National Pharmaceutical Services Association (NPSA) – Application for revocation of AA1000480 and the substitution of authorisation AA1000571 interim authorisation decision 10 September 2021

Decision

1. The Australian Competition and Consumer Commission (the **ACCC**) has decided to suspend the operation of authorisation AA1000480 and grant conditional interim authorisation in substitution for the suspended authorisation. The conditional interim authorisation is in respect of application AA1000571. This application was lodged by the National Pharmaceutical Services Association (**NPSA**) on 6 September 2021.
2. The NPSA has applied for authorisation on behalf of itself, its current and future members and other Community Service Obligation (**CSO**) Distributors[1] (the **Applicants**).
3. The ACCC grants interim authorisation to the conduct described at paragraphs 33 and 34 of this interim authorisation decision document. Broadly, interim authorisation is granted to enable the Applicants 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 conduct authorised under this interim authorisation is also extended to enable the Applicants to work together to ensure the equitable and timely distribution of COVID-19 Vaccines if engaged by the Department of Health.
4. This interim authorisation allows the previously authorised conduct to continue with the inclusion of new conduct related to COVID-19 Vaccine distribution. The conduct for which interim authorisation is granted differs from the conduct the NPSA is seeking re-authorisation for. The ACCC will consider the full range of conduct proposed by the NPSA as part of its assessment of the application for re-authorisation.
5. Interim authorisation is granted with the conditions set out in paragraph 36 of this interim authorisation decision document.
6. Interim authorisation commences immediately and remains in place until the date the ACCC's final determination comes into effect, the application for authorisation is withdrawn, or until the ACCC decides to revoke interim authorisation.

The application for re-authorisation

7. The NPSA lodged an application for the revocation of authorisation AA1000480 (the **Existing Authorisation**) and the substitution of authorisation AA1000571 in its place (re-authorisation).
8. The Existing Authorisation was granted on 17 September 2020 and is due to expire on 30 September 2021.

[1] '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.

9. The NPSA seeks re-authorisation to optimise the COVID-19 related supply chain challenges in the supply of Medicines and Pharmacy Products which are likely to continue beyond the expiry of the Existing Authorisation.

10. The NPSA seeks re-authorisation for 12 months from the date of the ACCC's final determination.

11. 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 (such as personal protective equipment, face masks, gloves, hand sanitisers and toilet paper);
    - **Customers** means purchasers of the Applicants' products, including pharmacies and hospitals; and
    - **Consumers** means end users of the Applicants' products, such as patients and individuals.

The Applicants

12. The NPSA is a peak industry body representing pharmaceutical wholesalers in Australia. Its members distribute medicines and pharmacy products to pharmacies and major hospitals in Australia.

13. The NPSA's current members are:

    - Australian Pharmaceuticals Industries Limited (**API**);
    - Sigma Healthcare Limited (**Sigma**);
    - Symbion Pty Ltd (**Symbion**); and
    - Friendly Society Medical Association Limited trading as National Pharmacies (**National Pharmacies**).

14. The four current, and any future, NPSA members that actually undertake distribution of Medicines and Pharmacy Products are referred to as the **Operating Applicants**.

15. NPSA advises there are currently six CSO Distributors operating in Australia, which, in addition to NPSA's four current members, are:

    - Barrett Distributors Pty Ltd, and
    - Clifford Hallam Healthcare Pty Ltd.

16. The NPSA requests that the authorisation would 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 Existing Authorisation

17. On 27 March 2020, the NPSA lodged an application for authorisation, and requested urgent interim authorisation, to enable the Applicants to engage in substantially similar conduct as the current application. The re-authorisation seeks protection for additional conduct related to the distribution of COVID-19 Vaccines, which was not explicitly included in the Existing Authorisation, and is described in paragraph 21 below.

18. The arrangements commenced on 31 March 2020 under interim authorisation. The ACCC granted authorisation on 17 September 2020. The Existing Authorisation is due to expire on 30 September 2021.

19. The NPSA submits that the Existing Authorisation has been effective in achieving its aims as the Applicants have collaboratively addressed significant COVID-19 related supply challenges that have arisen as a result of:

    a. interruption of supply chains, either due to a COVID-19 outbreak overseas or domestically including preventative measures in respect of Medicines at risk of short supply, i.e. due to restricted supply from a sponsor, and

    b. abnormal ordering patterns and 'panic buying' behaviour by Consumers of Medicines and Pharmacy Products.

