

Public Version

Application for Authorisation

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

27 March 2020

1. Application for Authorisation

The NPSA seeks Authorisation on behalf of its current and future members, (together, the **Applicants**), as well as CSO Distributors¹ that may in the future wish to participate, for short-term coordination in respect of the wholesale and retail supply of Medicines and Pharmacy Products. For the purpose of this Application for Authorisation:

- reference to Medicines includes all therapeutic goods (both prescription and non-prescription medicines, medical device sand biologicals); and
- reference to 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).

The Applicants consider that urgent coordinated action in respect of issues affecting the acquisition and distribution of Medicines and Pharmacy Products is the most effective way to promote a stable and workable supply chain which is being significantly disrupted as a result of the COVID-19 pandemic (**COVID-19**).

The proposed conduct is intended to promote continual, fair and equitable access to Medicines and Pharmacy Products for all Australians and is for a period of 12 months from the ACCC's grant of Final Authorisation.

To immediately calibrate the supply chain, the NPSA also seeks urgent Interim Authorisation for the period up until the ACCC has granted Final Authorisation to enable the Applicants to engage in the proposed conduct as soon as possible.

2. Parties to the Proposed Conduct

2.1 Applicant

Name, address (registered office), telephone number and ABN	Contact person's name, position, telephone number and email address	Description of business activities
National Pharmaceutical Services Association (NPSA) Level 7 167 Macquarie Street Sydney 2000	Elizabeth Cuming Executive Director & Company Secretary [REDACTED] [REDACTED]	Peak industry body for Australia's pharmaceutical wholesalers

¹ CSO Distributors refers to the entities that have entered into a deed with the Commonwealth in relation to the CSO Funding Pool and the NDSS Distribution Services.

2.2 Email address for service of documents in Australia

Ayman Guirguis

Policy and Regulatory Partner

K&L Gates

2.3 Other Persons who propose to engage in the Proposed Conduct/Contact details of wholesalers

The following Applicants are current members of NPSA and are involved in the wholesaling of Medicines and Pharmacy Products to community pharmacies and hospitals.²

These Applicants (and their related bodies corporate) 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, as well as, in some cases, having manufacturing facilities for the production and packaging of Medicines. Purchasers of the Applicants' products include pharmacies and hospitals (**Customers**). End users of these products are likely to be patients and other individuals (**Consumers**).

Name, address (registered office), telephone number and ABN	Contact person's name, position, organisation, telephone number and email address
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	Sam Lawson General Counsel & Company Secretary Sigma Healthcare Ltd [REDACTED] [REDACTED]
Symbion Pty Ltd ABN 25 000 875 034 (Symbion) Level 7, 737 Bourke Street, Docklands VIC 3008	Janelle Cain General Counsel [REDACTED]
Friendly Society Medical Association Limited trading as National Pharmacies ABN 69 088	Paul Dugan Principal

² Please note National Pharmacies and API currently only supply to community pharmacies.

347 602 (National Pharmacies) 52 Gawler Pl. Adelaide, SA, 5000 Australia	DMAW Lawyers Pty Ltd [REDACTED] [REDACTED]
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3. The Applicants

3.1 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 government, manufacturers, pharmacies, hospitals and other stakeholders to seek to enable Australians enjoy equitable access to affordable and safe Medicines and Pharmacy Products.

3.2 NPSA members seeking Authorisation

The NPSA seeks Authorisation on behalf of its members and their related bodies corporate. As at the date of the application, the participating members are API, Sigma, Symbion and National Pharmacies. The NPSA also seeks Authorisation on behalf of any future NPSA members and other CSO Distributors.

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**).

5. Proposed Conduct to be Authorised

5.1 Overview and rationale for Proposed Conduct

Supporting Consumers with ongoing, timely, equitable and sustainable access to Medicines and Pharmacy Products is, and should continue to be, a critical health priority in order to responsibly address COVID-19. The Proposed Conduct involves collaborative discussions and arrangements between the Applicants and other participants in the Medicines and Pharmacy Products supply chain which are intended to facilitate equitable Consumer access to these essential products.

Since the World Health Organisation's recent recognition of COVID-19 as a global pandemic, the Australian and State Governments have adopted a range of escalating measures to protect Australians by limiting any further outbreaks.

The rapid escalation of issues relating to COVID-19 have resulted in unprecedented demand from Consumers of Medicines and Pharmacy Products, as well as unusual ordering patterns from some Customers, placing significant pressure on all participants of the Medicines and Pharmacy Products supply chain.

