sup>20</sup>
  - the primary aim of the Proposed Conduct is to assist the Participants to address the supply chain issues arising from unprecedented Customer and Consumer demand, ultimately facilitating continual equitable access to Medicines and Pharmacy Products;
  - the Proposed Conduct excludes any price coordination behaviour between the Participants and the Participants will otherwise continue to compete with each other in respect of price and service quality and offerings;
  - the duration of the Proposed Conduct is no longer than necessary; the Participants have applied for a 12 month authorisation period;
  - the Proposed Conduct is conducted on a voluntary, 'opt in, opt out' basis so that any future NPSA members and other CSO Distributors can join and any Participant can cease their participation in the Proposed Conduct at any time;
  - the NPSA will keep the ACCC informed of all material developments in the Proposed Conduct, including any changes to the Applicant group; and
  - the Proposed Conduct will also be subjected to oversight by the relevant Government departments and aforementioned health regulatory bodies.

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

<sup>&</sup>lt;sup>19</sup> Re 7-Eleven Stores (1994) ATPR 41-357 at 42,683.

#### Interested party submissions

- 4.23. The Pharmacy Guild submitted that arrangements should be in place to ensure that the work done under this authorisation is not used to preferentially advantage any of the Participants' customers.<sup>21</sup>
- 4.24. NSW Health submitted that the conduct to be authorised should be limited to conduct which is for a purpose requested by the Commonwealth or one or more State or Territory governments. NSW Health also submitted that the authorised conduct should extend to exchange of information with the other level of the supply chain (i.e. importers/manufacturers) where that is directed or requested by the Commonwealth or one or more State or Territory governments.
- 4.25. The DOH submitted that the definition of Pharmacy Products is broad and the ACCC should consider narrowing the definition. If narrowing is not possible, DOH encouraged the ACCC to give additional consideration to how the reporting conditions may best be utilised during the authorisation period to ensure the Proposed Conduct is being used to only address relevant shortages due to the COVID-19 pandemic.<sup>23</sup>
- 4.26. The DOH submitted that there are a number of non-CSO Distributors that supply essential Medicines and Pharmacy Products, which are not Participants in the Proposed Conduct and DOH encourages the ACCC to consider whether conditional authorisation may be extended to these relevant organisations.<sup>24</sup>

## NPSA response to the DOH submission

- 4.27. In response to the DOH's submission, NPSA submitted:
  - The Participants require the full scope of the Proposed Conduct to ensure the timely and equitable distribution of Pharmacy Products in the event of COVID-19 related supply chain disruptions including:
    - potential COVID-19 outbreaks in the Participants' distribution centres and/or the Participants' logistics partners' facilities; and
    - Government decisions that may result in significant increases in demand for, or potential supply shortages of, Pharmacy Products.
  - In relation to including non-CSO pharmaceutical wholesalers and distributors, the scope of the 'Applicants' as defined in the application is sufficiently broad as it encompasses future NPSA members and other CSO wholesalers. In the absence of further information or consultation regarding the need or interest for non-CSO wholesalers and distributors to join the application, NPSA cannot make a considered decision about whether expanding the scope of the applicants is necessary.

#### ACCC view

4.28. Competitors sharing information and coordinating 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

<sup>&</sup>lt;sup>21</sup> The Pharmacy Guild of Australia, 24 April 2020, Submission, Available: Public register for NPSA

NSW Ministry of Health, 30 April 2020, Submission, available: Public register for NPSA

<sup>&</sup>lt;sup>23</sup> Department of Health, 6 August 2020, Submission, Available: Public register for NPSA

Department of Health, 6 August 2020, Submission, Available: Public register for NPSA

