12 May 2021

Medicines Australia Submission to the Productivity Commission report into Vulnerable Supply Chains

Securing Supply Chains for all Australians

Medicines Australia

Contents

Introduction

Medicines Australia recommends that strengthening Australia's medicines supply chain, including through crisis preparedness planning, requires an evidence-based nationally coordinated approach alongside industry and public stakeholders. This should be supported by domestic and international policy initiatives that support research and development, advanced manufacturing, medicines stockpiling, investment in the Pharmaceutical Benefits Scheme and international trade collaboration.

Medicines Australia is grateful for the opportunity to contribute to the Productivity Commission's report into Vulnerable Supply Chains. This submission provides an overview of the medicines supply chain in Australia and shows that it is strong and stood up well to the challenges posed by the COVID-19 pandemic. But Australia must not rest on its laurels, as we must acknowledge that Australia has not been affected by the pandemic as severely as other countries have been and continue to be. There is always an opportunity to strengthen Australia's supply chains and ensure, through better planning, coordination, government support and industry collaboration, that we will be even more flexible and able to adapt to future crisis. This will involve Australia being a trusted partner globally for research, development and supply of medicines, while fostering closer R&D and industry partnerships domestically.

This submission is divided into three main parts. First, it provides an overview of the global supply chain and Australia's place in it. This also includes high-level insights gleaned from surveys of innovative pharmaceutical companies in Europe and Australia in relation to their supply chains in the lead up to, and during, the global pandemic. The second part of the report details how industry and government have worked together during the pandemic and outlines recommendations for how the supply of medicines could be better supported in the future. The third part provides further insights into the domestic and international policies and initiatives that would strengthen Australia's pharmaceutical industry and subsequently make the supply chain more robust in times of crisis.

Medicines Australia is at the disposal of the Productivity Commission to address any additional issues it seeks to address in the context of drafting its final report. Enquiries can be directed to Anne-Maree Englund (Head of Strategic Policy Implementation,
or Peter Komocki (Manager, Industry and Regulatory Policy.

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CEO Medicines Australia

Recommendations

To mitigate and manage medicines supply issues through a crisis, Medicines Australia recommends the Government consider an evidence-based approach to the following:

- Medicines Australia should play a critical role in working with Government and industry stakeholders in crisis mitigation and response planning, including by strengthening supply chain vulnerabilities
- crisis planning and implementation should be evidence-based and coordinated at the national level, including through the Medicines Shortages Working Party, which should continue to meet on a regular basis
- demand and supply forecast modelling to ascertain medicine requirements, particularly in state and private hospitals, should be expanded and utilised for a wider variety of products, including for stockpiling purposes
- any crisis mitigation and response plan should allow for a regulated industry to directly control and restrict or ration distribution of medicines to ensure supply in times of emergencies
- mechanisms to increase medicines stockpiles for domestic and regional needs, which may be possible for an agreed set of medicines, with greater (co-) investment and partnership with government (i.e. including fit for purpose risk-sharing arrangements underpinned by appropriate policy settings)
- any framework developed to identify critical and vulnerable medicines should include additional consultation with government and industry peak bodies such as Medicines Australia
- consulting relevant stakeholders on other potential mechanisms to encourage investment in supply chain infrastructure, such as special economic zones or free trade zones, that could increase warehousing, storage, and distribution facilities for trade, trans-shipment, and re-export operations
- consulting with industry to develop improved mechanisms for emergency procurement of medicines in consultation with state and territory governments in times of crisis to boost

national stockpiles, in addition to maintaining relevant domestic and regional stockpiles, for national distribution
- continue to provide emergency logistics support (e.g. the International Flight Assistance Mechanism) for the import of medicines
- improving national infrastructure to allow for better supply chain transparency to monitor and manage stocks throughout the supply and distribution chain.

For a more resilient supply chain, Australia must be a trusted partner in a globally interconnected research-driven pharmaceutical industry. If the government wants to strengthen Australia's access to this supply chain for all Australian patients, including through manufacturing, it should:

- improve regulatory and reimbursement processes to better align with overseas jurisdictions
- ensure true value for innovative medicines is recognised to better reflect the value of medicines to patients and strengthens the Australian domestic market and supply chains to it
- invest more and provide greater incentives for:
    - Australia to become a regional hub for R&D, including pilot manufacturing
    - national and regional medicines stockpiling
    - increased value-add manufacturing, including contract manufacturing and vaccine partnerships
    - advanced manufacturing, for example in the regenerative medicines space
- pursue health sector specific regional and plurilateral trade agreements.

Australia's Medicines Supply Chain

In a globally complex and interconnected environment, Australia's medicines supply chains continue to stand up well in the face of the COVID-19 pandemic.

A National and Global context

Over several decades, Medicines Australia members have carefully built robust global supply chains to ensure patients around the world have ongoing access to medicines. Medicines Australia companies and the broader industry have invested significantly in the design and maintenance of manufacturing facilities and high-quality systems to ensure that medicines are produced safely and efficiently, at scale, so that patients have access to them as soon as possible. These carefully implemented measures continue to ensure the stability of international supply chains.

