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Application for Revocation and Substitution of Authorisation AA1000480-1

Lodged by
The National Pharmaceutical Services Association (NPSA) on behalf of its members

6 September 2021

***Please note that all the confidential claims in this application are in bolded red text and in square brackets [ ].**

1. Executive Summary

On 17 September 2020, the ACCC granted authorisation AA1000480-1 to the National Pharmaceutical Services Association (**NPSA**), its current and future members and other Community Service Obligation (**CSO**) Distributors[1] that may in the future wish to participate (together, the **Applicants**). The authorisation was for a period of 12 months, to enable the Applicants to discuss, agree and give effect to any contract, arrangement or understanding between them that has the purpose of:

- facilitating the supply of, and access to, Medicines and Pharmacy Products; and/or
- 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,

so as to address COVID-19 related supply chain challenges (excluding the sharing of any price information),

(**Existing Authorisation**).

Unfortunately, the circumstances relating to COVID-19, including supply chain challenges, have not subsided, and are likely to continue beyond the expiry of the Existing Authorisation period, 30 September 2021. The continued global spread of COVID-19, including the recent emergence of the highly infectious Delta strain, have resulted in abrupt and extended lockdowns in various States and Territories in Australia, with low vaccination rates exacerbating resultant challenges. The COVID-19 pandemic has continued to disrupt in international supply chains and led to instances of resurgence of consumer 'panic buying' of Medicines and Pharmacy Products and recent unprecedented Customer demand to access COVID-19 vaccines (**COVID-19 Vaccines**).

Cumulatively, these factors have resulted in a continuation of supply chain strains and presented challenges for the equitable and timely distribution of Medicines and Pharmacy Products within Australia, in some cases requiring ongoing collaboration between the Applicants and the Government.[2] Maximising the uptake of COVID-19 Vaccines is a critical component in the Government's response to the COVID-19 pandemic, and is a prerequisite to allowing Australians live and travel more freely (and avoid lockdowns).

While national supply shortages of COVID-19 Vaccines have eased in recent weeks following increased COVID-19 Vaccine imports, there is now an urgent need for the Government's current COVID-19 Vaccine strategy to continuously adapt to maximise the distribution of, and uptake of, COVID-19 Vaccines. While it is expected that 700 pharmacies is in a position to administer COVID-19 Vaccines since late August 2021, this remains a small fraction of the 4000 pharmacies that could become potential COVID-19 vaccination sites.[3]

In light of the above challenges, the Applicants are seeking a revocation and substitution of the Existing Authorisation (**New Authorisation**) to continue to engage in substantially the same conduct (on substantially the same conditions) that the ACCC authorised previously.

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[1] CSO Distributors refers to the entities that have entered, or in the future enter, into a deed with the Commonwealth in relation to the CSO Funding Pool and the National Diabetes Services Scheme Distribution Services.

[2] https://www.9news.com.au/national/coronavirus-sydney-panic-buying-resurgence-after-lockdown-announcement/e88e3ee5-21c9-4fe8-b77b-e0da1a411b19 (26 June 2021).

[3] https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/press-conference-in-canberra-on-2-august-2021-about-the-covid-19-vaccination-rollout-queensland-cases-delta-variant-and-phase-1b; https://mckellinstitute.org.au/wp-content/uploads/The-Missing-Link.pdf.

The only substantive addition to the proposed conduct is as follows:

- In the event that the Government/Department of Health (**DoH**) seeks to engage the Operating Applicants (i.e. the four current, and any future, NPSA members that actually undertake distribution of Medicines and Pharmacy Products) through the NPSA, the NPSA seeks to be able to collectively negotiate on behalf of the Operating Applicants as to the terms and conditions upon which the Operating Applicants can distribute the COVID-19 Vaccines (including if needed, booster shots and directly related consumables)[4] to community pharmacies (and any other third party that the Government requires), as part of ensuring the efficient and equitable distribution of such products, in compliance with the *Competition and Consumer Act* 2010 (Cth) (**CCA**). This includes all relevant terms and conditions, including remuneration, for the Applicants to undertake such distribution.

  The proposed conduct also covers the possibility that, if directed by the DoH, the NPSA will collectively negotiate (on behalf of the Operating Applicants) with specified third parties in respect of the abovementioned distribution of COVID-19 Vaccines (including if needed, booster shots and directly related consumables) (i.e. logistics service providers or transport companies/freight forwarders that are currently distributing the COVID-19 Vaccines).

Please note that in the event that the above collective negotiations will eventuate:

- **in respect of the COVID-19 Vaccines (including booster shots and directly related consumables), the Operating Applicants are only proposing to share information, including price related information and other relevant terms and conditions regarding potentially collectively supplying distribution services to the Government;**

- **to the extent that there is a need by the Operating Applicants, in responding to any request 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.[5] No Operating Applicant will share competitively sensitive information with other Operating Applicants or have visibility of other Operating Applicants' competitively sensitive information; and**

- **the above collective negotiations, involve only the NPSA and the Operating Applicants and may be extended to other CSO Distributors as required by the DoH. It does not involve any of the Other Participants as defined in section 2.2 below.**

  That is, the Other Participants will be involved on an 'as needed' basis in respect of all other aspects of the proposed conduct as set out in section 5.1 except for the NPSA's potential collective negotiations with the Government/DoH as described above.

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[4] Please note that references to 'directly related consumables' throughout this application include both COVID-19 vaccination consumables, such as syringes and needles, but also other equipment that may be needed to distribute the COVID-19 Vaccines (and booster shots) in a safe manner, such as Personal Protective Equipment.

The totality of the proposed conduct above and as set out further in this application will enable the Applicants to continue implementing appropriate COVID-19 related supply restrictions on Medicines and Pharmacy Products to ensure the equitable and timely distribution of these products, including the COVID-19 Vaccine, booster shots and directly related consumables to all Australians.

The Applicants submit that the New Authorisation is manifestly in the public interest and that the resultant public benefits clearly outweigh any potential public detriments that may arise. These public benefits include facilitating and promoting a sustainable supply chain in respect of Medicines and Pharmacy Products, amplifying the effectiveness of existing and proposed Government and regulatory bodies' responses to COVID-19, facilitating a safe and orderly environment for employees of the Medicine and Pharmacy Products supply chain and optimising the COVID-19 vaccination distribution model by maximising the uptake rate of COVID-19 vaccination by Australia and ensuring that all Australians receive equitable and timely access to COVID-19 Vaccines (including booster shots and directly related consumables).

