



**The Pharmacy
Guild of Australia**

**Submission to Productivity
Commission Study of Vulnerable
Supply Chains**

April 2021

Guild Recommendations

1. Through the Pharmacy Guild of Australia, community pharmacists must be formally recognised for inclusion in emergency, disaster and pandemic planning and preparedness by governments, as well as response and recovery measures impacting community pharmacies.
2. The Therapeutic Goods Administration should continue the Medicine Shortages Working Party on a permanent basis for the coordination and implementation of management strategies to maintain equitable and reliable access to pharmaceuticals by Australians with the capability to escalate activities during a crisis.
3. Regarding new or altered PBS policies or regulations, the Australian Government should:
 - a. Maintain a strong, competitive generics medicine sector.
 - b. Consider as a high priority the implications on the supply chain, particularly at times of supply chain stress, to ensure that the risk of disruption to medicine access for the Australian community is minimised.
 - c. Consider the implications on the competitiveness of Australia in the global medicines market, ensuring that the policies are adaptive and do not increase the risk of Australia being disproportionately affected at times of global shortage of individual medicines.
 - d. Ensure that PBS policies regarding supply guarantees, pricing and distribution is conducive to maintaining stock availability and equitable supply and distribution.
 - e. Consider streamlining the process for pharmaceutical price increases (while ensuring those price increases do not impact on patients).
 - f. Enable pharmacists to work to full scope of practice through autonomous therapeutic substitution to manage either national or regional medicine supply disruptions and to optimise patient care.
 - g. Enable the pharmaceutical supply chain to work together on an ongoing basis and not just during an emergency, to plan for and manage supply issues and ensuring equitable distribution, including through amendments to distribution arrangements and the Community Services Obligation (CSO).
4. National stockpiling requirements should be reviewed and aligned, including:
 - a. Routinely reviewing the lists of critical medicines maintained and monitored by the Therapeutic Goods Administration (TGA) and aligning the National Medical Stockpile with these lists.
 - b. Improving transparency and awareness by publishing the list of pharmaceuticals included in the National Medical Stockpile
 - c. Funding sponsors to maintain a minimum level of stock within their pre-distributor facilities of 'Medicines where interrupted supply could result in serious health consequences'.
 - d. Coordinating management of stockpiling of critical medicines at the pre-distributor stage to ensure equitable distribution around the country to pharmaceutical distributor warehouses and ultimately to community pharmacies and the Australian population.

Guild Recommendations

5. Items from the National Medical Stockpile such as Personal Protective Equipment should in future be distributed to community pharmacies and clinics through normal established distribution channels such as medical or pharmaceutical distributors and not through Primary Health Networks (PHNs).
6. There should be greater investment by governments in technology and data analytics to better manage pharmaceutical supply disruptions, including more timely identification of potential risks and implementation of management strategies along the supply chain.
7. The Australian Government as the monopsony buyer of subsidised pharmaceuticals on the Pharmaceutical Benefits Scheme (PBS) should address lack of transparency in supply chains by mapping and monitoring supply chains.

1. Introduction

The Pharmacy Guild of Australia ('the Guild') welcomes the opportunity to contribute to the Productivity Commission study of Vulnerable Supply Chains. Pharmaceuticals are essential to the wellbeing of many Australians and ultimately, the highly accessible and well distributed network of community pharmacies are the point of access for patients for most pharmaceutical supplies and hence an important element of the global pharmaceutical supply chain in Australia.

Our submission focusses on vulnerabilities of the pharmaceutical supply chain in Australia, and particularly the in-country availability, distribution and delivery of pharmaceuticals and the impact on community pharmacies and their patients – "Australians' wellbeing". Our submission highlights efforts and progress that has been made to limit and mitigate the risk and impact of pharmaceutical supply chain problems on Australians and make recommendations for further changes.

For this submission, the term pharmaceuticals is used for the products that are typically available to the Australian population through community pharmacy. This includes:

- Prescription medicines.
- Over-the counter (OTC) medicines.
- Complementary and alternative medicines (CAM).
- Therapeutic devices such as needles, syringes, and testing strips for people with diabetes as well as first aid supplies, braces, supports and patient aids.
- Disinfectant products such as hand sanitisers and wipes.

Australia has in place several schemes that subsidise the supply of pharmaceuticals to the public through community pharmacies, including:

- The Pharmaceutical Benefits Scheme (PBS).
- The Repatriation Pharmaceutical Benefits Scheme (RPBS).
- The National Diabetes Services Scheme (NDSS).
- The National Immunisation Program (operating in the jurisdictions of ACT, VIC, and WA).

Pharmaceutical supplies in general and medicines specifically are the most widely used health intervention in Australia. In 2019-20, over 304 million PBS prescriptions were dispensed¹ and an estimated 28 million NDSS items distributed during the Sixth Community Pharmacy Agreement. Medicines are used for a range of health conditions and many are lifesaving. Some are used as episodic, short-term treatments for acute conditions (e.g. antibiotics) while others may be used regularly on an ongoing basis to manage chronic conditions such as cardiovascular diseases, diabetes, obstructive respiratory diseases, or mental health conditions.

The World Health Organisation maintains a list of essential medicines which has been updated every two years since 1977, and now also includes a list of essential medicines for children.² The Therapeutic Goods

¹ PBS Expenditure and Prescriptions Report 1 July 2019 to 30 June 2020.

² <https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists>

Administration (TGA) also maintains a Medicines Watch List³ which is derived from a consensus review of existing state hospital Emergency and Life Saving Drug Lists and the World Health Organisation's Model List of Essential Medicines marketed in Australia.

Community pharmacies are the primary interface for the Australian public to access pharmaceutical products and consists of over 5,800 pharmacies distributed throughout the country, including rural and remote locations. Australians—including especially older and disadvantaged consumers—have a very high level of access to community pharmacy. In the capital cities, 97% of people have access to at least one pharmacy within a two-and-a-half-kilometre radius, while in the rest of Australia, 66% of people have similar access.