On a global level, companies are implementing robust risk management plans and carefully tracking and managing all the inputs required to maintain safe and reliable manufacturing, either domestically or offshore, as well as the delivery of their medicines to Australia. Manufacturing facilities around the world have, for the most part, remained open and continue to make millions of doses of medicines and vaccines every day having increased capacity and manufacturing output throughout the pandemic. Strict measures are in place to ensure staff and facilities are protected and able to maintain production. It must be noted that increasing production capacity in rapid response to global increases in demand, in itself is a considerable feat, usually requiring significant lead time.

Geographic diversity is proven to be key to the success of global supply chains, enabling manufacturers to quickly adjust their supply chain sourcing as needed, particularly during natural emergencies and global public health crises such as COVID-19. In developing their supply chains, manufacturers take into account the locations of each source facility and have extensive measures in place to manage the various elements of the production process.

A Survey of Innovative Pharmaceutical Companies During COVID-19

Medicines Australia surveyed our members throughout 2020 and 2021 to better understand their supply chain and medicines shortages issues (i.e. causes, responses, mitigation strategies). Our sister body in Europe (the European Federation of Pharmaceutical Industries and Associations (EFPIA)) did likewise and we have found that their responses are largely consistent and align between the European and Australia experiences. We have focused on Europe as the majority of medicine imports into Australia come from that region and have been largely manufactured there too.

These survey results showed the difficulty in deducing from medicine shortages notification processes the real magnitude of shortages as companies are obligated to report possible, imminent and actual shortages. So while reports of shortages increased in Europe in 2020, actual shortages that impact access for patients, can be difficult to ascertain. The same can be said for Australia. Notifying a risk of shortage early-on often results in overreporting, as many shortages will never eventuate. Better assessing the risk of actual shortages occurring can lead to more accurate notifications. Although this might also lead to notifications being made later, where shortages that occur are subsequently more difficult to mitigate and manage.

For example, of the 12 members that responded to Medicines Australia's April 2021 survey, four companies had experienced noticeably higher drug shortage events (defined broadly to include possible and actual medicine shortages) over the last three years than the other respondents. The survey results indicated that medicines shortage events, while perhaps more focused on products prone to hospital and public stockpiling due to Covid-19, did not increase in Australia in 2020.

For the similar EFPIA survey, of the 15 respondents, three companies did not make any notification for shortages throughout the survey period, and 40%-50% of companies notified less than 10 shortage events per year. At the other end of the spectrum, two companies accounted for 68% of all notifications across the period.

This notwithstanding, the combined survey of industry's experiences throughout the COVID-19 pandemic in Australia and Europe reveals useful patterns in the causes of medicines shortages. It also demonstrates consistent mitigation strategies that allowed companies to adapt and address supply chain vulnerabilities. These are explained below.

Demand for Medicines Increased

The demand for medicines surged in 2020 and put a strain on the global supply chain like never before. From the access to raw materials, production of APIs, medicine manufacture, freight and distribution, delivery to hospitals and dispensing at pharmacies, the logistical challenges stemmed from some reasonable, but importantly, some unreasonable demands for medicines. In Australia, this included demand spikes, (particularly in March and April 2020) driven by panic buying and stockpiling behaviour from state governments for their hospitals, as well as consumers for their prescription and over the counter medicines needs. Companies reported demand spikes well above average for the time of year, and well above the levels that were forecast.

The demand spike started with companies reporting increases in the range of 10 % to 30%, but soon increased to the range of 100% to 200%, and for some medicines as high as 300% in early April. This

increased demand saw a reduction in the levels of some safety stock, and the subsequent need for the Federal Government to step in and enable the enforcement of restrictions.

At the same time, companies came under pressure from some State Governments, seeking to procure and stockpile minimums of six months of base stockholding of pharmaceutical products across all essential medicines. This put unnecessary pressure on manufacturers and wholesalers to replenish the supply chain at a time when they were calling for calm. Wholesalers and manufacturers initiated measures to ration supplies to control stock levels. This led to inaccurate media reports of shortages, as State and territory Governments scrambled to prepare for worst-case health scenarios.

It was not until late April that medicines manufacturers reported that the demand had begun to normalise. Even as late as mid-May some manufacturers still reported that demand levels for some products were higher than forecast.

Freight and logistics

Freight and logistics proved the greatest challenges to medicines sponsors in meeting both normal and increased demand for medicines during the COVID-19 pandemic. While there were notable delays in freight of products by sea, the vast majority of companies responding to Medicines Australia's surveys were experiencing supply challenges due to air freight constraints.

The COVID-19 pandemic saw widespread lockdown of international borders, resulting in the grounding of a large proportion of international and domestic air travel. This highlighted the significant reliance on passenger planes as a source of medicines air freight capacity. The reduction in passenger traffic significantly affected the medicines supply chain, which is a highly globalised web of manufacturing, production, research and development and distribution.