In light of the need for the Applicants to be able to continue 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 Vaccines (including, if applicable, booster shots and directly related consumables), the Applicants also seek urgent interim authorisation for the period until the ACCC has granted final authorisation.

The Applicants are also requesting an authorisation period of one year, from the date of the ACCC's final authorisation.

2. The Applicant

2.1 NPSA

The NPSA is a peak industry body representing pharmaceutical wholesalers in Australia. NPSA Members distribute to all pharmacies and major hospitals in Australia. NPSA members work with Federal and State governments, manufacturers, pharmacies, hospitals and other stakeholders to seek to enable Australians enjoy equitable access to affordable and safe Medicines and Pharmacy Products.

Contact details for the NPSA and relevant details for service of documents relating to this authorisation are set out in **Annexure A.**

2.2 NPSA members and Other Participants

The NPSA seeks authorisation on behalf of its members and their related bodies corporate. Current NPSA members are involved in the wholesaling of Medicines and Pharmacy Products to community pharmacies and hospitals.[6]

As at the date of this application, the NPSA members are:

- Australian Pharmaceuticals Industries Limited (**API**);
- Sigma Healthcare Limited (**Sigma**);
- Symbion Pty Ltd (**Symbion**); and

[6] Please note National Pharmacies and API supply to community pharmacies but not to hospital pharmacies.

- Friendly Society Medical Association Limited trading as National Pharmacies (**National Pharmacies**).

The NPSA also seeks authorisation on behalf of any future NPSA members and other current and future CSO Distributors that may in the future wish to participate.

The NPSA also anticipates that there is the potential for:

- Medicines Australia (and its members)(**MA**); and/or
- Generic Biosimilar Medicines Association (and its members) (**GBMA**); and/or
- other manufacturers/sponsors of Medicines and manufacturers of Pharmacy Products,

to be involved as part of the proposed conduct on an 'as needed' basis, (collectively, **Other Participants**)

While the Applicants consider that the scope of the Existing Authorisation already enables them to collaborate with Other Participants on an 'as needed basis', for the avoidance of doubt, the Applicants wanted to explicitly include this cohort as part of the potential participants of the proposed conduct as:

- to the extent that MA may seek a revocation and substitution of its existing authorisation,[7] which enables collaboration between manufacturers and sponsors of Medicines to manage COVID-19 related supply chain issues, there remains a possibility that it does not authorise the conduct sought to be authorised under this application; and

- there have been instances, during the course of the Existing Authorisation, where the Applicants have participated in meetings involving certain MA/GBMA members, DoH and TGA to discuss potential shortages of Medicines and Pharmacy Products and where such Medicine manufacturers/sponsors may need to be involved in collective decisions to most effectively implement COVID-19 related supply chain restrictions. This has occurred recently in respect of collective supply decisions for [redacted] The more explicit references to Other Participants make clear the scope of the proposed conduct, including that collective discussions between these participants and the Applicants will continue to occur on an 'as needed' basis and ensure that it does not expose the Applicants (and NPSA and its members) to potential contraventions of the CCA (the specific provisions of which is set out in more detail in the application).

  As outlined in the Executive Summary above, the more explicit references to Other Participants makes clear that they may be involved in all aspects of the Proposed Conduct as outlined in section 5.1 below save for the NPSA's potential collective negotiations on behalf of the Operating Applicants with the DoH in respect of the COVID-19 Vaccines (including booster shots and directly related consumables).

Please note that, for the purpose of this application:

- references to **Medicines** include all therapeutic goods (both prescription and non-prescription medicines, medical devices and biologicals). Relevantly, it includes COVID-19 Vaccines, booster shots, and other vaccination consumables (including needles, syringes, alcohol wipes, labels etc.);

[7] Medicines Australia, authorisation AA1000486-1, with authorisation granted on a final determination basis on 24 September 2020.

- references to **Pharmacy Products** include all other goods available for sale at community pharmacies (including, but not limited to products such as personal protective equipment, face masks, gloves, hand sanitisers and toilet paper).

NPSA members and their related bodies corporate currently provide a range of services to hospitals and community pharmacies, including, in respect of community pharmacies, operating franchise and membership systems under a number of banners/brands. Purchasers of the Applicants' products include community pharmacies and hospitals (**Customers**). End users of these products are likely to be patients and other individuals (**Consumers**).

The contact details for current NPSA members, other CSO Distributors and a list of MA/GBMA members is also set out in **Annexure A.**

3. Application to be revoked

3.1 The registration number and date of the authorisation which is to be revoked

AA1000480-1

17 September 2020

3.2 Other persons and/or classes of persons who are a party to the authorisation which is to be revoked

The NPSA sought authorisation AA1000480-1 on behalf of its current and future members (including their related bodies corporate), as well as other current and future CSO Distributors who may wish to participate.

3.3 The basis for seeking revocation and substitution

The Existing Authorisation will expire on 30 September 2021. The NPSA, on behalf of the other Applicants outlined in section 3.2, is applying for the Existing Authorisation to be revoked and substituted with an authorisation that will be in force for 1 year from the date of the ACCC's Final Determination.

4. Brief overview of the relevant regulatory frameworks

To assist the ACCC's consideration, the Applicants provide a brief high level overview of the key regulatory frameworks applicable to Medicines (and some of the Pharmacy Products sold at community pharmacies) below. It is important to note that although the regulatory frameworks have various overlays, they all share the key overriding objectives of advancing the equitable, safe, effective and timely distribution of Medicines and Pharmacy Products to all Australians. These regulatory frameworks are described below.

4.1 Community Services Obligation (CSO)

The Australian Government has mandated a set of service standards and compliance requirements that CSO Distributors must adhere to, in order to receive Commonwealth funding for their delivery of Pharmaceutical Benefits Scheme (**PBS**) and National Diabetes Services Scheme (**NDSS**) medicines to the relevant distribution points. The primary objective of the CSO funding arrangements is to ensure that all Australians are provided with ongoing and timely access to PBS and NDSS medicines.

4.2 State/Territory Poisons Legislation

Each State/Territory has legislation restricting and regulating access to the higher risk medicines and poisons listed in the Schedules of the Poisons Standard. This includes pharmacy-only medicines, prescription medicines, and drugs of addiction. The restrictions and regulations vary between jurisdictions, but largely follow the recommended controls in the Poisons Standard.

Wholesalers of medicines scheduled in the Poisons Standard generally require a wholesale supply licence from the relevant State/Territory Health Department and must comply with the requirements set out in the relevant legislation and licences, including the requirements set out in the Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use (**Code**).