2. An overview of the global pharmaceutical supply chain for Australia

The pharmaceutical supply chain

In simplest terms, the pharmaceutical supply chain in Australia consists of:

- Manufacturers – both domestic and overseas based companies responsible for manufacturing the pharmaceutical in either Australia or overseas. According to IBIS World there are 452 manufacturing enterprises in Australia in 2020-21.⁴
- Sponsors – the company responsible for registering the pharmaceutical for marketing in Australia and where relevant, for listing the pharmaceutical for subsidisation under a Government funded scheme (e.g. PBS) – note that the manufacturer and sponsor may or may not be the same company.
- Pre-Distributors – responsible for the storage of pharmaceuticals after manufacture in Australia or arrival from overseas as well as the supply to the pharmaceutical distributors or wholesalers.
- Distributors – places orders with the pre-distributor and responsible for the distribution and delivery of pharmaceuticals to the consumer interface which for the purposes of this paper are community pharmacies. Eligible entities, known as Community Service Obligation (CSO) Distributors, fall under the CSO Funding Pool arrangements and receive Commonwealth payments for supplying PBS and NDSS items to community pharmacies⁵.
- Community pharmacies – responsible for the supply of the pharmaceutical to the consumer end-user along with counselling and support for its optimal and safe use. Ultimately, the highly accessible and well distributed network of community pharmacies are the point of access for patients for most pharmaceutical supplies and hence an important element of the global pharmaceutical supply chain in Australia.

³ <https://www.tga.gov.au/medicine-shortages-information-sponsors-suppliers>

⁴ IBIS World, *Pharmaceutical Product Manufacturing in Australia*, December 2020. IBIS World define an enterprise as “A division that is separately managed and keeps management accounts. Each enterprise consists of one or more establishments that are under common ownership or control”.

⁵ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

There are very strict Commonwealth and State/Territory laws which regulate all aspects of the pharmaceutical supply chain, including restrictions on access such as the requirement for a prescription for a medicine.

The manufacture and distribution of pharmaceuticals in Australia is undertaken in accordance with principles and procedures set out by the TGA, and in particular:

- Good Manufacturing Practice.⁶
- Good Wholesaling Practice.⁷

The quantity of pharmaceuticals available at any one time is dependent on the amount in stock across the supply chain. This is influenced by several factors but generally, a pre-distributor may have several months stock and a distributor holds a moderate amount of stock (e.g. 2-4 months). A community pharmacy holds a lower amount of stock (e.g. 1 to several weeks), complementing the monthly billing cycle of its suppliers. Factors that determine the stock on-hand for a community pharmacy but would also apply along the supply chain include:

- Access restrictions e.g. whether a medicine requires a prescription or not.
- Usage – larger quantities are typically maintained for high-volume turnover.
- Cost – smaller volumes likely to be held for higher cost items, particularly by small businesses such as a community pharmacy.
- Wastage – the expiry dates for pharmaceuticals can determine what stock is kept within the different elements of the supply chain e.g. influenza vaccines are seasonal and have shorter expiry than medicines in general.
- Storage requirements – some products require storage in safes (e.g. opioids) or require refrigeration and the specialised storage capacity can determine the amount of stock on hand.

The Guild understands that sponsors require a lead time of about 6 months to fulfil a manufacturing order, and that the capability to urgently bring forward orders is limited and influenced by a number of factors, not the least being the pricing policy of the country of the order. General economic principles would indicate that priority is given to companies that pay more for the same product.

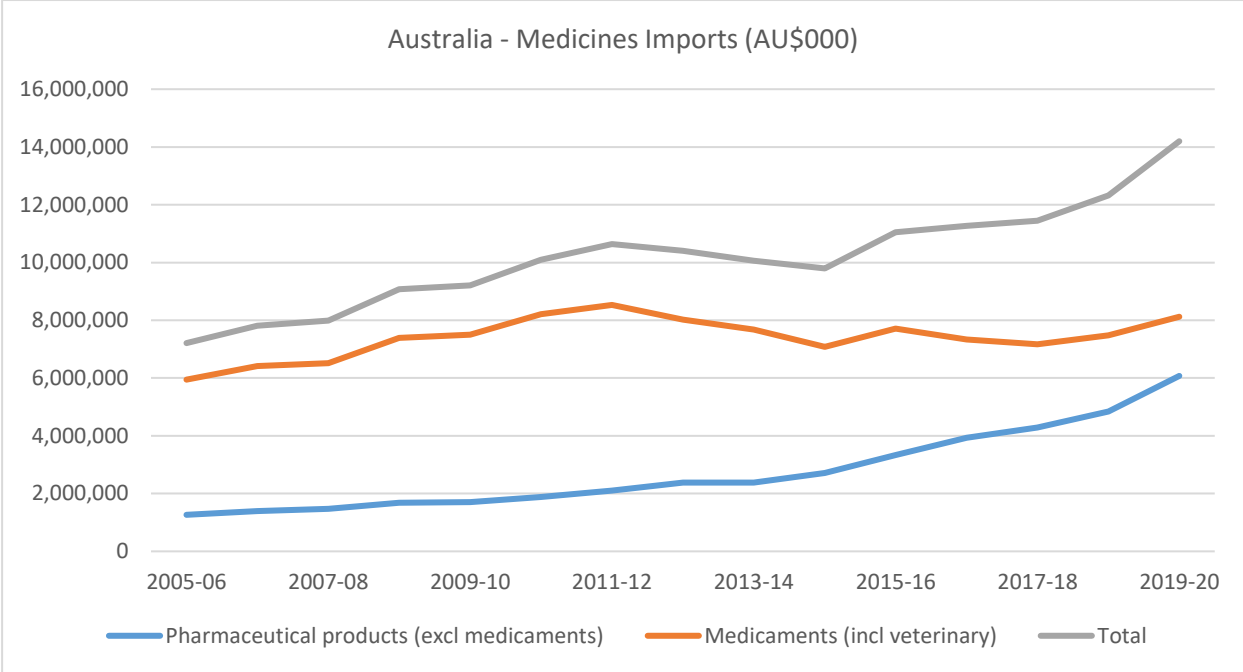
Global supply linkages

There is no one superior classification of trade statistics that comprehensively show the global nature of the pharmaceutical supply chain in Australia. Moreover, definitions of what constitutes a pharmaceutical product varies by classification. Chart 2 shows 'medicine' imports using one such classification – the Standard International Trade Classification (SITC) which includes the categories 'pharmaceutical products' and 'medicaments'. The chart shows the increase in the value of imports to Australia driven in recent years primarily by a rise in pharmaceutical products. Total imports have grown from \$7.2 billion in 2005-06 to \$14.2 billion in 2019-20.