The reduction in flight numbers led to many medicines' manufacturers losing reliable import routes to Australia, with many reporting challenging timelines for supply due to flight delays and cancellations. The logistics onus fell upon these companies who were required to work with multiple airlines and multiple jurisdictions to find alternatives to ensure supply would reach Australia.

An ongoing challenge with sourcing alternate routes was the lack of available cargo space on many flights. These delays alongside the increased competition for freight space resulted in exponential increases to freight costs. These costs should not be underestimated particularly as, in some instances, the cost of freight was significantly higher than the cost of goods.

The delays and restricted movement challenges for companies were notable. Every major medicine supply location in the world was adversely affected by COVID-19 and supply issues reverberated across the globe.

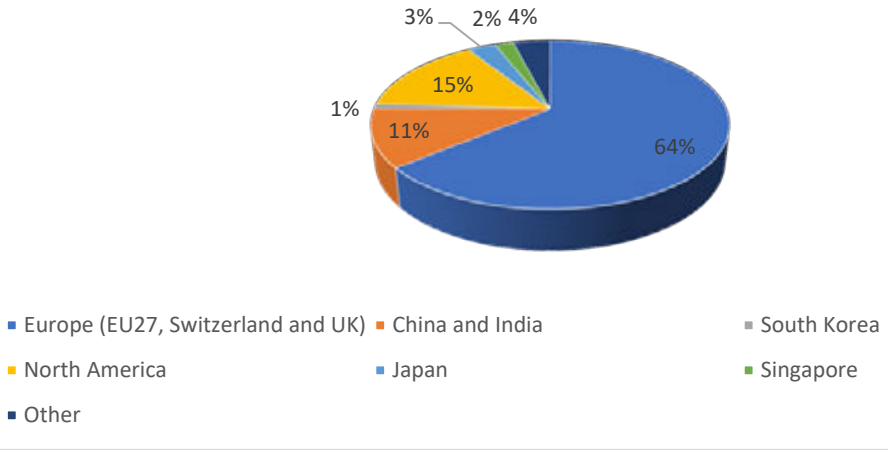
This included many European nations such as Italy, Germany, France, Switzerland and the Netherlands which are home to a number of multi-national pharmaceutical companies. It also included major distribution points in Dubai and Singapore and included the large-scale manufacturing zones of India and China. Delays were also experienced in Korea, the United States and in New Zealand.

Nevertheless, Australian medicines manufacturers acted quickly to coordinate their global supply chains and Medicines Australia responded promptly to facilitate supply coordination with Government, which rapidly mitigated potential for catastrophic outcomes.

Manufacturing, APIs and Raw material

Results from Medicines Australia's recent survey indicate that for the Australian market most APIs are sourced from the European region (the European Union, Switzerland and the United Kingdom). China or other Asian countries are not the largest suppliers of most APIs, indicating less than 30% of supplies of medicines from these regions. These results are consistent with the EFPIA's survey, which indicated that 64% (number of participant companies, n=15) of APIs are manufactured in Europe (see fig 1).[1]

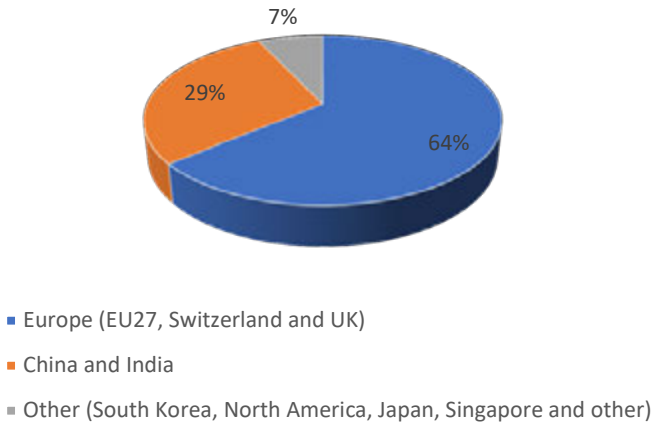
Fig 1: Number of APIs (biological and chemical) sourced or Manufactured per Region of Origin (irrespective of value/volume)



[1] Source: EFPIA Survey (2020-2021) available on an in-confidence basis

Among them, 29% (number of participant companies, n=8) of their raw materials are sourced from India and China, indicating Europe as the main source of raw materials and APIs (see Fig 2). [2]

Fig 2: Origin of Raw Materials and Intermediates for chemical APIs manufactured in Europe.



Exports

While the primary focus during the pandemic has been on the global supply chains where medicines were imported to Australia, there were also challenges for pharmaceutical manufacturers who export products from Australia. As global freight options diminished, it was just as hard for some companies to move products out of Australia, to overseas destinations. This included moving stock to both Europe and to Asia, with limited cargo space on the air freight options that were still running.

Not only was international export an issue, but some manufacturers had added challenges of moving stock across state borders which had been closed due to COVID restrictions. This created challenges where some manufacturers needed to transport (often cold chain) stock across state lines so that they could export stock internationally.