The Code is issued by the Therapeutic Goods Administration and includes requirements for matters such as buildings, storage, personnel, stock handling and stock control, transport, complaints management, record-keeping, security measures, and specific provisions dealing with cold chain medicines, controlled drugs and drugs with a high illicit value.

4.3 State/Territory Pharmacy Legislation

State/Territory legislation prohibits persons other than registered pharmacists from owning, operating or controlling a community pharmacy. There are also limits on the number of pharmacies a registered pharmacist can own. Community pharmacies must be approved by/registered with the relevant State/Territory authority and comply with the requirements of the relevant jurisdiction.

4.4 Therapeutic Goods Administration (TGA)

All therapeutic goods (e.g. medicines, medical devices and biologicals) need to be listed, registered or included in the Australian Register of Therapeutic Goods (**ARTG**), unless an exception, exemption or alternative approval applies. A therapeutic good must be listed/registered/included in the ARTG before or at the time it is listed on the PBS Schedule. The national regulatory framework set out in the *Therapeutic Goods Act 1989* (Cth) is intended to ensure acceptable standards are upheld in respect of the quality, safety and efficacy of therapeutic goods.

4.5 Pharmaceutical Benefits Scheme (PBS)

The PBS scheme entitles eligible Australians to receive medicines at a Government subsidised price. For PBS listed medicines, the price that pharmacies pay for the listed medicines is negotiated between the Government and the manufacturer/drug supplier via the Pharmaceutical Benefits Pricing Authority (**PBPA**).

4.6 COVID-19 vaccines

The Australian Government's COVID-19 Vaccine and Treatment Strategy supports early access to, and delivery of, safe and effective COVID-19 Vaccines (including booster shots and directly related consumables), as soon as possible to all Australians.[8] Released in March 2021, the Federal Government's COVID-19 Vaccine Roll-out Roadmap stipulates that

[8] https://www.health.gov.au/resources/publications/australias-covid-19-vaccine-and-treatment-strategy.

multiple parts of the healthcare ecosystem need to be activated to achieve maximum vaccine delivery, including through:[9]

- the Aged Care and Disability Care program;
- General Practitioner led Respiratory Clinics;
- Aboriginal Community Controlled Health Services;
- General practices; and
- Community pharmacies.

Currently there are three TGA provisionally approved COVID-19 Vaccines in Australia:

- **AstraZeneca** - provisionally approved for people 18 years and older; [10]
- **Pfizer/BioNTech** - provisionally approved for people 12 years and older;[11] and
- **Moderna** - provisionally approved for people 18 years and older.[12]

Other COVID-19 Vaccines may be introduced into Australia in the future, including Novavax, pending successful clinical trials and TGA approval. In Australia's National Plan to transition its National COVID-19 Response, indicative targets have been set at ~70% vaccination (2 doses) and ~80% vaccination (2 doses) to trigger significant transition phrases and the relaxation of social restrictions for vaccinated residents.[13] COVID-19 Vaccines are recognised as an important 'shield' to protect Australians against the COVID-19 pandemic.

Understandably, the Government's COVID-19 Vaccine delivery strategy continues to develop, as required, to increase the accessibility of COVID-19 Vaccines for all Australians. This has included the introduction of vaccination through new locations, such as its recent partial roll out to community pharmacies, drive-through vaccination clinics as well as workplace and retail hubs expected to be operating by the end of 2021.[14]

Given the rapid pace of the evolution of the COVID-19 Vaccine strategy, and the complexity of its operationalisation (i.e. having regard to storage requirements and matching Vaccines with relevant consumables, integration of the Government's IT system for recording Vaccine distribution), the NPSA understands that the Government may need to engage with the NPSA, on behalf of the Applicants, on short notice, to implement an equitable distribution of Vaccines to Customers, particularly to community pharmacies, as well as others that will be administering the COVID-19 Vaccines to Australians. [redacted]

[9] https://www.health.gov.au/sites/default/files/documents/2021/03/covid-19-vaccine-rollout-update-on-14-march-2021-covid-19-vaccine-rollout-presentation-on-14-march-2021.pdf.

[10] https://www.tga.gov.au/covid-19-vaccine-astrazeneca-chadox1-s.

[11] https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna-approved-use-individuals-12-years-and-older.

[12] https://www.tga.gov.au/media-release/tga-provisionally-approves-modernas-covid-19-vaccine.

[13] https://www.pm.gov.au/sites/default/files/media/national-plan-to-transition-australias-national-covid-19-response-30-july-2021.pdf. Please note the % targets is based on the eligible population (individuals who are 16 years and older).

[14] https://www.theguardian.com/australia-news/2021/aug/04/updated-national-plan-suggests-80-of-australians-could-be-fully-vaccinated-by-end-of-2021.

[redacted]

As will be set out in more details in section 5.1 below, in the event that the DoH was to engage with the Operating Applicants through the NPSA in respect of the COVID-19 Vaccine roll out (including, if needed, booster shots and directly related consumables), the NPSA and the Operating Applicants seek to be in a position to be able to collectively negotiate the terms and conditions of the distribution arrangements with the Government, including compensation, for providing these services in compliance with the CCA. The NPSA and the Operating Applicants consider that this is likely to result in the most efficient decision-making process to facilitate the delivery of highly critical COVID-19 Vaccines (and if needed, booster shots and directly related consumables).

The proposed conduct also covers the possibility that, if directed by the DoH, the NPSA will collectively negotiate (on behalf of the Operating Applicants) with specified third parties in respect of the abovementioned distribution of COVID-19 Vaccines (including if needed, booster shots and directly related consumables) (i.e. logistics service providers or transport companies/freight forwarders that are currently distributing the COVID-19 Vaccines).

5. The Proposed Conduct

5.1 Proposed Conduct

The Applicants seek authorisation to continue to engage in substantially the same conduct and subject to substantially the same conditions as authorised by the ACCC in respect of the Existing Authorisation.

As foreshadowed in the Executive Summary, the only substantive addition to the proposed conduct involves the NPSA seeking to collectively negotiate (on behalf of the other Operating Applicants) with the Government/DoH regarding the terms and conditions upon which the Operating Applicants can distribute the COVID-19 Vaccines to community pharmacies (and any other third party that the Government requires). This will include discussion regarding remuneration terms for the Operating Applicants to undertake such distribution. Such discussions may also be extended to other CSO Distributors as required by the DoH.