⁶ <https://www.tga.gov.au/good-manufacturing-practice-overview>

⁷ <https://www.tga.gov.au/publication/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8>

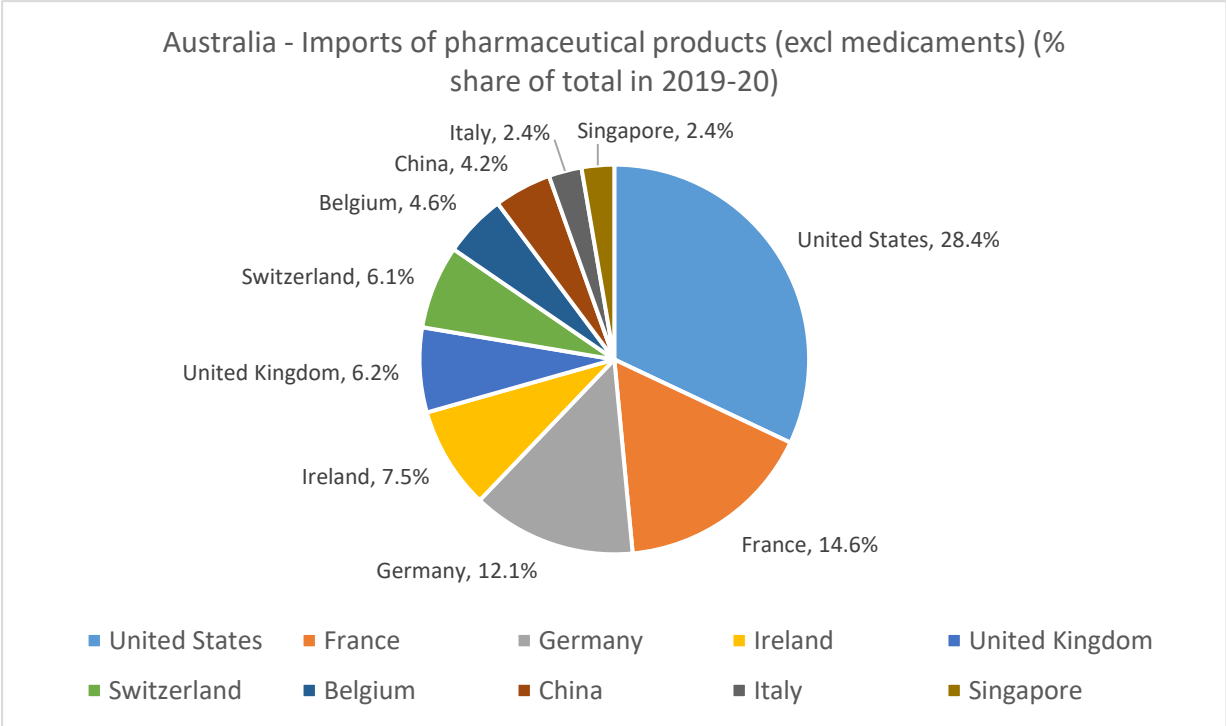
Chart 2: Medicines imports to Australia

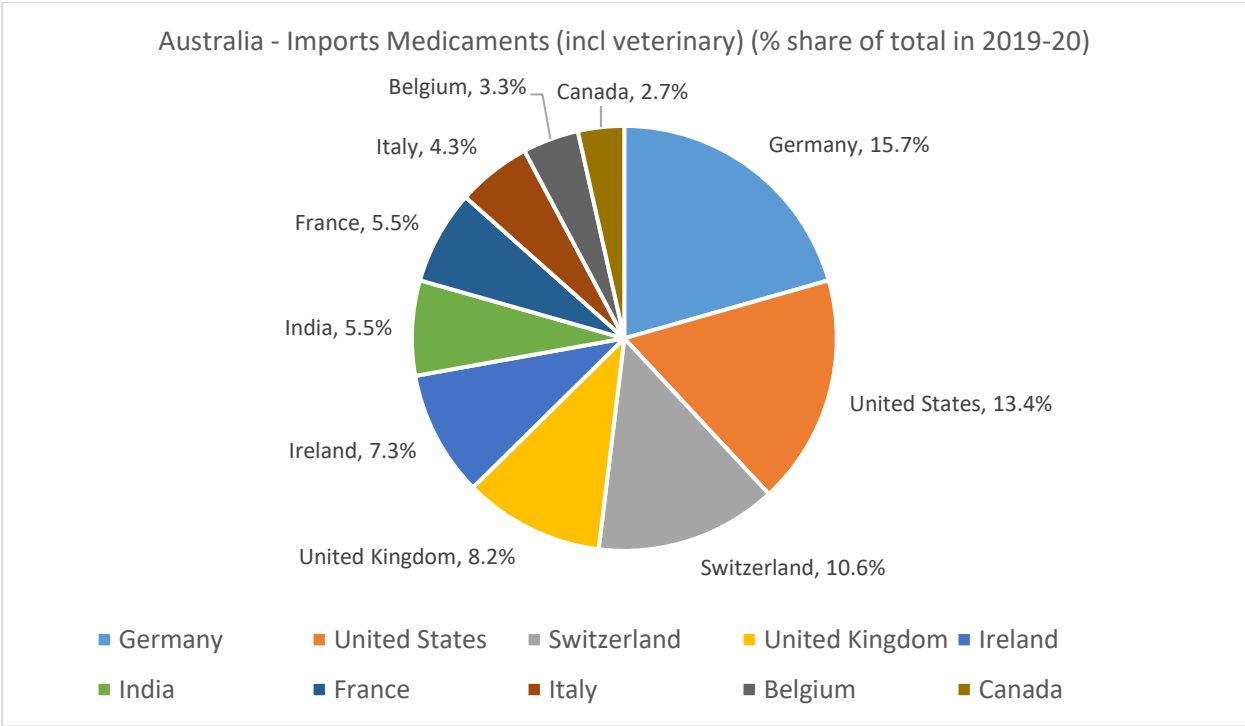


Source: Trade, investment and economic statistics, Department of Foreign Affairs and Trade.

Chart 3 shows medicines imports to Australia by dollar value in 2019-20 by top ten source nations. The top panel in the chart shows that for pharmaceutical products, the top ten source nations accounted for 88.6 per cent of all imports of pharmaceutical products. The bottom panel in the chart shows that for medicaments, the top ten source nations accounted for 76.4 per cent of all imports of medicaments. In both cases, imports are dominated by the United States and European countries.