Company initiatives to ensure supply

Most medicines sponsors in Australia routinely carry safety stocks to cover three to six months' demand to account for increases in demand and disruptions of the supply chain. The innovative medicines industry does not operate a "just-in-time" supply chain model, as the principle goal is to ensure that patients access to medicines is not disrupted. During CVOID-19, sponsors did seek to increase their local inventory holdings, wherever possible, as demand surged or forecast errors could exceed the safety stock cover.

In tandem with increasing stocks, sponsors implemented a number of additional approaches to strengthening their supply chains, including:

[2] Source: EFPIA survey (2020-2021)

- Expediting shipments, for example by changing traditional transports such as switching from trucks to planes, and from sea to airfreight
- Increasing and prioritising manufacturing
- Holding regular meetings with logistics, supply planning, and other stakeholders in their contracted delivery pipeline adapt supply chain strategies while engaging with the Government's COVID Supply Chain network
- Booking space on charter flights while planning and pre-booking cargo space in advance
- Putting customer orders on manual release to avoid wholesaler/customer stockpiling
- Regularly communicating with customers on key lines
- Holding discussions chaired by the Therapeutic Goods Administration and facilitated by Medicines Australia/Generic and Biosimilar Manufacturers Association, with other sponsors of a medicine potentially in shortage under Medicines Australia's interim (and subsequently full) authorisation to conduct stock coordination discussions.

Companies that reported no drug events also reported that they avoided any drug shortage events through carefully monitoring supply and demand and changing their transport options (such as outlined above).

Supply Chain Crisis Management

Medicines Australia recommends that future crisis management planning be nationally coordinated (i.e. at the Federal Government level) and include Medicines Australia and other industry stakeholders as key development and implementation partners.

A National and Global Partnership

Medicines Australia agrees with the Productivity Commission's Interim Report that supply chain risk management strategies should be developed, first and foremost, by individual companies as they understand their own networks best.

However, strengthening coordination in preparation for and during future crises in Australia will require strong working partnerships between government, industry and patient at the national federal level. Importantly, any developed responses must be based on the most current data and evidence available to government and industry. This will allow for consistent national and international coordination and collaboration between governments, international institutions (such as the World Health Organisation) and medicines sponsors and their supply chains to ensure patients have uninterrupted access to medicines.

Medicines Australia's (and our members') experience in managing supply chain and medicine shortages issues through COVID-19 has demonstrated the critical need for and benefits of a nationally coordinated and evidence-based response to the crisis. This includes the exchange of information between government and industry stakeholders, as well as those stakeholders working together to forecast and manage supply and demand issues. In particular, Medicines Australia is a member of the Medicines Shortages Working Party (MSWP) that is chaired by the Therapeutic Goods Administration and includes representatives from across the health sector. The MSWP worked tirelessly throughout 2020 to discuss and develop measures that managed or mitigated shortages, particularly in relation to communicating with patients and the general public.

Subsequent work overseen by the Therapeutic Goods Administration with state and territory government health bodies, including hospitals and hospital pharmacies, resulted in the development of a demand/supply forecast model for critical medicines required in hospitals to treat COVID-19 patients. This provided a transparent, evidence-based and nationally coordinated mechanism on the

capacity to treat specific numbers of COVID-19 patients, including taking into consideration existing stocks in hospitals and allowing industry to consider whether their existing and future supplies would meet current and potential future demand.

Medicines Australia recommends that such national coordination, cooperation and forecast modelling be continued and leveraged to prepare for future emergency situations. This should include in the context of maintaining and managing domestic and regional stockpiles of medicines when preparing for various crisis scenarios.

To ensure supply and mitigate medicines shortages from panic buying and stockpiling, medicine sponsors (i.e. importers/manufacturers) and distributors restricted or limited filling orders for medical products that were exceedingly above seasonally expected demand. Cooperation between industry and government, including through authorisation by provided by the Australian Competition and Consumer Commission to conduct Therapeutic Goods Administration-led discussions with sponsors on specific stock and supply issues, provided an additional mechanism to address supply chain issues and mitigate and manage medicine shortages. These types of actions should be a routine part of any future supply chain crisis planning activities.[3]

As noted above, the main cause for concern in respect of supply for Australia resulted from the lockdowns of international passenger flights and airports. This is because the vast majority of innovative pharmaceuticals and medical supplies are imported into Australia on passenger flights, particularly from Europe and the US. With fewer flights available, including cargo flights, the cost of freight increased exponentially. While this often made the import of medicines not commercially viable, our members continued to bring in products to meet Australian patient needs. It must be noted that Medicines Australia members did not pass on these additional costs to the government or patients. The Australian Government must also be commended for introducing the International Freight Assistance Mechanism, which prioritised cargo capacity for medical products on return legs to Australia.