In particular, the Applicants are seeking authorisation 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 Operating Applicants' proposed distribution of the COVID-19 Vaccines (including booster shots and directly related consumables)** that has the purpose of:

(i) 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.

In particular, in seeking to maintain the integrity of the supply chain, the Applicants propose, if necessary, to 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. For the avoidance of doubt, where appropriate, these arrangements include acquisitions of, and determination of

appropriate supply restrictions of, COVID-19 Vaccines (including if needed, booster shots and directly related consumables);

(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 its Operating Applicants, the terms and conditions with the Government/DoH, and/or specified third parties if directed to do so by the Government/DoH, 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.

Relevantly, in respect of (d), this will involve only the NPSA and the Operating Applicants and may be extended to other CSO Distributors as required by the DoH. It does not involve any of the Other Participants as defined in section 2.2 above.

The Other Participants will be involved on an 'as needed' basis in respect of all other aspects of the Proposed Conduct except for the NPSA's potential collective negotiations with the Government/DoH as described in (d) above.

It is proposed that authorisation of the Proposed Conduct is subject to the conditions set out in paragraph 5.2 below.

Together, the conduct referred to in this paragraph 5.1 constitutes the **Proposed Conduct.**

It is important to note that:

- the Proposed Conduct, while sought to be extended, is temporary and is required to optimise the Medicines and Pharmacy Products supply chain during the period in which COVID-19 is affecting supply chain and demand for Medicines and Pharmacy Products;

- the Proposed Conduct is primarily aimed at supporting a sustainable supply chain and maximising the effectiveness of the Government's COVID-19 Vaccine distribution strategy. This will assist Customers and Consumers to equitably access Medicines and Pharmacy Products, including COVID-19 Vaccines. **It will exclude any price coordination behaviour in respect of the sourcing of, or arrangements relating to, the supply of Medicines and Pharmacy Products except where applicable, in the limited context of enabling the NPSA to negotiate on behalf of the Operating Applicants an equitable COVID-19 Vaccine (including if needed, booster shots and directly related consumables) distribution model with the DoH or any specified third parties if directed to do so by the Government/DoH (i.e. logistics service providers or transport companies/freight forwarders that are currently distributing the COVID-19 Vaccines), including remuneration**;

- the Proposed Conduct is voluntary and open in respect of all of the Proposed Conduct other than the conduct outlined in section 5.1(d) above in that any participant (including the NPSA, its current and future members, other CSO Distributors, and Other Participants, can opt 'in' or out of the Proposed Conduct at any time. In respect of the conduct outlined in section 5.1(d) above, the conduct may be extended to other CSO

Distributors as required by the DoH and the Other Participants are excluded from this conduct;

- the NPSA will, if required by the ACCC, continue to notify the ACCC, on a fortnightly basis, of any material developments in relation to the Proposed Conduct, including any material recommendations made by the Working Groups and any changes to the participant group;

- To the extent that there is a need by the Operating Applicants, in responding to any request by the DoH, as part of the negotiations in respect of the proposed distribution of COVID-19 Vaccines (including 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. No Operating Applicant will share competitively sensitive information with other Operating Applicants or have visibility of other Operating Applicants' competitively sensitive information.

- the Proposed Conduct will be subjected to relevant oversight from Government and other regulatory bodies, including the TGA and the DoH; and

- the ACCC can, upon the Applicants' initiative or on its own initiative, revoke the authorisation under section 91B of the CCA should there be a material change in circumstances (e.g. COVID-19 vaccinations, including boosters, are no longer required).

5.2 Proposed conditions

If required by the ACCC, the Applicants propose that authorisation of the Proposed Conduct be subject to substantially the same conditions that applied to the Existing Authorisation. The Applicants' proposed modifications will be <u>underlined</u> below as against the original conditions for the Existing Authorisation for clarity.[15]

(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. 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;

- information regarding any meeting or discussion between two or more of the Participants relating to the Proposed Conduct;
  - the attendees at the meeting or discussion;
  - the agenda items of the meeting or discussion relating to the Proposed Conduct; any minutes of the meeting or discussion relating to the Proposed Conduct; and
  - an overview of the topics discussed that are related to the Proposed Conduct.

- any changes to the participant group, <u>including to the extent that Other Participants or any other specified third parties as directed by the DoH (in respect of the</u>

[15] The conditions relevant to the Existing Authorisation are contained in 5.12 of the ACCC's Final Determination in respect of the application for Authorisation lodged by National Pharmaceutical Services Association dated 17 September 2020.

COVID-19 Vaccine distribution, including if needed, booster shots and directly related consumables)become involved in discussions with the Applicants in respect of any relevant aspects of the Proposed Conduct

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

5.3 Changes to the conduct between the Existing Authorisation and the New Authorisation

As discussed in section 5.1, the Applicants seek authorisation to engage in substantially the same conduct and subject to substantially the same condition as authorised by the ACCC in the Existing Authorisation.

As noted above, the only substantive addition is that in the event that the Government/DoH seeks to engage the Operating Applicants through the NPSA, the NPSA seeks to be able to collectively negotiate on behalf of the Operating Applicants as to the terms and conditions upon which the Operating Applicants can distribute the COVID-19 Vaccines (including if needed, booster shots and directly related consumables) to community pharmacies (and any other third party that the Government requires), as part of ensuring the efficient and equitable distribution of such essential products. Such discussions may include consideration of the appropriate remuneration the Operating Applicants should receive for their involvement in the model and may involve the NPSA collectively negotiating on behalf of the Operating Applicants with any specified third parties as directed by the DoH (i.e. freight forwarders that currently distributes the COVID-19 Vaccines).

The key consequential changes to the Proposed Conduct which arise from this are as follows:

(i) as part of the New Authorisation, the Applicants wish to continue to execute any measures agreed on and implemented by the Applicants under the Existing Authorisation;

(ii) for the avoidance of doubt, clarification that COVID-19 Vaccines, booster shots and directly related consumables are within the scope of the New Authorisation (falling under the definition of Medicines);

(iii) for the avoidance of doubt, clarification that potential participants of the Proposed Conduct include Other Participants affected by COVID-19 related supply chain issues on an 'as needed' basis, including MA/GBMA (and their respective members) in respect of all aspects of the Proposed Conduct outlined in section 5.1 above save for the NPSA's potential collective negotiations with the DoH;

(iv) **there remains no sharing of any pricing information between the Operating Applicants** save for the NPSA seeking to collectively negotiate on behalf of the Operating Applicants 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) in respect of an equitable distribution model for the COVID-19 Vaccines (including, if needed, booster shots and directly related consumables). Such discussions will include the appropriate remuneration for the Operating Applicants' involvement in the model; and

[redacted]

(v) the Applicants request that the New Authorisation is granted for 12 months following the date of the ACCC's Final Determination.