20. The NPSA submits that the impacts of COVID-19 that led to the grant of the Existing Authorisation have not substantially improved, and are highly unlikely to entirely abate, before the expiration of the Existing Authorisation.

Proposed changes to the Existing Authorisation

21. The substantive change to the Existing Authorised conduct involves the NPSA seeking to collectively negotiate (on behalf of the Operating Applicants) with the Government regarding the terms and conditions upon which they can distribute COVID-19 Vaccines (including booster shots and directly related consumables) to community pharmacies and any other third party that the Government requires (the **Additional Conduct**), as part of ensuring the efficient and equitable distribution of COVID-19 Vaccines.

22. The Additional Conduct will include discussion of the appropriate remuneration terms for the Applicants to undertake vaccine distribution. The conduct otherwise is subject to a prohibition on the sharing of any price information between the pharmaceutical wholesaler Applicants.

23. The NPSA submits the Additional Conduct is aimed at supporting a sustainable supply chain and maximising the effectiveness of the Government's COVID-19 Vaccine distribution strategy. This will assist with the equitable access to Medicines and Pharmacy Products, including COVID-19 Vaccines, for all Australians through coordinated action to promote a stable supply chain for those products.

24. In addition to the persistent need to continue collaboration in the supply chain activities of Medicines, the Applicants submit recent developments indicate the need for further collaboration between the Applicants in respect of Covid-19 Vaccine distribution, in particular:

    - the urgency with which Australians are being encouraged to take up vaccines
    - the Government's concerted efforts in accelerating the involvement of community pharmacies to assist in the COVID-19 vaccination roll out, including aiming to increase the number of participating pharmacies that can start providing the COVID-19 Vaccines to 700 (out of a potential 4000) by late August 2021
    - the recent Government announcement that 16-39 year olds will be eligible to receive the Pfizer vaccine from 30 August 2021
    - the continual evolution of the Government's COVID-19 Vaccination strategy and health advice (including changes to the health advice in respect of the AstraZeneca vaccine and the recent approval of the Moderna vaccine).

25. NPSA submits that the Operating Applicants can add value in terms of further improving the efficiency of this segment of the COVID-19 vaccination supply chain, as follows:

- providing tailored deliveries to pharmacies, (i.e. having regard to available supplies, directing more quantities to hotspots at short notice depending on the severity of COVID-19 outbreaks);
- being able to deliver to pharmacies on a daily basis, which will significantly improve order predictability, increase volumes as required, as well as dramatically reduce COVID-19 Vaccine wastages; and
- providing a trusted local avenue for Consumers to access their COVID-19 Vaccines (including booster shots) and improving uptake with easier booking options, with 7% of Australians identifying a local pharmacy as their preferred location for receiving their COVID-19 vaccinations.

The authorisation process

26. Authorisation provides protection from legal action for conduct that may otherwise breach the competition provisions of the *Competition and Consumer Act 2010* (Cth) (the **Act**). Broadly, the ACCC may grant authorisation if it is satisfied that the benefit to the public from the conduct outweighs any public detriment, including from a lessening of competition. The ACCC conducts a public consultation process to assist it to determine whether a proposed arrangement results in a net public benefit.

Interim authorisation

27. Section 91 of the Act allows the ACCC, where it considers it appropriate, to grant interim authorisation. This allows the parties to engage in the proposed conduct while the ACCC is considering the substantive application.
28. The NPSA requests urgent interim authorisation because the Existing Authorisation is due to expire on 30 September 2021 and there is a need for the Applicants to implement appropriate COVID-19 related supply chain restrictions on Medicines and Pharmacy Products without interruption and the possible need for the Applicants to distribute the COVID-19 Vaccine at the request of the DoH.
29. The NPSA requested interim authorisation due to:
    - the need for the Applicants to be able to continue to implement COVID-19 related supply restrictions for Medicines and Pharmacy Products that were agreed and implemented under the Existing Authorisation without interruption for a period determined by the Applicants;
    - the ongoing urgent need for the Applicants to implement further COVID-19 related supply restriction in respect of these essential products, including if needed, to enable the NPSA (on behalf of the Operating Applicants) to engage with the DoH/any specified third parties as directed by the DoH (i.e. logistics service providers or transport companies/freight forwarders that are currently distributing the COVID-19 Vaccines) to facilitate the efficient and equitable distribution of the COVID-19 Vaccines (including, if needed, booster shots and directly related consumables).