In this context, future preparedness and government initiatives should include programs such as International Freight Assistance Mechanism and, in consultation with industry and state/territory governments, consideration of how to boost national stockpiles through emergency procurements

[3] For more background see: https://www.tga.gov.au/critical-medicines-supply-modelling-supports-return-elective-surgery
https://www.tga.gov.au/sites/default/files/critical-medicines-supply-modelling-supports-return-elective-surgery-background.pdf
https://www.tga.gov.au/sites/default/files/critical-medicines-supply-modelling-supports-return-elective-surgery-graphs.pdf
https://www.accc.gov.au/system/files/public-registers/documents/Final%20Determination%20-%2024.09.20%20-%20PR%20-%20AA1000486%20MA.pdf

of some critical medicines. This would be particularly important should a crisis become protracted, freight costs continue to increase and importing critical medicines (which are often genericised and of low commercial value) into a small domestic market become commercially unsustainable. Regional stockpiles, with their larger purchasing power, could also be of benefit to addressing such situations domestically. The government could give further consideration of government-to-government (such as across the Pacific) and industry risk sharing agreements for establishing regional stockpiles (see below).

National and Regional Stockpiling

During the initial stages of the pandemic and throughout its height in Australia, a lack of national coordination of medicine supply issues led to state governments seeking to procure and stockpile increased quantities of medicines. It was not possible for industry to meet these supply orders so sponsors and distributors, as noted above, restricted or limited filling these in full in order to preserve supply. The unfortunate consequence of these actions, however, was that states were competing against each and at the expense of each other's population/patients to secure a limited supply of medicines. National coordination from the outset, including a boosted medicines stockpile, could have provided a more predictable, evidence-based and sustainable path forward for governments, industry and clinicians in treating COVID-19 patients and, indeed, all patients that required care. Future crisis preparations could consider the broader value and scope of a nationally managed and coordinated stockpile of medicines, alongside its distribution, which could be similarly applied to a regional level in relation to, in particular, our close Pacific neighbours.

National stockpiles could be strengthened, in coordination with state and territory governments and sponsors, to cover a wider array of medicines and products and for longer periods. However, this would require close and timely collaboration with medicines sponsors to ensure supply, storage and distribution capacity. A review of current government procurement processes and consideration of fit-for-purpose government-industry risk sharing agreements could facilitate a path forward. For example, the existing model of state government (i.e. for public hospitals) contracts with pharmaceutical companies, where companies must maintain several months of medicines reserves at their own risk, would not be appropriate should greater stores of medicines and for longer periods be expected. The risk of wastage would be too great as would the financial loss for the company, in addition to factoring in the extra warehousing that would be required. New risk sharing and government procurement models would subsequently be required. Additionally, in response to the Productivity Commission's interim report on these issues, Medicines Australia notes that government mandating that industry extend and broaden its own stocks would not be appropriate. Increasing the existing risk burden on industry could make the supply of medicines so financially insecure as to be unsustainable, where companies would not be a position to enter into supply and stockpile contracts with governments.

Medicines Australia has previously canvassed the idea of the Australian government housing regionally focused medicines stockpiles.[4] There is an opportunity for Australia to continue to play a key strategic role in the Indo-Pacific, and particularly the Pacific, region by standing up a stockpile of medicines for and with our nearest neighbours and for our own domestic purposes. The Australian Government could strengthen its relationships with Pacific and Indo-Pacific nations, provide support to the region and share the load of managing medicine supply chain and shortages risks. This would provide countries in the region with greater flexibility in managing potential supply challenges when disruptions in manufacturing countries (the US, EU, China and India) might occur. In particular, the Australian Government could investigate creating regional stockpile agreements between governments and industry to ensure continued management and supply of medicines and medical products. This could include regional and bilateral agreements, for example, between New Zealand, Pacific Nations, India, Indonesia, Malaysia, and Singapore. As in the national stockpile scenario, new risk-sharing models would need to be developed between government and industry and additional investment in warehousing may also be required. But in addition to providing peace of mind domestically and regionally for access to critical medicines, such buying power could also open opportunities for encouraging some levels of domestic manufacturing (for example, through final value-added packaging or labelling) as companies have certainty of an initial government procurement customers in Australia and regionally which provide both domestic and export (or re-export) markets. The Government could consider such stockpiles alongside other mechanisms to incentivise investment in supply chain infrastructure initiatives, including through special economic zones or free trade zones, that could increase warehousing, storage, and distribution facilities for trade, trans-shipment, and re-export operations.

Enhancing supply chains

In addition, Medicines Australia has previously recommended the following in relation to strengthening supply chains[5]:

1. That the Federal Government foster the implementation of a modern technology enabled supply chain that ensures efficient resource utilisation and effective and timely delivery of medicines to Australian patients, through:
    a. Realising cost efficiencies through transparency of costs for each part of the supply chain
    b. Implementing mechanisms to enable national visibility of stock management processes
    c. Enhancing track and trace capability, including serialisation
    d. Leveraging additional data streams to support healthcare system policy and decision-making

[4] https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Submission-Joint-Standing-Committee-on-Foreign-Affairs-Defence-and-Trade-inquiry-into-COVID.pdf
[5] See Medicines Australia submission to the Senate Select Committee on COVID-19: https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Submission-Senate-COVID-Committee-inquiry.pdf

e. Embedding the provision of direct delivery options for patients
f. Enabling and expanding data transfer of electronic prescribing