5.4 The relevant provisions of the *Competition and Consumer Act 2010* (Cth) (CCA) which might apply to the Proposed Conduct

The Applicants compete in the acquisition of, and wholesale and retail supply of, all Medicines and Pharmacy Products and associated logistics services.

Consequently, without authorisation, the Proposed Conduct may give rise to contraventions of the CCA, including in particular, sections 45AD, 45AF, 45AG, 45AJ, 45AK, 45, 46(1) and 47(1) of the CCA.

5.5 Rationale for the proposed conduct

The impacts of COVID-19 pandemic that led to the grant of the Existing Authorisation have not substantially improved, and are highly unlike to entirely abate, before the end of the Existing Authorisation period. During the past year, the continued global prevalence of COVID-19 and the emergence of new variants of the virus, including the recent Delta strain, have exacerbated the challenges that necessitated the grant of the Existing Authorisation.

A significant number of COVID-19 outbreaks have occurred since the Existing Authorisation, including in Sydney (December 2020 and since June 2021-present), Melbourne (six lockdowns since March 2020, including July 2021-present). Lockdowns have also occurred in other States including, Queensland, Western Australia and South Australia.

In light of the above, the Applicants have collaboratively addressed significant COVID-19 related supply challenges (and will continue to need to do so), including as a result of:

(i) interruption of supply chains, either due to a COVID-19 outbreak overseas or domestically [redacted] Pursuant to the Existing Authorisation, the Applicants have also been able to take preventative measures in respect of Medicines at risk of short supply, i.e. due to restricted supply from a sponsor. These instances will be detailed further below; and

(ii) 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. For example, there were some Consumer concerns regarding the supply chain conditions of [redacted] There were also unprecedented Consumer demand for particular Medicines due to their potential to be used to treat COVID-19 following press coverage, such as have occurred with [redacted] This will also be detailed further below.

Further, given the urgency of encouraging as many Australians as possible to take up the COVID-19 Vaccines as well as the significant opportunity that exist for the Operating Applicants 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 Applicants) to collectively negotiate a timely and efficient COVID-19 Vaccine distribution model through various locations, including community pharmacies, is essential to facilitate the welfare of all Australians.

In particular, recent developments have indicated that further collaboration between the Applicants in respect of the COVID-19 vaccination roll out is urgently required, including:

- the Commonwealth 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. In addition, the Government has recently announced that 16-39 year olds will be eligible to receive the Pfizer vaccine starting from 30 August 2021;[16] and

- the continual evolution of the Government's COVID-19 vaccination strategy and health advice, including the changing health advice in respect of the AstraZeneca vaccine and the recent approval of the Moderna vaccine. As at August 2021, while the uptake of the COVID-19 vaccination has accelerated, there remains opportunities to increase the vaccination rate which currently remains at ~31% of Australia's total population being fully vaccinated.[17] Prime Minister Scott Morrison has also publicly stated that he only expects Australia to reach Phase 2 of a four-phase National COVID-19 Response Plan in 2022.[18]

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[16] https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/press-conference-in-canberra-on-2-august-2021-about-the-covid-19-vaccination-rollout-queensland-cases-delta-variant-and-phase-1b (3 August 2021); https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/getting-vaccinated-for-covid-19/covid-19-vaccination-program-for-16-to-39-year-olds.

[17] https://www.health.gov.au/sites/default/files/documents/2021/08/covid-19-vaccine-rollout-update-24-august-2021.pdf.

[18] https://www.pm.gov.au/media/national-cabinet-statement-6 (2 July 2021).

The NPSA and the Operating Applicants 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.

[redacted]

A recent report prepared by the McKell Institute in July 2021, titled 'The Missing Link: How Pharmacies Can Accelerate Australia's Vaccine Roll-Out' provides detailed considerations of the various inefficiencies in the current model and how community pharmacies can fill these gaps.[19]

While the Applicants will detail in section 8, the 'Public Benefits' that result from the Proposed Conduct, set out below are details of the value the Operating Applicants can add in terms of further improving the efficiency of this portion 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, rather than [redacted] 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.[20]

[redacted]

As a part of formulating a proportionate and practical response to COVID-19, the Applicants have been engaging with the Government in a proactive and consultative manner. These discussions have resulted in recent Government directives instructing the Applicants to impose appropriate supply restrictions in respect of certain Medicines affected by COVID-19.

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[19] https://mckellinstitute.org.au/wp-content/uploads/The-Missing-Link.pdf (July 2021).

[20] Based on data gathered from Australian Bureau of Statistics, Household Impacts of COVID-19 Survey, June 2021: https://www.abs.gov.au/statistics/people/people-and-communities/household-impacts-covid-19-survey/latest-release#data-download.

In parallel, the Applicants have been, and continue to be, part of various existing regulatory and industry working groups seeking to address COVID-19 developments including the TGA coordinated Medicines Shortages Working Group (**Working Groups**).

As imports account for a significant portion of the Applicants' 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 equitable distribution of these products on a continual basis to all Australians.

5.6 The term of authorisation sought

The Applicants anticipate that there will be a continued need to take urgent industry-wide action to minimise the impact of COVID-19 and Government restrictions to ensure the equitable and timely distribution of Medicines and Pharmacy Products beyond the expiration of the Existing Authorisation, being 30 September 2021.

As noted in the Existing Authorisation application, a significant portion of the Medicines and Pharmacy Products supply chain is reliant on international imports which may take longer to recover from the supply chain disruption precipitated by the pandemic.[21] Further, as set out in the 'Rationale for the Proposed Conduct' section, domestically, the COVID-19 situation remains fragile and volatile, necessitating the need for the Applicants to take collaborative actions at short notice, including in respect of the COVID-19 Vaccine roll out (and the roll out of any subsequent booster shots).

Accordingly, the Applicants seek authorisation to engage in the Proposed Conduct for a period of 12 months from the date of a Final Determination by the ACCC.