Chart 3: Medicines imports to Australia by \$ value in 2019 - top ten source nations



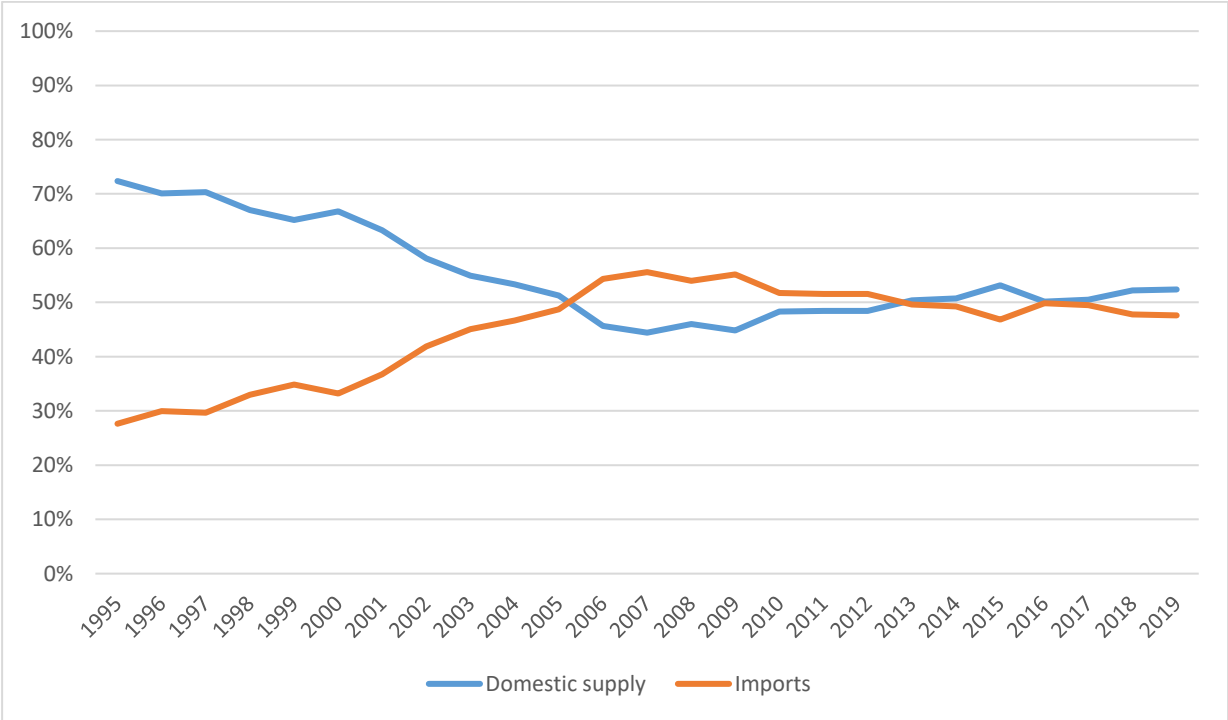


Source: Trade, investment and economic statistics, Department of Foreign Affairs and Trade.

The reliance on medicine imports relative to domestic supply has also changed over time for Australia. Chart 3 shows this using another classification – the supply-use product group classification (SUPG) from the Australian Bureau of Statistics (ABS) where medicines are defined as ‘human pharmaceutical and medicinal products’.

Chart 4 shows that the imports share of total supply grew relative to domestic supply over the decade 1995 to 2005, and in recent years imports have averaged around 48% of total supply.

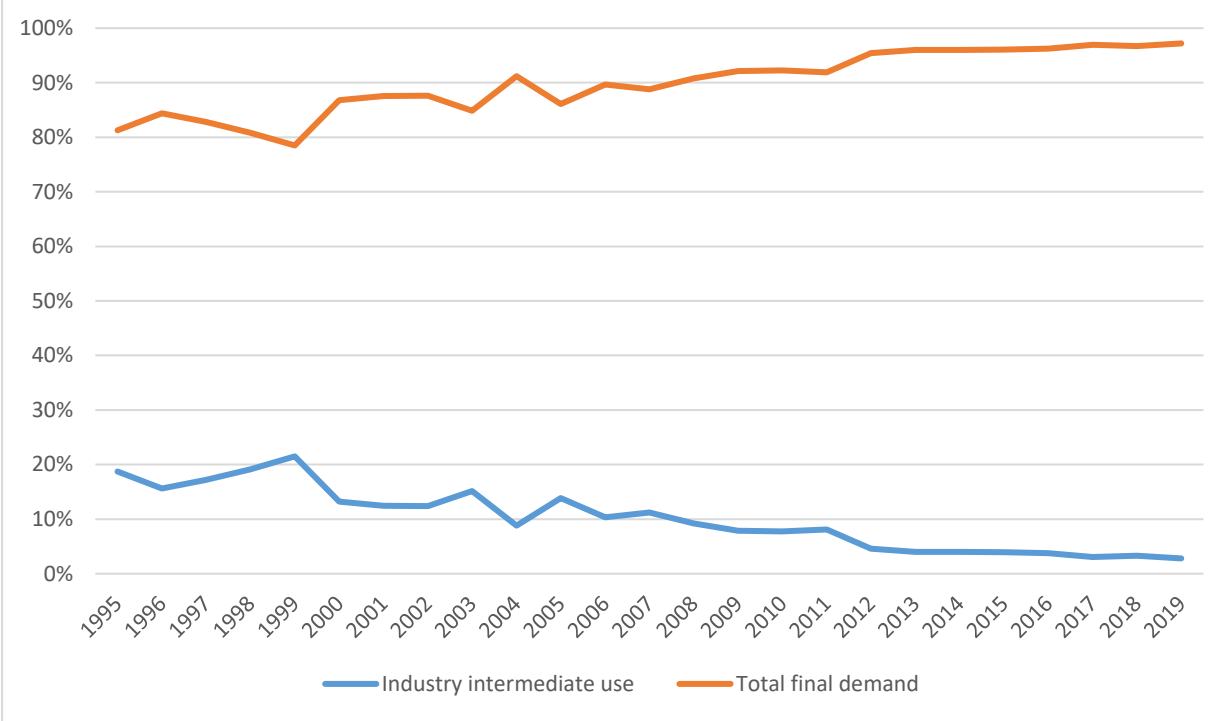
Chart 4: Domestic supply versus imports of medicines to Australia - per cent share of total supply



Source: Australian Bureau of Statistics. Based on data in \$AU in basic prices.

Using the same ABS classification, Chart 5 shows human pharmaceutical and medicinal products supplies are predominantly used in final demand – such as final household and government consumption expenditure rather than used as intermediate inputs to production by industries.

Chart 5: Intermediate versus final use of human pharmaceutical and medicinal products in Australia - per cent share of total supply



Source: Australian Bureau of Statistics. Based on data in \$AU in purchasers’ prices.

While human pharmaceutical and medicinal products supplies are predominantly used in final demand, basic chemical manufactured products are a significant intermediate input to production by human pharmaceutical and medicinal products manufacturers in Australia. For example, in 2018-19 the chemical manufacturing industry in Australia (of which human pharmaceutical and medicinal products manufacturers is one component) accounted for 14 per cent of total intermediate usage of basic chemical manufactured products across all industries.⁸ Furthermore, of the total supply of basic chemical manufactured products in 2018-19, 43 per cent were imported. Of various chemical products imported into Australia in 2019-20, a few nations such as China tend to dominate as illustrated in Table 1.