2. That the Federal Government, for the purposes of national supply management:
    a. work with Medicines Australia to consider policy options to encourage greater supply chain redundancy and stock levels for identified/agreed products of clinical significance
    b. introduce national coordination of medicines supplies at all health levels including hospitals, States and Territories, to agree safe and equitable distribution during crisis
    c. ensure dispensing is appropriate to manage supplies at all times, but particularly during times of crisis
    d. ensure effective communication to consumers regarding stock shortages and stock-outs with advanced warning of stock shortages or stock-outs, rather than just a reliance on the Therapeutic Goods Administration website and at pharmacy level
    e. establish a national mechanism to support patients in what they need to do to get access to medicines if there is a stock-out.

Identifying Vulnerable Products

It remains difficult to identify and target which medicines are critical and vulnerable to shortages. The World Health Organisation maintains a watchlist of critical medicines, as does Australia's Therapeutic Goods Administration. These are often antibiotics and hospital-specific medicines such as those required for surgeries. But any medicine that substantially improves a person's quality of life or, indeed, keeps them alive can be considered critical and, given the reliance on medicines imports, subsequently vulnerable to supply chain disruptions. For example, some Medicines Australia members would list medicines as critical and/or vulnerable to supply issues as either cold chain and/or a product that a patient cannot or should not miss a single dose. In the case of cold chain reliant products, their supply typically requires a seamless transport from the manufacturing site to Australia.

In this context, the Productivity Commissions' framework for identifying critical and vulnerable medicines is only partially appropriate as all or most medicines will require the third step in its framework; seeking expert opinion. Given the number of medicines in Australia this step is difficult to implement. In the case of medicines or medical products, Medicines Australia suggests the Productivity Commission consider an additional step where the Therapeutic Goods Administration is consulted, before reaching out to industry (including through conduct authorised by the Australian Competition and Consumer Commission)

Recommendations

To mitigate and manage medicines supply issues through a crisis, Medicines Australia recommends the Government consider an evidence-based approach to the following:

- Medicines Australia should play a critical role in working with Government and industry stakeholders in crisis mitigation and response planning, including by strengthening supply chain vulnerabilities
- crisis planning and implementation should be evidence-based and coordinated at the national level, including through the Medicines Shortages Working Party, which should continue to meet on a regular basis
- demand and supply forecast modelling to ascertain medicine requirements, particularly in state and private hospitals, should be expanded and utilised for a wider variety of products, including for stockpiling purposes
- any crisis mitigation and response plan should allow for a regulated industry to directly control and restrict or ration distribution of medicines to ensure supply in times of emergencies
- mechanisms to increase medicines stockpiles for domestic and regional needs, which may be possible for an agreed set of medicines, with greater (co-) investment and partnership with government (i.e. including fit for purpose risk-sharing arrangements underpinned by appropriate policy settings)
- any framework developed to identify critical and vulnerable medicines should include additional consultation with government and industry peak bodies such as Medicines Australia
- consulting relevant stakeholders on other potential mechanisms to encourage investment in supply chain infrastructure, such as special economic zones or free trade zones, that could increase warehousing, storage, and distribution facilities for trade, trans-shipment, and re-export operations
- consulting with industry to develop improved mechanisms for emergency procurement of medicines in consultation with state and territory governments in times of crisis to boost national stockpiles, in addition to maintaining relevant domestic and regional stockpiles, for national distribution
- continue to provide emergency logistics support (e.g. the International Flight Assistance Mechanism) for the import of medicines
- improving national infrastructure to allow for better supply chain transparency to monitor and manage stocks throughout the supply and distribution chain.

For additional detail regarding management of COVID-19 related medicine issues, please see Medicines Australia submission to the Senate Select Committee on COVID-19.

Supporting Supply Chains

Medicines Australia believes that for Australia to create a more resilient supply chain, it must become a trusted partner in a globally interconnected research-driven pharmaceutical industry. This will require greater government support and investment in the pharmaceutical benefits scheme and its related processes, research and development, pilot and advanced manufacturing and international collaboration such as through sector specific free trade agreements.

Strengthening Australia's international role in research and development

Strengthening Australia's supply chains means not only strengthening the logistical elements of importing medicines to Australia, it means being a trusted part of the international ecosystem of partnerships that research and develop new medicines, treatments and manufacturing capabilities.

Australia has a strong and internationally competitive research and develop sector that could be better leveraged to pave the way for manufacturing of home-grown discoveries where commercial translation will be key to Australia's success. Australia must keep pace with Europe, Asia and Latin America who are backing up strategies with heavy investment in universities, public-private research collaborations, workforce training, early-stage capital funds and modern science parks to ensure their success in competing for advanced biopharmaceutical industries.