- necessary to address shortages due to the COVID-19 pandemic. Such conduct could reduce competition in relation to these products.
- 4.29. In response to the submission made by the Pharmacy Guild, the ACCC notes that prior to the COVID-19 pandemic, some pharmacies have experienced difficulties in accessing some Medicines; this situation is unlikely to be made worse by the Proposed Conduct.
- 4.30. In response to the submission by NSW Health, the ACCC considers that:
  - The Participants proactively responding to and anticipating shortages and supply chain disruptions is likely to minimise the effect of any shortages and disruptions and may inform future Government directives to alleviate shortages and disruptions that affect the supply of Medicines and Pharmacy Products.
  - The members of NPSA have joined the Medicines Australia interim authorisation and they participate in various associated working groups, which discuss shortages of Medicines and associated medical devices with manufacturers and importers of medicines.
- 4.31. 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 considers the conditions of authorisation will ensure the ACCC maintains an appropriate level of oversight of the authorised conduct during the period of authorisation.
- 4.32. 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 during the public consultation on the application and the draft determination.
- 4.33. Although the long-term effects of the COVID-19 pandemic are uncertain, the ACCC considers that there are a number of factors that mean it is unlikely that the Proposed Conduct will significantly impact competition beyond the short term:
  - The Proposed Conduct 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. This will assist Customers and Consumers to equitably access Medicines 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.
  - The Proposed Conduct, in relation to Medicines, will be subject to relevant oversight from Government and other regulatory bodies, such as the TGAcoordinated Medicines Shortages Working Group and the Department of Health's Medicine Shortages Working Party.

- The amended reporting condition set out below will allow the ACCC to continue to monitor the Proposed Conduct engaged in under the auspices of an authorisation.
- 4.34. 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.

#### Reporting condition

- 4.35. The ACCC considers the Proposed Conduct is broad, particularly the conduct in relation to Pharmacy Products. Further, future COVID-19 infection rates and the demand for Medicines and Pharmacy Products are uncertain.
- 4.36. Accordingly, the ACCC has decided to include a reporting condition to allow the ACCC to maintain oversight of the conduct for the duration of the authorised period. In the draft determination, the ACCC proposed to impose a condition requiring NPSA to provide the ACCC with fortnightly reports and a requirement to provide information requested by the ACCC.
- 4.37. NPSA submitted the following amendments to the reporting conditions set out in the draft determination:
  - Reporting within five business days of a Medicines Shortages CSOD Supply Restriction (MSSR) Working Group meeting (convened and attended by the Participants) or otherwise on a monthly basis, rather than reporting fortnightly as proposed in the draft determination.
  - Reporting on meetings of the MSSR Working Group rather than all Working Groups. Discussion and decisions made during Government convened Working Group meetings may include information that is confidential to those parties. NPSA submitted that the ACCC can liaise directly with third parties to obtain relevant information.
  - The ACCC should have regard to the confidentiality/sensitivity of information made available on its public register to avoid creating unnecessary consumer concerns regarding the availability of certain essential products.

#### ACCC View

- 4.38. Given the broad scope of the conduct, the ACCC considers fortnightly reporting is appropriate. The ACCC recognises that if NPSA considers there is nothing to report to the ACCC, NPSA can submit a 'nil' report.
- 4.39. The ACCC accepts NPSA's submission that reporting on 'Working Group' meetings is unnecessarily broad, and instead will require NSPA to report on meetings/discussions of the MSSR Working Group. The ACCC will liaise directly with relevant Government agencies and obtain information on discussions and decisions at Government convened Working Group meetings.
- 4.40. In the draft determination, the ACCC proposed to publish on the public register, reports provided to the ACCC as part of any reporting condition, subject to the ACCC deciding to exclude material from the register. When providing reports to the ACCC, NPSA should identify information that it considers is confidential and the ACCC will make an assessment of that information and decide whether it will be published on the public register. The ACCC may decide to publish redacted versions of the reports on the public register.

## Balance of public benefit and detriment

- 4.41. The ACCC considers that the Proposed Conduct is likely to result in significant public benefits by facilitating the supply of Medicines and Pharmacy Products, particularly in the event of an increase in COVID-19 infection rates in Australia or worldwide. In the event that infection rates remain low, the ACCC considers that there are public benefits in the Participants maintaining readiness to deal with supply risks due to possible outbreaks.
- 4.42. 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.
- 4.43. Overall, the ACCC considers that the Proposed Conduct is likely to result in a public benefit and that this public benefit would outweigh any likely detriment to the public from the Proposed Conduct.
- 4.44. The ACCC grants 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 the COVID-19 pandemic.