6. Persons who may be directly impacted by the Proposed Conduct

The Proposed Conduct may directly impact on the same persons that could have been directly impacted by the Existing Authorisation, namely all participants of the Medicines and Pharmacy Products supply chain and international upstream players who directly supply Medicines and Pharmacy Products into Australia, including:

- Government bodies such as the DoH and TGA, as well as relevant working groups such as the Medicines Shortages Task Force;
- other CSO Distributors;
- international Medicines manufacturers/sponsors and Pharmacy Products manufacturers and distributors;
- domestic Medicines manufacturers/sponsors and Pharmacy Products manufacturers, wholesalers, and other suppliers, including their distribution centre staff;
- medicine manufacturers' associations including MA and the GBMA and their members;
- logistics and transport companies, either as partners of the Operating Applicants, involved in the fulfilment of relevant Medicines and Pharmacy Products orders, or that supply logistics and transport services more generally, with whom the Operating Applicants could potentially partner, including as directed by the DoH;

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[21] See 5.5 of NPSA application for Authorisation AA1000480-1, 27 March 2020.

- community pharmacies, state and private hospitals;
- nursing homes, retirement villages and other aged care providers; and
- Consumers.

Contact details for the relevant persons affected are provided in **Annexure B.**

7. Counterfactual

In the absence of the Proposed Conduct:

- more broadly, in respect of the supply of Medicines and Pharmacy Products, the Applicants may be able to take action following the issuing of an appropriate direction by the Australian Government (i.e. from the DoH/TGA). However, even where such measures and actions are taken by the Applicants individually, concerns remain regarding supply chain issues including logistics, distribution and import of Medicines and Pharmacy Products in Australia.

  While the Applicants will continue to address COVID-19 related supply chain challenges, they will do so in a less effective, timely and efficient manner, with relevant disruptions on international and domestic supply chains likely to continue for a longer period with more frequent wholesale and retail stock shortages/outages

- more specifically, in respect of the distribution of COVID-19 Vaccines (including booster shots and directly related consumables), the Applicants have limited (and passive) involvement in the roll out, with their degree of involvement inhibiting the implementation of a more efficient COVID-19 Vaccine delivery model in respect of the Applicants' distribution points, and in particular, community pharmacies. As discussed in section 5.5 above, there are a number of inefficiencies associated with the current COVID-19 Vaccines delivery model, particularly in respect of community pharmacies. [redacted]

  The continuation of these operational inefficiencies may well act as an unwelcome and prolonged 'bottleneck' to the COVID-19 vaccination roll out in light of the ample (or soon to be) supply of COVID-19 Vaccines (and booster shots).

  A series of bilateral negotiations is likely to result in both delays in each Applicant commencing their involvement in the roll out of COVID-19 Vaccines (including booster shots and directly related consumables) to community pharmacies. More importantly, it may reduce the level of efficiencies that can result from a coordinated distribution rollout, through potentially differentiated terms, including service standards. These factors can have critical implications from a community health perspective, particularly in light of the rapidly deteriorating COVID-19 outbreak situation as observed in NSW since June 2021.

8. Significant public benefits

In its Final Determination concerning the Existing Authorisation,[22] the ACCC accepted that coordination permitted by the urgent interim authorisation had given rise to significant public benefits which were likely to continue if the Existing Authorisation was granted, namely (refer to paragraph 4.17 of the Final Determination):

[22] Final Determination, Application for authorisation AA1000480, lodged by NPSA, dated 17 September 2020.

(a) **facilitating and promoting a sustainable 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);**

Pursuant to the Existing Authorisation, the Applicants have been able to collaborate to facilitate and promote a sustainable supply chain to respond to Customers' demand in a responsible manner.

As discussed above, in light of the global nature of the Applicants' supply chain, COVID-19 outbreaks in other countries could significantly impact on domestic supply.

For example, the Applicants explicitly considered the potential impacts on domestic supply chains for Medicines in May 2021 in light of the Delta COVID-19 outbreak in India.

More recently, in July 2021, the Applicants had to impose supply chain restrictions on due to supply chain pressures in respect of this Medicine arising from the broader use of this Medicine in the treatment of COVID-19 globally. In this instance, the Applicants were able to discuss with

There were also other instances where the Applicants were able to proactively identify Medicines that was at risk of short supply and take preventative measures to smooth any supply chain strain.

For example, in July 2020, the Applicants identified Given the focus on addressing issues during COVID-19, the Applicants proactively worked together to impose appropriate supply restrictions and reassess them on a regular basis. These restrictions facilitated the equitable distribution of this Medicine into community pharmacies nationally.

Also in July 2020, the Applicants proactively identified Given the lifesaving nature of this Medicine, the Applicants were able to promptly agree to manage available supply, which facilitated the equitable distribution of this Medicine into hospitals and community pharmacies nationally.

(b) **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;**

During the Existing Authorisation, the Applicants were able to amplify the effectiveness of existing and proposed Government and regulatory bodies' response to COVID-19, either through:

- **taking action and proactively suggesting appropriate regulatory bodies' responses to COVID-19 -** during July 2021, the TGA noted a rise in consumer demand for particular

[redacted] and

- **amplifying the effectiveness of existing Government responses to COVID-19 by anticipating potential drivers of abnormal demand -** During the Existing Authorisation, there have been instances where media coverage regarding the potential use of a Medicine in the treatment of COVID-19 required prompt collaborations between the Applicants. Two illustrative examples include:

  - [redacted] During April 2020, the Applicants were able to promptly apply supply restriction on the stock that was still available from the manufacturer/sponsor.

  - [redacted] In anticipating potential supply chain shortages, within less than 12 hours of the media coverage, the Applicants were able to work together to assess and apply appropriate supply restrictions as appropriate.

  In addition, the Applicants have regularly discussed other contextual issues on an 'as needed basis' that may necessitate a COVID-19 related supply chain response, including the state of COVID-19 Vaccine distribution, potential 'abnormal ordering' behaviour by Consumers prompted by COVID-19 State lockdowns, and significant COVID-19 outbreak overseas (which may impact domestic supply chain given that a significant portion of the supply chain for Medicines and Pharmacy Products involves overseas manufacturers/sponsors). Collectively, the Existing Authorisation has empowered the Applicants to collaborate effectively and provide a holistic response to COVID-19 related challenges.