To compete in this space, not only do we need strong incentives and a cultural mindset change to collaboration between academia and industry, we also need to invest in pilot manufacturing facilities where research institutes and industry can test home-grown discoveries. This capability will encourage private-public collaboration and direct research and development towards translating discoveries into products that can be manufactured in Australia. Otherwise, the current cycle of discoveries not being commercialised at all, or being commercialised and manufactured overseas, will continue.

Medicines Australia has variously proposed in government inquiries a range of incentives that the government could implement to further encourage research and development in Australia, including:

- strengthening intellectual property protections, including aligning regulatory data protections with those in the European Union

- providing targeted tax incentives on profits from intellectual property developed and manufactured in Australia as well as for private-public research and development collaborations
- facilitate public-private partnerships across other portfolios, including Defence (e.g. health and defence medical countermeasures initiative), to co-fund domestically focussed health security measures and pandemic preparedness
- incentivise and recognise Australian discoveries and development
- provide price premiums and expedited PBS listing for home-grown and manufactured medicines
- embed clinical trials into the core healthcare infrastructure, including in regional areas, as part of the standard treatment of care with costs co-covered by Medicare and study sponsors
- promote domestically and internationally that Australia is open for business to conduct clinical trials to further develop a sector worth over AUD1 billion
- harmonise ethics, governance and regulatory processes nationally for consistently faster and more efficient establishment of clinical trials across Australia, building on the proposed Federal Department of Health One-Stop-Shop and Front Door initiatives and work underway through the Australian Commission on Safety and Quality in Health Care
- focus investment in STEM education, higher skills development and supporting skilled migration for identified gaps in scientific and senior managerial positions
- expand existing policy options such as, realigning the Medical Research Future Fund to:
    - encourage and reward public-private collaboration
    - link with the EU Horizon fund to tap into international co-investment and collaboration opportunities
- invest in translational centres of excellence for discoveries of Australian-made products
- focus on public-private manufacturing initiatives (i.e. through the CSIRO Innovation fund).

For the pharmaceuticals industry in Australia, much of the research and development investment is focused on conducting clinical trials. In economic terms, total direct expenditure for ongoing clinical trials was estimated at $1.1 billion in 2015. The majority of this funding is provided by innovator companies bringing in foreign direct investment (FDI). The estimated total expenditure supports approximately 6,900 highly skilled staff.[6] Australia has well developed and highly-regarded clinical trial facilities and medical infrastructure to conduct clinical trials in all phases of drug development. There are additional strengths in early phase (phase 1) capabilities.

In bringing more of those trials here, we have the chance to grow Australia's clinical trial sector, the benefits of which include:

- access to the supply chain for new innovative medicines

[6] MTPConnect. Clinical Trials in Australia: The economic profile and competitive advantage of the Sector". June 2017

- elevated research and development capabilities
- closer international collaboration
- improvements to the healthcare system in metropolitan and rural areas
- clinical trials becoming imbedded in the health infrastructure's standard of care
- earlier access for Australian patients to the newest medicines
- more patients receiving world-class innovative treatments
- will also improve our health-care system, strengthen research and development and improve patients' health outcomes.

The roles of manufacturing in strengthening supply chains

The role of medicines manufacturing in Australia requires further consideration and discussion between government and industry, particularly relating to the objectives government wishes to achieve and how this relates to the supply of medicines. This will further dictate what levels of investment would be required from government and industry to make different types of manufacturing an economically viable and sustainable endeavour.

This is because we do not necessarily need greater domestic manufacturing capability to improve access to world class medicines. For the most part, we already have this access and have had it throughout the pandemic as demonstrated by being amongst the first countries in the world to purchase and receive COVID-19 vaccines. The government's ability to better value innovative medicines, particularly to patients, is paramount to ensuring continued access to new medicines and to the general supply chain.

It is difficult to revitalise a once thriving manufacturing base in Australia, including for medicines. There are pragmatic barriers that prevent companies from considering Australia as an external innovation hunting ground, including:

- a perception of limited opportunities in Australia (often stemming from a lack of international visibility)
- geographical isolation that consists of long flights, often requiring connections and at a considerably higher cost and time commitment than other regions
- Australian innovation not being considered demonstrably superior and different relative to other, more accessible, major markets
- perceptions that innovators in Australia have low commercial acumen making their discoveries less 'investment ready'
- a market where regulatory and reimbursement processes are increasingly difficult to engage in comparison to overseas jurisdictions which are not only easier to navigate but value medicines, including for the social and economic value they provide.

These barriers can be overcome through policy changes and new investment incentives that match major innovation leaders, particularly the US, EU and Japan.

Medicines manufacturing for Australia could take a variety of pathways. These include building manufacturing facilities from the ground up, expanding existing manufacturing and contract manufacturing facilities, value-added/finishing manufacturing, supporting advanced manufacturing, and investing in research and development pilot manufacturing capabilities. Each path is not mutually exclusive from the other but requires differing levels of government co-investment and policy incentives to achieve different outcomes.