⁸ The ABS supply-use tables do not split the chemicals manufacturing industry into its components of which human pharmaceutical and medicinal products manufacturing is one component. The intermediate usage statistics are based on purchasers’ prices.

Table 1: First and second largest sources of imports of basic chemical manufactured products

	Share of total value of imports to Australia in 2019-20 (%)
Carboxylic acids & derivatives:	
China	43%
United Kingdom	4%
Nitrogen-function compounds:	
China	47%
India	12%
Organo-inorganic compounds:	
China	55%
Germany	12%
Other organic chemicals:	
China	28%
United States	18%

Source: Trade, investment and economic statistics, Department of Foreign Affairs and Trade.

3. Factors that make Australia's pharmaceutical supply chain vulnerable

Australia accounts for only around 1% of the global market for pharmaceuticals and the vulnerability of the supply chain depends on several factors, including:

- Head office manufacturing decisions (priority markets, reference pricing).
- Trade policies (restrictions / tariffs / agreements).
- Natural disasters / pandemics / border controls.
- Government subsidisation schemes (e.g. PBS), including pricing policies.
- Operation and scale of domestic manufacturers of global companies.
- Lack of (but improving) timely and co-ordinated information on shortages.
- Exclusive distribution arrangements between a manufacturer and a single distributor.
- Equitable distribution of available stock, to distributors and community pharmacies; especially important for products with limited availability through a supply disruption.

Disruption to pharmaceutical supplies in general and medicine shortages in particular has become a constant and ongoing problem in Australia.^{9,10} It has led to the TGA implementing a Medicine Shortages Information Initiative and website¹¹, launched in 2014, after which further policy and regulatory changes have been made to assist in more timely identification and management of supply disruptions.

⁹ <https://pubmed.ncbi.nlm.nih.gov/27383246/> 2016

¹⁰ <https://www.nps.org.au/australian-prescriber/articles/medicine-shortages-in-australia-what-are-we-doing-about-them> 2018

¹¹ <https://apps.tga.gov.au/prod/MSI/search/>

Manufacturing Issues

The TGA highlights that manufacturing issues are a major contributing factor to medicine shortages.¹² Shortages may arise due to several reasons including:

- Problems sourcing the active pharmaceutical ingredient. Disruptions in the supply of raw or bulk materials are frequently responsible for drug shortages.¹³ These shortages are especially problematic when a primary or sole-source supplier of a raw material delays or discontinues production, affecting multiple manufacturers and global supply.

In addition to the supply of active pharmaceutical ingredient, consideration also needs to be given to the integrity of supply of ancillary agents to produce a pharmaceutical, including devices for many medicines. Injectable medicines require ampoules or vials as well as needles and syringes for injection. There can be very specific devices for self-administered injections such as pens for insulins or adrenaline auto-injectors. Other ancillary agents for medicines with special modes of administration include the ingredients for aerosol medicines (e.g. salbutamol inhalers).

- Unexpected increase in demand – Companies market medicines in Australia based on anticipated demand, with lead in times for ongoing manufacturing and transport. Many medicine shortages arise due to an unexpected increase in demand, often due to a supply disruption for another brand. The impact depends on the market share of the initial brand experiencing the shortage and the available stock levels in the supply chain and the ability to bring forward any manufacturing orders.
- Product Discontinuation – Companies may discontinue the marketing of a pharmaceutical in Australia due to commercial reasons, which may be affected by factors such as pricing policies, availability of raw ingredients and shipment costs.
- Product recalls – Product recalls can result in a shortage both for the product being recalled as well as other products due to a change in demand.
- Natural disaster – Can affect the availability pharmaceuticals, either locally or globally. As an example, damage caused by Hurricane Maria in Puerto Rico in 2017 decreased global manufacturing productivity and led to worldwide medicine shortages for several lines.¹⁴ Local disasters can affect the supply chain, such as disruptions to deliveries as result of the 2019/20 bushfires¹⁵ or road closures during the 2019 floods and bushfires.¹⁶

Transport and Distribution Issues

During COVID, there had been some concerns when container ships were prevented from docking in Australia¹⁷. Any hold up on freight through ports, including as part of a pandemic management strategy or industrial action can affect the in-country supply of essential products that may be on the container ship.

¹²Management and communication of medicine shortages and discontinuations in Australia; Guidance for sponsors and other stakeholder bodies; version 1.1, May 2019; <https://www.tga.gov.au/sites/default/files/management-and-communication-medicine-shortages-and-discontinuations-australia.pdf>

¹³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/>

¹⁴ <https://strategichs.com/blog/2018/01/29/drug-shortages-plague-healthcare-facilities-while-natural-disaster-recoveries-continue/>

¹⁵ <https://www.npsa.org.au/2020/01/13/npsa-update-on-bush-fire-emergency/>

¹⁶ <https://www.npsa.org.au/2019/04/01/flood-and-bushfire-affected-areas-still-getting-critical-medicine-deliveries/>

¹⁷ [Maritime Union of Australia pauses industrial action at ports across the country - ABC News](https://www.abc.net.au/news/2020-03-23/maritime-union-pauses-industrial-action-at-ports/12048444)

Once in country, Australia's warehousing, transport, and distribution system for pharmaceuticals is highly advanced and appropriately regulated, particularly for PBS medicines and NDSS items which are covered under the CSO. CSO compliant pharmaceutical distributors (CSODs) must deliver PBS and NDSS items to any PBS approved community pharmacy within Australia, generally within one working day and no more than 3 working days. These arrangements ensure community pharmacies can meet the needs of their local community, including for new or unexpected prescriptions. The distribution of pharmaceuticals is predominantly met by three major CSODs (Australian Pharmaceutical Industries (API), Sigma and Symbion) and some smaller CSODs (Clifford Hallam Healthcare, Barrett Distributors and National Pharmacies).¹⁸ Between them, these CSODs maintain a range of local distribution warehouses around the country, enabling the prompt delivery of pharmaceuticals to any pharmacy, including in rural and remote locations. Factors that negatively affect this distribution network can have a flow on effect to community pharmacies and ultimately to patient access.

Exclusive pharmaceutical distribution arrangements (whereby a manufacturer supplies their products through only one distributor) can also affect access as these distributors do not have to comply with the CSO requirements and they do not have the same obligations with regards delivery schedules. There is also less capacity for pharmacies to manage situations when a delivery fails. The Guild has long recommended that while Government subsidised schemes such as the PBS should allow preferred distributors for specific medicines, these medicines should also be available through the CSO-compliant distributors to minimise supply chain vulnerabilities and ensure equity of access.