(c) **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;**

During the Existing Authorisation, the Applicants' ability to determine whether there was a need, and where there is such a need, to impose timely and appropriate COVID-19 related restrictions on Medicines and Pharmacy Products have directly led to a safer and orderly working environment for employees of the Medicines and Pharmacy Products supply chain, including:

- being able to promptly recalibrate supply chain arrangements following an outbreak in a distribution centre or in another essential facility that forms part of the supply chain. [redacted]

[redacted] However, pursuant to the Existing Authorisation, the Applicants were able to monitor the unexpected COVID-19 outbreaks in the supply chain and reassess the need for collaboration as these supply chain interruptions unfolded; and

- the appropriate management of Medicines and Pharmacy Product supply (including the examples set out in 8d) below, have significantly mitigated any potential 'panic buying' behaviour that may have occurred, and in doing so, facilitate compliance with social distancing requirements as well as fostering a safer working environment for all relevant employees.

(d) promoting continued equitable access to Medicines and Pharmacy Products for all Australians; and

To date, pursuant to the Existing Authorisation, the Applicants have considered and applied COVID-19 related supply chain restrictions in respect of over [redacted] Medicines, which have helped to promote continued equitable access to Medicines for all Australians.

Illustrative examples include:

- [redacted] As a result of the Existing Authorisation, the Applicants were able to promptly discuss and determine appropriate supply restrictions in early April 2020, which directly led to a stabilisation of the supply situation in June 2020. The Applicants were able to reapply appropriate restrictions to manage subsequent shortages during the COVID-19 pandemic.
- [redacted] Given the lifesaving nature of this Medicine, the Applicants were able to work together to agree to manage supply on the products that were available from [redacted] These restrictions enabled the equitable distribution of this Medicine to community pharmacies nationally.

While the Applicants did not need to apply supply chain restrictions for Pharmacy Products within the Existing Authorisation, the Applicants did consider the potential to do so in July 2020, including having discussed:

- [redacted] - the Applicants briefly discussed the supply chain conditions for [redacted] but shared the view that given the numerous sales channels for consumers to access [redacted] and that community pharmacies were not the only supply sources, they did not consider access to masks as posing a substantive supply chain concern requiring collaborative action; and
- [redacted] - the Applicants similarly considered the supply chain conditions for the [redacted] but confirmed there are no shortages of the [redacted] in the market due to COVID-19.

Further, as discussed above, in the instance that there is a disruption to the supply chain (such as a COVID-19 outbreak at a distribution centre or a logistic partners' facility, [redacted] it is essential that the Applicants can collaborate on short notice in respect of Pharmacy Products if and when needed to holistically address COVID-19 related supply chain challenges.

Through the specific examples provided above regarding the collaborative actions that the Applicants were able to take pursuant to the Existing Authorisation, the Applicants' collaborations have successfully ensured the continual and equitable access to Medicines and Pharmacy Products for all Australians.

The Applicants submit that the significant public benefits identified by the ACCC in its Final Determination in respect of the Existing Authorisation have continued since the Existing Authorisation was granted (including as exemplified by the selected examples above) and will continue to be realised if the Proposed Conduct is authorised.

In addition, the Applicant identify an additional public benefit that is inextricably linked to the NPSA's ability to collectively negotiate with the Government in respect of the terms and conditions associated with the negotiation of the COVID-19 Vaccine (including booster shots and directly related consumables), being:

(e) maximising the rate of uptake of the COVID-19 vaccination by Australians and ensured all Australians receive equitable and timely access to COVID-19 Vaccines (and if needed, booster shots) and reduce adverse economic impacts.

As set out in section 5.5 above, the current COVID-19 vaccination distribution model to pharmacies may be improved significantly so as to maximise its effectiveness.

The NPS and the Operating Applicants consider that the only way for the above efficiencies to be achieved in a timely way, is for 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 consider arriving at an agreement with the NPSA on behalf of all of the Operating Applicants in respect of their involvement in the COVID-19 Vaccine (including if needed, booster shots and directly related consumables) roll out. [redacted]

Further, the Operating Applicants can only achieve efficiency and equity of access regarding the COVID-19 Vaccine roll out if they operate on the same contractual terms and incentives (with any difference in incentives/terms likely to lead to delays in negotiation and integration of relevant systems in order to most effectively implement optimal COVID-19 Vaccines distribution systems), such terms to be reflective of the efficiencies that a coordinated roll out is likely to achieve.

Given the potential urgency of such negotiations if they were to eventuate, a collective negotiation context would significantly reduce potential transaction costs (as compared to if the Operating Applicants were to negotiate with the DoH separately for the COVID-19 Vaccine roll out). Moreover, the NPSA and the Operating Applicants consider that the inclusion of equitable contractual terms and incentives, including having the same compensation terms, will be essential to, and is an intrinsic part of, creating and implementing a coordinated, equitable and effective COVID-19 vaccination distribution model.

In addition to the above, the following considerations are also relevant:

[redacted]

[redacted]

- through a coordinated COVID-19 vaccination distribution model (including, if needed, booster shots and directly related consumables), it can reduce the overall freight cost, potential wastage through vaccine expiry (noting the short shelf life of most COVID-19 Vaccine products), enhance the ability of the Operating Applicants to coordinate delivery of directly related consumables with the delivery of the vaccine (i.e. syringes, Personal Protective Equipment etc.) and ensure the efficient disposal of used syringes and Medicine containers associated with the COVID-19 Vaccines (and if needed, booster shots);

- the Government has indicated that the forthcoming 10 million Moderna vaccine doses to be delivered in 2021 will be prioritised to be rolled out through pharmacies and workplace vaccination sites, which increases the importance of pharmacies as a COVID-19 Vaccine distribution channel.[23] The Operating Applicants can leverage operational insights gained through the Existing Authorisation (as well as other vaccine delivery experience such as the flu vaccine) to maximise the effectiveness of this delivery channel; and

- in light of the dire situation of the COVID-19 pandemic, including in NSW which has seen its highest number of cases since the start of the pandemic in March 2020, with an average of over 1200 daily cases as at early September 2021, achieving high vaccination rates is critical to ending/reducing the severity of state lockdowns and possibly opening up international borders. For example, the McKell Institute's modelling has shown that reaching the 80% population vaccination point (which the NSW Premier had indicated as a possible signpost for reducing restrictions) 56 days earlier would avoid $12.3 billion in economic costs.[24]

Not only is the potential prevention of such a significant and adverse economic impact a worthy cause to seek to achieve, the reality is that ~7% of all Australians prefer to get their vaccination through their local pharmacy.[25] Pharmacies can also attract Australians who may not book a COVID-19 Vaccines (and booster shots) proactively but may be prompted

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[23] https://www1.racgp.org.au/newsgp/clinical/no-moderna-access-for-general-practice-in-2021.