It is worth noting that establishing a new manufacturing facility from the ground up has the most barriers and is least likely to be a viable option, including in strengthening supply chain resilience. This is because of

- pre-existing competition from overseas manufacturing
- comparatively high operating (e.g. energy and labour) and freight costs
- the impact of currency exchange rates
- the ongoing need to import overseas produced manufacturing equipment, raw ingredients and APIs
- lack of supporting ancillary manufacturing and inventory
- lack of immediate access to and contracts into export markets
- the requirements for an immediate customer base domestically, regionally and beyond.

There is also no guarantee that the ongoing need for imports of raw materials and APIs will not be disrupted in a crisis. A manufacturer also requires a patient market domestically and internationally first and foremost in an already competitive market.

All of the aforementioned manufacturing options would need to be underpinned, to a greater or lesser extent depending on the option pursued, by

- government co-investment or similar support
- increased tax incentives
- stronger intellectual property protections
- guarantees of market access through the Pharmaceutical Benefits Scheme and, for example, through domestic or regional stockpiling initiatives.

Medicines Australia is open to discussing these manufacturing options in more detail separately. However, the recommended focus for government should be one that leverages and strengthens our research and development capabilities into precisions medicines, vaccines and the subsequently required pilot manufacturing facilities.

International Trade and Strategic Supply Agreements

Further efforts to cement Australia as a global leader and trusted partner should be supported by the Government seeking to strengthen the international rules-based order, including to ensure that in times of crisis medicinal supply chains face minimal disruptions. As many medicines rely on passenger commercial flights to transport medicines, alternative mechanisms should be available in times where these are restricted. This could include strategic agreements for the airfreight of goods with Australia's closest trading partners to ensure cross-border flows of critical medicines and other products, in particular, the EU, UK, US, South Korea, Singapore and Japan. Australia has also previously advocated for the Australian Government to take a leadership role to promote and strengthen the global rules-based order, including seeking for health-related trade and supply chains to have a special legal status in times of crisis to ensure patient needs are met. This could be further supported by internationally agreed green lanes for pharmaceutical products.

In the broader international trade context, Australia should be playing a leading role in developing sector specific agreements from a bilateral, regional and multilateral perspective. This will not only strengthen strategic supply chains, but ensure that Australia positions itself as a critical part of the research, development and supply ecosystem as a regional leader and strong global player.

With 90% of Australia's trade soon to be covered by free trade agreements, Medicines Australia believes that the next logical step is for the Government to pursue sector specific agreements in bodies like the World Trade Organisation and the Asia Pacific Economic Forum, as well as regionally through new or existing bilateral and regional agreements. Australia is already part of an intricate web of free trade agreements and can leverage these further, including the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), Regional Comprehensive Economic Partnership (RCEP) and Australia, ASEAN, New Zealand Free Trade Agreement (AANZFTA). These agreements should not only look at broadly eliminating tariffs but be aligned with the future needs of the industry in respect of

- research and development
- supporting innovative new treatments, such as precision medicines and ones that harness pharmaceuticals, devices and services as part of standard of care
- intellectual property
- skilled migration
- regulatory harmonisation
- ensuring the safety and security of supply chains.

Recommendations

For a more resilient supply chain, Australia must be a trusted partner in a globally interconnected research-driven pharmaceutical industry. If the government wants to strengthen Australia's access to this supply chain for all Australian patients, including through manufacturing, it must:

- improve regulatory and reimbursement processes to better align with overseas jurisdictions
- ensure true value for innovative medicines is recognised to better reflect the value of medicines to patients and strengthens the Australian domestic market and supply chains to it
- invest more and provide greater incentives for:
    - Australia to become a regional hub for R&D, including pilot manufacturing
    - national and regional medicines stockpiling
    - increased value-add manufacturing, including contract manufacturing and vaccine partnerships
    - advanced manufacturing, for example in the regenerative medicines space
- pursue health sector specific regional and plurilateral trade agreements.

About Medicines Australia

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Medicines Australia's members play a vital role in the health of the Australian economy and its citizens. Our members contributed approximately $9 billion to the Australian economy in 2016-17; employ, directly and indirectly, over 23,000 Australians; invest over $1 billion into research and development annually to help 33,000 Australians get early access to emerging innovative therapies. In 2017-18, our industry exported $1.6 billion worth of medicinal products (rising to nearly $4 billion if medicaments are included). None of this, of course, accounts for the additional and largely unquantified benefits to Australian patients' health, wellbeing and the significant economic spill-over effects.

Pharmaceutical companies represented by Medicines Australia have a broad and deep pipeline of innovative medicines, diagnostics, treatments and vaccines. Our members develop, manufacture, and supply critical medicines and vaccines available on the pharmaceutical benefits scheme (PBS), the Life Saving Drugs Program (LSDP), the national immunisation program (NIP) and companion diagnostics or other treatments available through the Medical Benefits Scheme (MBS) and National Blood Authority (NBA). Our membership comprises small, medium, and large Australian and multi-national companies. Many of the world's multi-national medicines manufacturers are members of Medicines Australia through their local affiliates. These local affiliates provide a critical worldwide connection that enables Australians to access globally developed breakthrough medicines and therapies.