Disruption to Consumer Access to Pharmacies

No matter how successful and reliable the supply chain is, ultimately consumers access their pharmaceuticals from their preferred pharmacy and anything that affects the operation of the pharmacy highlights a vulnerability that can have consequences for consumer health care. Over the past several years, we have seen that one of the greatest risks impacting access to essential pharmaceuticals has been the forced closure of a pharmacy, such as with a natural disaster (flood, fire, cyclone) or as result of a pandemic risk.

During the COVID-19 pandemic, community pharmacies were one of the few businesses that were continually open to the public, recognising the essential community service a community pharmacy provides. Pharmacies implement stringent protocols and procedures to minimise the risk of COVID transmission and exposure by both staff and patients. But there were incidences in which pharmacies were visited by a person with COVID requiring the pharmacy to shut down until it could complete a cleaning and decontamination process. Such closures required significant coordination as patients may have prescriptions on file at the pharmacy, have medicines awaiting collection or even having arrangements for daily dosing at the pharmacy.

During the 2019-20 bushfires, community pharmacies were an essential service, operating extended hours or providing outreach services to support affected communities. This included working with local hospitals and other pharmacies as well as the local pharmaceutical distributors and local emergency services to manage deliveries of essential pharmaceuticals to either the pharmacy or to isolated patients

¹⁸ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

which were affected by road closures.^{19,20} Community pharmacists also ensured patients had continuity of medication supply where lack of access or forced evacuation meant they left needed medication at home. Local community pharmacists helped their community by supplying not only needed medicines (with no prescription available through patient history), but personal care items. These services were greatly appreciated by persons enduring significant stress at that time.

As the final consumer interface for pharmaceutical supply, pharmacy operability must be considered as part of any risk-management strategy for managing vulnerabilities within the pharmaceutical supply chain. This is particularly critical as part of any emergency planning such as with disasters or pandemics. Through the Guild as the primary representative for community pharmacy, community pharmacists must be formally recognised for inclusion in emergency, disaster and pandemic planning and preparedness, and response and recovery measures at Commonwealth, State/Territory, or regional level.

4. Impact of vulnerable pharmaceutical supply chains on pharmacies and their patients

The COVID-19 Experience

Supply disruptions for pharmaceuticals in 2020 were exacerbated by the pandemic through early panic-buying and stockpiling as well as local and global supply disruptions. Some of the issues encountered regarding pharmaceutical supplies were because of Australia relying on the supply of products manufactured overseas, and included interruption to:

- Access to raw ingredients for manufacture of medicines e.g. from China during pandemic (see earlier section on China's import shares to Australia).
- Production at manufacturing plants e.g. in India during pandemic.
- Transport from overseas manufacturing plants and managing air or sea freight disruptions.

Within the Australian arm of the supply chain, non-standardised and changing ordering and supply restrictions implemented by pharmaceutical manufacturers and/or distributors early during the crisis caused confusion for pharmacy staff placing orders and resulted in inequitable access. As a result, many pharmacies were unable to reliably meet their community needs with many essential medicines.

In response to COVID-19, the TGA organised the newly reformed Medicine Shortages Working Party to regularly meet, initially on a weekly basis. Consisting of all elements of the supply chain, the TGA Medicines Shortage Working Party worked together to implement:

- Limits for the supply of some prescription and OTC medicines²¹ – pharmacists dealt with verbal and sometime physical abuse while trying to uphold limits.
- Scheduling changes controlling supply for high demand medicines such as salbutamol²² and hydroxychloroquine.²³

¹⁹ How community pharmacies rose to the bushfire challenge; Guild Forefront; 15 Jan 2020; <https://www.guild.org.au/news-events/news/forefront/v10n01/how-community-pharmacies-rose-to-the-bushfire-challenge>

²⁰ Pharmacists on the front line, AJP 6 Jan 2020; <https://ajp.com.au/news/pharmacists-on-the-front-line-2/>

²¹ <https://www.tga.gov.au/media-release/limits-dispensing-and-sales-prescription-and-over-counter-medicines>

²² *ibid*

²³ <https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19>

- A Serious Shortage Medicine Substitution (SSMS) process ('therapeutic substitution')²⁴ to enable pharmacists to supply according to available forms and strengths of prescribed medicines
- Regulatory changes to enable manufacturing and pharmacist compounding of hand sanitisers to meet public needs.²⁵

As part of the COVID-19 arrangements, elements of the pharmaceutical supply chain also applied for exemptions from the Australian Competition and Consumer Commission (ACCC) to enable them to work together to manage supply problems.^{26,27} The Department of Health also varied the deed arrangements with the CSODs enabling them to responsibly manage the supply of PBS and NDSS products where there were supply disruptions or unusual ordering patterns.

These changes enabled the Government agencies and the supply chain to work together to identify and manage any risks due to supply disruptions or changes to ordering patterns. While the early measures addressed the initial problem of panic buying and stockpiling, it was recognised that there remained a need to manage supplies of pharmaceuticals according to need. As an example, children are particularly vulnerable as they require specific formulation of medicines to manage variable doses according to age or weight. Pharmacies that service residential facilities or remote Indigenous communities had different supply needs to meet bulk supply and scheduled delivery arrangements.

The avoidance of critical shortages (or the lack of noticeable impact of them) was in part due to the actions and adaptability of industry participants including community pharmacists. It was also due to policy modification (such as the advice to not dispense all-at-once) and a recognition that the supply chain would be more vulnerable if alternative policies were introduced – such as 60-day dispensing or tendering for medicine generics.

It not only makes sense for these arrangements to continue while COVID still remains a risk for the Australian community, it would be reasonable to implement these arrangements on a permanent basis so that all elements of the supply chain can continue to work together to manage supply disruptions and ordering arrangements to ensure equitable supply throughout the supply chain. While the dispensing restrictions remain in force, the Guild understands that the CSO deed exemptions have not been extended which limits the capacity of the CSODs to assist with distribution management strategies.

Impact of supply disruptions on the Australian population

A survey of community pharmacists by the Guild identified key issues experienced by community pharmacies including delivery of incomplete orders, cancellation of backorders without being requested and lack of awareness of ordering restrictions implemented by distributors.²⁸

The survey highlighted the following issues associated with medicine supply disruptions:

- Vulnerable patient groups were most at risk (Indigenous Australians, aged care residents, rural and remote communities, people living with chronic health conditions).