It is important to note that these logistical challenges and proposed solutions are not unique. Other suppliers, both of medical equipment and grocery and household goods have also formed the view that coordinated action between suppliers is essential to stabilise the relevant supply chains.³

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 that the Applicants impose appropriate supply restrictions as a part of delivering a responsible and evolving emergency management strategy during COVID-19. In parallel, there are various existing regulatory and industry working groups seeking to relevantly address COVID-19 developments, including the TGA coordinated Medicines Shortages Working Group and the Department of Health's Medicine Shortages Working Party (which the NPSA is a contributor to) (**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 continued and equitable distribution of these products to all Australians.

The Proposed Conduct would enable the Applicants to seek to address these outstanding concerns in an expeditious manner, in urgent circumstances, in parallel with, or to enable the optimal implementation of, Government decisions. It would allow the Applicants to optimise their supply chains to better meet the CSO objectives of providing broad access to essential Medicines for all Australians, in the context of the pandemic's unprecedented challenges.

5.2 The Proposed Conduct

The Applicants propose, if necessary, to engage in a number of coordinated activities with the primary aim of assisting Customers and Consumers with continual access to Medicines and Pharmacy Products in an equitable and timely manner for the duration of COVID-19.

However, as the ACCC may appreciate, the rapid and uncertain development of COVID-19, coupled with a current absence of a long-term direct health solution (i.e. vaccine) means that the coordinated conduct the Applicants may engage in is necessarily flexible and dynamic. It is therefore not possible to envisage all of the types of coordinated conduct that the Applicants may need to engage in to appropriately calibrate their supply chains to respond to the unprecedented consumer demand.

The Applicants seek Authorisation to have discussions, enter into or give effect to arrangements between them, or engage in conduct (excluding the sharing of any price-information):

- that have the purpose of facilitating the supply of, and access to, Medicines and Pharmacy Products; and/or
- that have the purpose of facilitating the supply of, and access to, Medicines and Pharmacy Products, including co-operating in relation to any conduct which has been recommended by the Australian Government and/or Working Groups.

In seeking to maintain the integrity of the supply chain, the Applicants propose, if necessary, to engage in activities relating to:

³ See supermarkets: *Coles Group on behalf of itself and participating supermarkets* application for Authorisation (20 March 2020, with Interim Authorisation granted on 23 March 2020); see also medical technology companies: *Medical Technology Association of Australia* application for Authorisation (24 March 2020, with Interim Authorisation granted on 25 March 2020).

- a) sustainable coordinated stock acquisition, including liaising with manufacturers/suppliers of Medicines and Pharmacy Products and/or relevant industry peak bodies regarding purchasing arrangements and importing logistics;
- b) coordinate inventory management strategies, such as stock reservation, including allocation of supplies of Medicines and Pharmacy Products to Customers; and
- 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 them to pharmacies, using pharmacies as a central delivery point and sharing of distribution centre resources, and when appropriate, collaborating with Customers and other haulage providers.

Together, the conduct referred to in this paragraph 5.2 constitutes the **Proposed Conduct**.

It is important to note that:

- the Proposed Conduct is a temporary and urgent measure to optimise the Medicines and Pharmacy Products supply chain during this critical period.
- the Proposed Conduct is primarily aimed at smoothing supply chain issues to support a practical and sustainable supply chain. This will assist Customers and Consumers to equitably access Medicines and Pharmacy Products. **It will exclude any price coordination behaviour** in respect of the sourcing of or arrangements relating to the supply of Medicines and Pharmacy Products;
- the Proposed Conduct is voluntary and open. Any Applicant can opt out of the Proposed Conduct at any time, and any future NPSA members and other CSO Distributors can 'opt in' to participate in the coordinated conduct;
- the NPSA will notify the ACCC regarding any material developments in relation to the Proposed Conduct as the COVID-19 position evolves, including any material recommendations made by the Working Groups and any changes to the Applicant group; and
- accordingly, the Proposed Conduct will be subjected to relevant oversight from Government and other regulatory bodies.

5.3 Urgent Interim Authorisation Required

In light of the above COVID-19 developments, the Applicants seek urgent Interim Authorisation to engage in the Proposed Conduct as soon as practicable. Recent media articles have shed further light on the risks to Consumers and sections of the supply chain being unable to equitably access Medicines and Pharmacy Products.