[24] https://mckellinstitute.org.au/wp-content/uploads/The-Missing-Link.pdf (July 2021), p5.

[25] https://www.abs.gov.au/statistics/people/people-and-communities/household-impacts-covid-19-survey/latest-release#data-download

to do so while visiting a pharmacy to purchase other essential products, such as Medicines and face masks.

The significant number of pharmacies, in addition to their local customer base, will also make vaccination bookings easier, further encouraging its uptake. The Applicants' capability to fully push out COVID-19 Vaccines (including if needed, booster shots and directly related consumables) through pharmacies, and the significant role that effective utilisation of the pharmacy channel can play in avoiding disastrous economic consequences, cannot be achieved without the Operating Applicants being able to collaborate on fair and equitable terms in respect of a vaccine roll out of unprecedented scale, urgency and significance.

9. No or limited public detriment

The Applicants submit 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.

In its Final Determination of the Existing Authorisation, the ACCC found that the Proposed Conduct is unlikely to significantly impact competition beyond the short term (and consequently have minimal public detriments), having regard to the fact that the Proposed Conduct:[26]

- is a relatively temporary measure to optimise the Medicines and Pharmacy Products supply chain during the COVID-19 pandemic;
- is of limited scope - only applies to arrangements and conduct for the purposes set out in the authorisation;
- excludes any price coordination behaviour except via the NPSA in order to facilitate an efficient distribution model for the COVID-19 Vaccine (including booster shots and directly related consumables);
- is engaged on a voluntary and open basis, in that any Applicant can 'opt out' of the Proposed Conduct at any time, and any future NPSA members, other CSO Distributors and Other Participants can 'opt in' to participate in the Proposed Conduct. In respect of the conduct outlined in section 5.1(d) above, the conduct may be extended to other CSO Distributors as required by the DoH and the Other Participants are excluded from this conduct; and
- there will be appropriate and regular oversight by the ACCC (having regard to the reporting conditions) and from Government and other regulatory bodies (in relation to Medicines).

The Applicants submit that these findings continue to apply in the context of the New Authorisation.

In addition, any public detriment arising from the Proposed Conduct will be further limited as:

- to the extent that there is a need by the Operating Applicants, in responding to any requests by the DoH, as part of the negotiations in respect of the proposed distribution of

[26] 4.28 - 4.34, in particular 4.33 of Final Determination, Application for authorisation AA1000480, lodged by NPSA, dated 17 September 2020.

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 Applicant will share competitively sensitive information with other Operating Applicants or have visibility of other Operating Applicants' competitively sensitive information.

10. Urgent interim authorisation

In light of:

- 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).

the Applicants request that the ACCC prioritises its consideration of this application and provides urgent interim authorisation at the earliest opportunity, and in any event, earlier than within 28 days following the lodgement of this application.

Annexure A - Contact Details of the Applicants

The NPSA and the other Operating Applicants listed below should be contacted at first instance via their legal representatives:

Ayman Guirguis
Competition and Consumer Law Partner, K&L Gates
Level 31, 1 O'Connell Street
Sydney NSW 2000, Australia
[redacted]

Name, address (registered office), telephone number and ABN	Contact person's details
National Pharmaceutical Services Association (**NPSA**) Level 7 167 Macquarie Street Sydney 2000	Elizabeth Cuming Executive Director & Company Secretary [redacted]
Australian Pharmaceutical Industries Limited ABN 57 000 004 320 (**API**) 250 Camberwell Road, Camberwell VIC 3124	Anne Mustow General Counsel & Company Secretary Australian Pharmaceutical Industries Limited [redacted]
Sigma Healthcare Limited ABN 44 004 132 923 (**Sigma**) 3 Myer Place Rowville VIC 3178	Kate Curnow Senior Legal Counsel [redacted] Peter Patterson Interim General Counsel & Company Secretary Sigma Health Pty Ltd [redacted] Gary Woodford Corporate Affairs Manager Sigma Healthcare Ltd [redacted]
Symbion Pty Ltd ABN 25 000 875 034 (**Symbion**) Level 7, 737 Bourke Street, Docklands	Janelle Cain General Counsel

VIC 3008	[redacted]
Friendly Society Medical Association Limited trading as National Pharmacies ABN 69 088 347 602 (**National Pharmacies**) 52 Gawler Pl. Adelaide, SA, 5000	Ryan Klose General Manager [redacted]

Annexure B - Relevant Interested Parties and Other Potential Participants in the Proposed Conduct

Relevant Interested Parties	Contact person's detail
Minister for Health	**Sam Develin** **Senior Adviser** Office of the Hon Greg Hunt MP Minister for Health Minister Assisting the Prime Minister for the Public Service and Cabinet Federal Member for Flinders [redacted]
Department of Health	**Nick Henderson** **Assistant Secretary** National COVID Vaccine Taskforce [redacted] **Adriana Platona** **First Assistant Secretary** Technology Assessment and Access Division [redacted] **Ben Sladic** **Assistant Secretary, COVID-19 Primary Care Response - Pharmacy** [redacted] **Jerome Boland** **Acting Director - CSO Services and Supply** Technology Assessment & Access Division | Health Resourcing Group Pharmacy Branch [redacted]

	[redacted]
Medicines Shortages Task Force	**Adjunct Prof John Skerritt FTSE FIPAA (Vic)** **Deputy Secretary for Health Products Regulation** **Department of Health** (The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control) [redacted]
Therapeutic Goods Administration (TGA)	**Cath Brown** **A/g Director – Medicine Shortages Section** Medicines Regulation Division | Health Products Regulation Group Pharmacovigilance and Special Access Branch Australian Government Department of Health [redacted] **Elspeth Kay** Director Risk Management Section Pharmacovigilance and Special Access Branch [redacted]

Potential Participants in the Proposed Conduct

Other CSO Distributors

Unfortunately, the Applicants do not have specific contact names/details for the two other CSO Distributors currently operating in Australia, being:

- Clifford Hallam Healthcare Pty Ltd (**CH-2**); and

- Barrett Wholesalers Distributors Pty Ltd (**Barrett**).

However, the Applicants are happy to provide general contact details if that assists.

MA Members

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

GBMA Members

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

GBMA Associate Members

- Commercial Eyes Pty Ltd
- IQVIA
- Sinapse Pty Ltd

Declaration by Applicant(s)

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

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

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

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

Signature of authorised person

Executive Director, NPSA

Office held

(Print) Name of authorised person: Elizabeth Cuming

Date: 6th September 2021