## Length of authorisation

- 4.45. The Act allows the ACCC to grant authorisation for a limited period of time.<sup>25</sup> This enables the ACCC to be in a position to be satisfied that the likely public benefits will outweigh the detriment for the period of authorisation. It also enables the ACCC to review the authorisation, and the public benefits and detriments that have resulted, after an appropriate period.
- 4.46. In this instance, the NPSA applied for a 12 month authorisation period, noting that if the COVID-19 situation improves and international and domestic supply chains are restored before the end of the 12 month period, the Participants intend to cease engaging in the Proposed Conduct at that time and will notify the ACCC in that event.
- 4.47. DOH supported conditional authorisation until September 2021 on the understanding that flexible extensions to a shorter initial authorisation period may not be possible under the Act.<sup>26</sup>
- 4.48. In the context of the evolving and uncertain nature of the COVID-19 pandemic, as well as the recent increase in infections, the ACCC has decided to grant conditional authorisation until 30 September 2021.

#### 5. Determination

## The application

- 5.1. On 27 March 2020, the NPSA lodged application AA1000480 with the ACCC, seeking authorisation under subsection 88(1) of the Act.
- 5.2. The NPSA sought authorisation for the Proposed Conduct on behalf of the Participants, to enable them to coordinate activities for the purpose of promoting

<sup>&</sup>lt;sup>25</sup> Subsection 91(1)

<sup>&</sup>lt;sup>26</sup> Department of Health, 6 August 2020, Submission, Available: <u>Public register for NPSA.</u>

- continual, fair and equitable access to Medicines and Pharmacy Products during the COVID-19 pandemic.
- 5.3. A draft determination was made on 24 July 2020.

#### 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 determination, the ACCC is satisfied, in all the circumstances, that the Proposed Conduct is 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.

### Conduct which the ACCC has decided to authorise

- 5.6. The ACCC grants conditional authorisation AA1000480 to the NPSA to enable the Participants to engage in the Proposed Conduct. The ACCC grants conditional 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 the COVID-19 pandemic.
- 5.7. The ACCC grants conditional authorisation AA1000480 until 30 September 2021.
- 5.8. This determination is made on 17 September 2020.

#### Condition of authorisation

- 5.9. The ACCC may specify conditions in an authorisation.<sup>27</sup> The legal protection provided by the authorisation does not apply if any of the conditions are not complied with.<sup>28</sup>
- 5.10. The ACCC may specify conditions in circumstances where, although the relevant public benefit test is met, without the conditions the ACCC would not be prepared to exercise its discretion in favour of authorisation.<sup>29</sup>
- 5.11. The ACCC considers it appropriate to specify a reporting condition so that it can maintain an appropriate level of oversight in the current dynamic environment.
- 5.12. The ACCC grants authorisation subject to the following conditions:
  - (a) The NPSA will 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 the NPSA) (the Fortnightly Report). The Fortnightly Report shall report on any meetings, discussions, developments and decisions in relation to the Proposed Conduct as the COVID-19 pandemic evolves. The Fortnightly Report must include, insofar as the following information has not already been provided in a previous Fortnightly Report:
    - any material recommendations made by the MSSR Working Group:

Section 88(3) of the Act.

<sup>&</sup>lt;sup>28</sup> Section 88(3) of the Act.

<sup>&</sup>lt;sup>29</sup> Application by Medicines Australia Inc (2007) ATPR 42-164 at [133].

- 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
  - o an overview of topics discussed that related to the Proposed Conduct;
- any changes to the Participant group.
- (b) The NPSA will provide to the ACCC, within a reasonable timeframe, all information requested by the ACCC in relation to the Proposed Conduct.
- 5.13. 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.

## 6. Date conditional authorisation comes into effect

This determination is made on 17 September 2020. If no application for review of the determination is made to the Australian Competition Tribunal it will come into force on 9 October 2020.