²⁴ <https://www.tga.gov.au/serious-shortage-medicine-substitution-notice>

²⁵ <https://www.tga.gov.au/hand-sanitisers-information-manufacturers-suppliers-and-advertisers>

²⁶ <https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/medicines-australia-0>

²⁷ <https://www.accc.gov.au/public-registers/authorisations-and-notifications-registers/authorisations-register/national-pharmaceutical-services-association-npsa>

²⁸ Medicine Shortages – Community Pharmacy Survey conducted by the Pharmacy Guild of Australia (April 2020) – Report Information available on request

- Patients were inconvenienced while pharmacists worked to access medicines (ranging from increased wait times, to traveling sometimes hundreds of kilometres to another pharmacy to obtain their medicine).
- Patients having to visit multiple pharmacies at a time when they were being requested to stay home.
- Patients missing doses of medicines (reported by over 60% of pharmacy respondents).

Personal Protective Equipment (PPE)

It was not only medicine supplies that proved to be problematic. The global shortage of PPE, particularly masks, provided a challenge to Australia's pandemic response, particularly for front-line health care workers. Access to pharmaceuticals during the pandemic was critical and community pharmacies continued to operate, including for personal attendance by patients to have prescriptions filled and to obtain other essential pharmaceuticals. Pharmacies maintained and followed strict processes to maintain infection control and reduce risks of transmission, including use of PPE.

The Guild recognises the prioritisation of the limited supply of masks to those health services most likely to come in contact with a suspected or confirmed case of COVID-19, and were pleased to be included in the providers who received limited supplies of masks from the National Medical Stockpile distributed through Primary Health Networks (PHNs) in each tranche.

However, many community pharmacies reported extreme difficulty in obtaining access to these masks, with some PHNs hesitant to provide PPE to pharmacies. Community pharmacists have continued face-to-face interactions with patients throughout the pandemic with physical distancing whenever possible. Pharmacies have reported patients being instructed by their GP during a telehealth consultation to attend the pharmacy for point of care testing such as blood pressure measurements putting the transmission risk on to the pharmacist. Yet, there have been extensive problems with community pharmacies accessing PPE from PHNs.

Concerns were being expressed that the supply restrictions reflected availability rather than evidence-based clinical need. In future emergency situations, the clinical needs should be first assessed, and recipients prioritised and then supply arrangements implemented according to availability.

Additionally, and recognising that supply and distribution is not their primary role, the capacity of PHNs to provide logistical support to primary care in this manner and magnitude may not be as efficient as the distribution through existing mechanisms such as medical or pharmaceutical distributors. The latter have arrangements in place to deliver medicines subsidised under the PBS to almost any pharmacy within Australia within 24 hours and it would make sense to capitalise on this capability and expertise.²⁹

5. Risk management strategies

National Medical Stockpile

The Productivity Commission interim report states: "The Australian Government National Medical Stockpile (NMS), managed by the Department of Health, provides strategic reserves of pharmaceuticals, vaccines, antidotes and personal protective equipment (PPE) for use during the national response to a

²⁹ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/community-service-obligation-funding-pool>

public health emergency which could arise from natural causes (risks) or terrorist activities (threats). It is intended to supplement state and territory supplies in a health emergency”.³⁰

The Government’s website³¹ provides very general information about the National Medical Stockpile and notes that it is a strategic reserve and is not a general supplier of product and that information about content is not published for security reasons. While it is understandable that locations for the stockpile should be secure, the Guild believes that the publication of items maintained via the stockpile would be in the public interest.

As highlighted in the introduction, the TGA maintains a “Medicines Watch List’ being a legislative instrument setting out a list of known critical medicines derived from a consensus review of existing state hospital Emergency and Life Saving Drugs Lists and the World Health Organization’s Model List of Essential Medicines that are contained in the Australian Register of Therapeutic Goods.³²

Without any knowledge of what pharmaceuticals are on the National Medical Stockpile, it is unclear as to what is the difference between that and the TGA’s Medicines Watch List. Nor is there any indication as to cross-over with the lists of prescription and non-prescription medicines identified in the early stages of COVID for which interrupted supply could result in serious health consequences³³ (Health Consequence List). The TGA’s Medicines Watch List is more focused on hospital supplies whereas the latter list is more for medicines for community-based management of a range of health conditions.

While all have a place in emergency arrangements, it would be sensible to have greater transparency of the National Medical Stockpile as to what pharmaceuticals are included, and to clarify the purpose of each list.

From the Guild’s perspective, the ‘Health Consequence List’ has most relevance to community-based health care and ultimately to the greater population and it would make sense to have a risk-management strategy in place for these medicines for all contingencies to complement the National Medical Stockpile and the Medicines Watch List. This could be done by implementing an efficient mechanism to stockpile the listed medicines, noting that many of these are commonly used PBS medicines.

As with any stockpile, wastage is an issue and the expertise for minimising waste lies within the existing medicine supply chain. Consideration should be given to funding sponsors to maintain a minimum level of stock (e.g. 12 months) of the Health Consequence List medicines within their pre-distributor facilities. As these are commonly used medicines, the pre-distributor would rotate stock to fulfil standard orders, reducing wastage. The TGA would be responsible for overseeing risk-management plans if supplies were disrupted and the minimum level could not be maintained. The pre-distributor and/or the sponsor would be responsible for notifying the TGA of any instance when in-country supplies went below the minimum level so the risk-management plan could be initiated.

Incentives to invest in risks management at the firm level

The Guild agrees with the Productivity Commission interim report statement: “Government is directly responsible for managing supply chain risks where they deliver or procure goods and services on the

³⁰ Productivity Commission 2021, Vulnerable Supply Chains, Interim Report, Canberra, page 80.

³¹ <https://www.health.gov.au/initiatives-and-programs/national-medical-stockpile>

³² <https://www.tga.gov.au/medicine-shortages-information-sponsors-suppliers>

³³ <https://www.tga.gov.au/media-release/limits-dispensing-and-sales-prescription-and-over-counter-medicines>

community's behalf, including in delivering health services, national security and many other public services. Governments have a direct responsibility in many of the supply chains that would be considered essential as part of the framework proposed in this study — such as water, health, communications (provision of broadband internet and the telecommunications universal service obligation), and government (chapter 3)".³⁴

Furthermore, the Productivity Commission states: "In some essential industries (such as in utilities or health provision), regulated prices may not provide sufficient financial incentives for firms to invest in risk management despite their importance to society. For example, pharmacies might choose not to stockpile additional amoxicillin to prevent a shortage, if they could not charge a premium when a shortage occurred."³⁵ In response to this point, the Guild observes that it is likely to be counterproductive for pharmacies to attempt to stockpile any medicine. In the event of a shortage, any stockpiling by individual pharmacies or pharmacy groups would have the effect of worsening the effects of the shortage for other pharmacies, resulting in complete outages in some geographical areas that may otherwise have been avoided. Management of stockpiling must always be well co-ordinated, and the Guild believes this is best managed at the pre-distributor stage to ensure equitable distribution around the country to pharmaceutical distributor warehouses and ultimately to community pharmacies and the Australian population.