Government warnings and directions empowering the Applicants individually to make discretionary principled decisions regarding the supply of Medicines and Pharmacy Products in these exceptional circumstances have not been sufficient to address the ongoing pressure on the relevant supply chains. As a result, the Applicants consider that urgent Interim Authorisation is required to seek to:

- assist the Applicants to promptly understand any significant changes in respect of the supply of, or demand for, Medicines and Pharmacy Products and addressing such operational challenges in a coordinated manner at both the wholesale and retail level;

- mitigate or avoid excessive strain on the wholesale Medicines and Pharmacy Products supply chains, including in manufacturing, distribution centres, transport and other logistical arrangements involved in the fulfilment and delivery of orders to Customers;
- facilitate the Applicants' ongoing efforts to smooth supply chain issues (in terms of matters such as production/inventory volume, frequency of distribution) which may result in stock shortages or outages, and appropriately supporting Customers to maintain sufficient stock levels to meet volatile demand;
- facilitate the safety of community pharmacy and hospital dispensary staff, including by alleviating staff workload and congestion at community pharmacies (which can assist to limit COVID-19 outbreaks); and
- alleviate current community concerns about the availability of Medicines and Pharmacy Products.

5.4 Provisions of the CCA potentially applicable 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 *Competition and Consumer Act 2010* (Cth) (**CCA**), including in particular, sections 45AD, 45AF, 45AG, 45AJ, 45AK, 45, 46(1) and 47(1) of the CCA.

5.5 Duration of Authorisation

The Applicants propose to engage in coordinated behaviour on a temporary basis to promote continual, equitable and fair access to all Australians of Medicines and Pharmacy Products for the duration of COVID-19.

As noted previously, 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.

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. However, if the supply chain recovers from COVID-19 disruptions earlier than expected, the Applicants intend to cease the Proposed Conduct at that time and will notify the ACCC accordingly.

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

The Proposed Conduct is likely to directly impact on all participants of the Medicines and Pharmacy Products supply chain and international upstream players who directly supply Medicines and Pharmacy Products into Australia, including:

- international Medicines and Pharmacy Products manufacturers and distributors;
- domestic Medicines and Pharmacy Products manufacturers, wholesalers, and other suppliers, including their distribution centre staff;
- logistics and transport companies involved in the fulfilment of relevant Medicines and Pharmacy Products orders;
- community pharmacies, state and private hospitals;

- nursing homes, retirement villages and other aged care providers; and
- Consumers.

7. Counterfactual

As noted in section 5.1, the Australian Government has already directed the Applicants to impose supply restrictions to address recent surges in demand for Medicines and Pharmacy Products.

However, as discussed in section 5.1, even with the current measures and actions taken by each Applicant individually, there remains concerns regarding supply chain issues including logistics, distribution and import of Medicines and Pharmacy Products in Australia.

Without the Proposed Conduct, the Applicants will continue to address COVID-19 challenges but 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.

8. Significant public benefits

The Proposed Conduct is expected to generate significant public benefits by positioning the Applicants to adopt a proactive approach to address current supply chain challenges and alleviate heightened levels of consumer anxiety regarding the availability of Medicines and Pharmacy Products, particularly for those most in need.

The key public benefits arising from the Proposed Conduct are that it will:

- facilitate and promote a sustainable and strong supply chain to respond to Customers' demand in a responsible manner (especially for critical life-saving Medicines, as well as Pharmacy Products which are in short supply);
- amplify the effectiveness of existing and proposed Government and regulatory bodies responses to COVID-19 in attempting to smooth any supply chain strain;
- facilitate a safe and orderly environment for Medicines and Pharmacy Products supply chain employees, such as distribution centres, pharmacies and hospital staff to work in. This can in turn facilitate the enforcement of social distancing rules, limiting further outbreaks of COVID-19 and employment opportunities for the relevant supply chain staff; and
- promote continual equitable access to Medicines and Pharmacy Products for all Australians.

9. No or limited public detriment

The Applicants assert that the public benefits arising from the Proposed Conduct will outweigh any public detriments as:

- the primary aim of the Proposed Conduct is to assist the Applicants to address the supply chain issues arising from unprecedented Customer and Consumer demand, ultimately facilitating continual equitable access to Medicines and Pharmacy Products;

- The Proposed Conduct **excludes any price coordination behaviour** between the Applicants and the Applicants will otherwise continue to compete with each other in respect of price and service quality and offerings;
- the duration of the Proposed Conduct is no longer than necessary. The Applicants have applied for a 12 month period. However, if the COVID-19 situation improves and international and domestic supply chains are restored prior to that period, the Applicants intend to cease engaging in the Proposed Conduct at that time;
- the Proposed Conduct is conducted on a voluntary, 'opt in, opt out' basis so that any future NPSA members and other CSO Distributors can join and any Applicant can cease their participation in the Proposed Conduct at any time;
- NPSA will keep the ACCC informed of all material developments in the Proposed Conduct, including any changes to the Applicant group; and
- the Proposed Conduct will also be subjected to oversight by the relevant Government departments and aforementioned health regulatory bodies.

Declaration by 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 & Company Secretary

Office held

(Print) Name of authorised person

Elizabeth Cuming

The 26th day of March 2020