Consultation

30. The ACCC has not conducted a public consultation process in respect of the request for urgent interim authorisation due to the need for the Applicants to have protection should they need to quickly take steps to engage in the Interim Authorised Conduct, in particular the Additional Conduct outlined in paragraph 21, as well as the compelling nature of the public benefits likely to result from the conduct the subject of the request for interim authorisation.
31. The ACCC will conduct a public consultation process on the substantive application for re-authorisation shortly. Details regarding how to make a submission will be available on the ACCC's authorisations public register.

Conditional interim authorisation

32. The ACCC grants interim authorisation for the 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 and/or to facilitate the COVID-19 vaccine roll-out to pharmacies.

33. Interim authorisation is granted for the Applicants 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 between the Operating Applicants except in relation to the NPSA's negotiations with the Government in respect of the Applicants' 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.

34. In particular, in seeking to maintain the integrity of the supply chain, the Applicants are authorised to, if necessary, engage in activities relating to:

    a. sustainable coordinated stock acquisition including liaising with manufacturers/suppliers of Medicines and Pharmacy and/or relevant industry peak bodies regarding purchasing arrangements and importing logistics;

    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 Applicants 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 Applicants, 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.

35. Together, paragraphs 33 and 34 constitute the **Interim Authorised Conduct**.

36. Interim authorisation is granted with the same conditions as the Existing Authorisation, being:

    (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 Authorised Conduct. 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 Medicines Shortages CSOD Supply Restriction (**MSSR**) Working Group;
        - information regarding any meeting or discussion between two or more of the Applicants relating to the Authorised Conduct, including:
            - the attendees at the meeting or discussion;

- the agenda items of the meeting or discussion that are related to the Authorised Conduct;
- any minutes of the meeting or discussion relating to the Authorised Conduct; and
- an overview of topics discussed that related to the Authorised Conduct;

- any changes to the Applicant group.

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

37. The Interim Authorised Conduct is substantially the same conduct and subject to substantially the same conditions as authorised by the ACCC in respect of the Existing Authorisation granted on 17 September 2020, except for the addition at paragraph 34(d).

38. In respect of paragraph 34(d), NPSA submits that this will involve only the NPSA and the Operating Applicants 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 16 above.

39. The conduct proposed by the Applicants in their application for revocation and substitution – which can be found on the ACCC's authorisations public register – includes other amendments. The ACCC has not assessed the effect and implications of the proposed changes as part of the request for urgent interim authorisation. The further changes to the proposed conduct will be considered as part of the ACCC's assessment of the application for re-authorisation.

Reasons for decision

40. The ACCC notes that there is urgency about the request for interim authorisation given the current authorisation expires soon and the potential for the parties to need to respond quickly to assist with an efficient and expedient roll out of the COVID-19 vaccine to pharmacies.

41. In granting interim authorisation, the ACCC considers that:

- substantially the same conduct has been authorised since 31 March 2020 when interim authorisation was first granted. No issues under the Existing Authorisation or the preceding interim authorisation have been raised with the ACCC
- there are likely to be continued significant public benefits given the current unprecedented circumstances, including promoting continued equitable access to Medicines and Pharmacy Products for all Australians
- it is unlikely that interim authorisation will materially alter the competitive dynamics in any market, and markets will be able to return to substantially their current state once the emergency circumstances subside
- to the limited extent that sharing of price information is authorised, competitively sensitive information will only be provided on a confidential basis directly from each Operating Applicant to the NPSA
- The Interim Authorised Conduct, and especially the imposition of supply restrictions, will be subject to oversight from Government and other regulatory bodies, such as the TGA-coordinated Medicines Shortages Working Group and the Department of Health as well as the ACCC through the reporting condition.
- Under interim authorisation, the Applicants must provide regular reports to the ACCC regarding any material developments in relation to the Interim Authorised Conduct. This provides the ACCC with visibility of what the parties are doing under the interim authorisation and can revoke it at any time if it has concerns.

Reconsideration of interim authorisation

42. The ACCC may review the interim authorisation at any time, including in response to feedback raised following this grant of interim authorisation. Any parties that have concerns with the way the Applicants are dealing with them during the period of interim authorisation are encouraged to advise the ACCC.

43. The ACCC's decision in relation to the interim authorisation should not be taken to be indicative of whether or not the final authorisation will be granted.