As the market for medicines is global, one country can experience shortages or outages for certain medicines if the regulated pricing in that country is so low that it is not internationally competitive. More stock will naturally flow to those countries considered to be more profitable by the manufacturer. Through its PBS pricing policies and mechanisms, Australia must ensure that the pricing of medicines remains internationally competitive and adaptive to changing global conditions. The current process through which prices for PBS medicines can be increased (which may be necessary in times of global shortage) is cumbersome. Furthermore, while the PBS price disclosure policy results in price decreases when the market price of medicines is found to be below a set threshold, there is no monitoring to ensure that the reduced price is globally appropriate on an ongoing basis as market conditions change. This may lead to the withdrawal of certain manufacturers from the Australian market, increasing the vulnerability of the supply chain for specific medicines.

Serious Scarcity Substitution

In March 2021, new legislation was passed to allow pharmacists to substitute a different medicine when a patient's usual medicine has been declared to be in 'serious scarcity'.³⁶ The substitution arrangement is automatically recognised in all jurisdictions and allows pharmacists to substitute specific medicines without prior approval from the prescriber, relieving pressure on doctors and helping patients get faster access to alternative medicines when there is a serious scarcity.

While this is a welcome initiative that enables pharmacists to more effectively manage a supply disruption to ensure continuity of care for patients, there is still much that needs to be done. Current arrangements do not allow the substituted medicine to be dispensed as a pharmaceutical benefit, affecting affordability for patients, and posing a barrier to access. The arrangement also requires identification of the 'serious scarcity' by the TGA to undertake the necessary processes to enable pharmacist substitution. While the

³⁴ Productivity Commission 2021, *Vulnerable Supply Chains, Interim Report*, Canberra, page 87.

³⁵ Productivity Commission 2021, *Vulnerable Supply Chains, Interim Report*, Canberra, page 88.

³⁶ <https://www.tga.gov.au/alert/new-legislation-support-medicine-substitutions>

TGA sources information about supply disruptions from a variety of sources, there needs to be greater investment by the Government in technology and resourcing that enable the TGA to expeditiously conduct the necessary data analysis so as to implement the necessary management strategies in a timely manner.

The Commonwealth also should work with the State and Territory Health Departments to enable pharmacists to work to their full scope of practice to better manage supply disruptions for prescription medicines. Pharmacists have the capability for more autonomous therapeutic substitution, not only to support the clinical care of patients but also when faced with supply disruptions. Pharmacists are medicines experts, and the straightforward dose, form and equivalency therapeutic substitutions are within the competence of every pharmacist in Australia to manage autonomously with their patients. This is already permitted in equivalent countries, such as the USA and Canada, without compromising safety and should be allowed here as well.

Section 6 highlights international examples of technology being used to manage pharmaceutical supply disruptions as well as where pharmacists have greater autonomy for therapeutic substitution.

6. International examples addressing medicines shortages

Spain – Medicine Shortages Monitoring Technology

Spain has implemented a system to assist pharmacists with managing medicine shortages. Cismed³⁷ is an application which is embedded in the pharmacy stock management system. It works as follows:

- The stock management system has a list of the distributors the pharmacy purchases from. Consejo, the organisation managing the monitoring system, is configured as the last “virtual” distributor. When a pharmacy receives a prescription for which it does not have product in stock, the pharmacy would place an order to the stock management system, and the system would address the order for this product to the first distributor. If the first distributor cannot supply, the order would go automatically to next, and so forth until exhausting the list of distributors. If no actual distributor can supply, the order goes to the virtual “Consejo distributor”, where this information is recorded as a short supply.
- The system is automatic, and the pharmacist does not have to register any new data, which ensures reliability and efficiency of use, and it registers all supply issues in real time.
- Currently there are more than 9,000 pharmacies in Spain reporting each day through Cismed. Once the information is gathered, there is an analytical process based on the data to assess when a short supply becomes a problem of shortage. First, there is a quantitative measure at regional level: if a minimum significant number of pharmacies in a province report a supply problem on a product during three days within the week, this is considered to be a problem of short supply for that province. There is another analytical process to determine the shortage at national level, and to anticipate national shortages based on a monitoring of the trend of short supplies.

³⁷ <https://www.pgeu.eu/wp-content/uploads/2020/08/CISMED.pdf>

The implementation of such a system in Australia would be of great value, however the establishment and ongoing monitoring of the system would require significant investment. Given the national risks associated with supply, this investment would be best made by the Commonwealth government.

Canada – Autonomous Therapeutic Substitution

In Canada, pharmacists are able to therapeutically substitute a prescribed medicine to help ensure patients receive safe and effective care.³⁸ This involves pharmacists working to professional protocols and guidance to substitute a prescribed medicine with another within the same therapeutic class that is expected to have a similar therapeutic effect. Canada has recognised instances when this may be appropriate, such as managing medicine recalls or shortages or to optimise patient care.

³⁸ <https://www.bcpharmacists.org/readlinks/helping-patients-receive-safe-and-effective-drug-therapy-through-therapeutic-substitutions>



The Pharmacy
Guild of Australia

About the Pharmacy Guild of Australia

The Guild is a national employers' organisation with over 90 years of experience in representing and promoting the value of the role of community pharmacy in the Australian health care system. Community pharmacies are a vital part of our national health system with the potential to make an even bigger contribution to the health of all Australians.

The Guild shares with the Commonwealth Government responsibility for the implementation of the National Medicines Policy, as evidenced by successive Community Pharmacy Agreements (CPA) enshrined in the *National Health Act 1953*, including the current 7th CPA underpinned by the shared principles of:

- Stewardship of the health system and a shared responsibility for the stewardship of the PBS.
- Partnership in the implementation of Australia's National Medicines Policy.
- Stability and certainty of the Government's investment in the medicine supply chain, as well as timely availability of medicines through a well-distributed community pharmacy network.
- Integrity of Australia's health system, including patient safety and high value clinical care.

The Guild and the broader community pharmacy network have made significant contributions to the achievement of the National Medicines Policy objectives for patient outcomes.