

4 May 2021

Productivity Commission  
Locked Bag 2, Collins St East  
Melbourne VIC 8003  
Department of Home Affairs

## **Vulnerable Supply Chains Study**

Thank you for the opportunity to contribute our industry's perspective and insights to the above study, and provide comment on the study's interim report, released 26 March 2021.

Consumer Healthcare Products (CHP) Australia is the leading industry association representing the manufacturers and distributors of consumer healthcare products, including nonprescription medicines.

9 out of 10 Australians use nonprescription medicines regularly<sup>1</sup>, including analgesics, hand sanitisers, cold & flu medicines, nicotine replacement therapies, vitamin and mineral supplements, hay fever and allergy relief products, sunscreens and many more.

With over 14,000 nonprescription products helping keep Australians healthy and productive<sup>2</sup>, annually our industry generates approximately \$8 billion in domestic sales, \$2 billion in export revenue and employs over 10,000 Australians<sup>3</sup>.

Although the majority of medicines Australians' use are imported, there is a small, but vibrant, nonprescription medicines manufacturing industry in Australia supporting high quality, skilled jobs and generating economic growth.

Additionally, the breadth of potential growth in the export market for Australian made health products has yet to be fully realised.

However, Australia does not have the capacity to support medicines self-sufficiency and access to the vast majority of medicines Australians use regularly to maintain productivity and healthy lives will depend on a resilient, robust and effective global supply chain.

Similar to many modern supply chains, the nonprescription medicines supply – both for manufacturing raw materials (active ingredients, excipients, packaging and labelling

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<sup>1</sup> Consumer Behaviour Factbook (March 2015) Macquarie University

<sup>2</sup> TGA Bilateral Meeting Presentation (December 2019)

<sup>3</sup> CHP Australia estimates based on:

- IQVIA & Nielsen Scan Data Sept 2019. Combined Pharmacy & Grocery
- IBIS Pharmaceutical Product Manufacturing in Australia, March 2019. IBIS World Pty Ltd
- IBIS Pharmaceutical Wholesaling in Australia, March 2019. IBIS World Pty Ltd



components) and finished products - is an “intricate web of economic interdependencies” relying on inputs from across the globe.

Flexibility in the supply chain is essential to ensuring the ongoing supply of medicines, and the rapid mitigation of supply issues cannot be achieved by simply running the machines longer.

The production and distribution of medicines is a long and complex process. It is reliant on forward planning to have all starting materials, not just the active ingredients but also excipients, packaging components and printed labelling available to manufacture the number of batches required to meet the order quantity. The starting materials may need to be sourced from multiple countries and must meet approved quality standards before release for manufacture. Firm orders for the medicine therefore often need to be placed six months or more ahead of the planned date of manufacture.

CHP Australia would agree with the interim report that recent constraints and pressures on the global supply chain have emphasised the need to develop a better understanding of Australia’s supply chains at a market level, and strategies to mitigate vulnerabilities and reinforce supply chain resilience.

On-shoring of manufacturing should not be viewed as a pathway to complete medicines self-sufficiency. However, with competitive international market conditions and the higher costs of domestic operations, it is in the interest of consumers, government, and a sustainable industry that the supply chain for packaging, raw materials, and medicinal products remains robust. Even wholly domestic product manufacturing operations would continue to be reliant on the international supply chain for raw materials and components.

Furthermore, based on CHP Australia’s work and experiences as part of the TGA’s Medicines Shortages Working Group and the Department of Industry’s Supply Chain Roundtable, we agree with the report’s assessment that:

*“Australia’s supply chains proved generally resilient in response to the COVID-19 pandemic, but the experience with COVID-19, following the devastating 2019-20 bushfires has highlighted Australia’s potential vulnerability to supply chain disruptions.”*

Co-ordination between Government and industry has been essential to resolving issues, keeping the supply chain framework intact and managing continuity of supply of medicines, diagnostics, and medical devices.

Industry has also moved at unprecedented speed to source products from alternative sources across the globe where shortages have been identified, working creatively to resolve complex challenges, particularly where there has been disruption in supply chains, including in India and China.

Additionally, Australia’s local medicines manufacturing’s flexibility and responsiveness has assisted distributors in responding to the evolving needs of government procurement, the



healthcare system, and consumers. A capability that is enhanced by nimble contract manufacturers who make up a large proportion of domestic operations.

Unfortunately, despite considerable effort and investment from both Government and industry, some challenges in the COVID-19 supply chain are yet to be fully resolved. Most notably, the limited availability, reduced reliability and, in some instances, prohibitive cost of freight. Given the necessity and value of Australia's health and infection containment protocols, this issue may only be resolved by the resumption of international travel. While Australian governments have been working with industry sectors to resolve the issues around sea freight within their control, it is clear that greater collaboration is necessary at a global level to review the causes and develop plans to resolve the ongoing issues.

Australia's experience of the COVID-19 global supply chain is consistent with observations and conclusions reached by the UK's Life Sciences sector in their *COVID-19 Roadmap to Recovery*<sup>4</sup> report:

*"While supply chains have responded well in the crisis, additional resilience could be provided through improved demand forecasts and transparency along the supply chain, support for supply diversification, international inventory management and development of a strategic reserve of essential medicines."*

As such, CHP Australia is encouraged by this current study and its remit to examine the nature and source of risks to the effective functioning of the Australian economy and Australians' wellbeing associated with disruptions to global supply chains, identifying any significant vulnerabilities and possible approaches to managing them.

To date, the collaborative efforts of regulators, industry and trade officials have been sufficient and effective in resolving the COVID-19 supply issues stemming from this vulnerability, including export restrictions on active pharmaceutical ingredients.

However, the increasing prevalence of medicines nationalism, international factionalism, political interference, and trade wars have increased the sovereign risk in this space and highlighted a vulnerability in the global supply chain.

To help mitigate these political vulnerabilities, and potential future challenges, additional resilience needs to be built into the supply chain, and we are supportive of the framework outlined in the Commission's interim report. The development of a standardised framework by which the government periodically reviews and updates the list of goods and services that are vulnerable to supply disruptions and essential for the wellbeing of Australians, will support the country's resilience as supply chains change over time.

We welcome the wisdom that *"risks are best managed by those who have direct incentives to mitigate against them"* and that government intervention in private sector risk management

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<sup>4</sup> UK Life Sciences COVID-19 Roadmap to Recovery - <https://www.pagb.co.uk/content/uploads/2020/06/Life-Sciences-Recovery-Roadmap-3rd-June-2020.pdf>



would need to be justified. We recognise and support range of options available to government — *“from providing better information to taking more direct ownership of risk management (such as maintaining government stockpiles, mandating, or subsidising private stockpiles, or maintaining domestic production capacity)”*.

As indicated in the report, governments need an understanding and respect of the confidential nature of the structure of the supply chain for each product and for the arrangements each firm has put in place to provide for assurance of supply. There is a significant cost in the design of a supply chain which can provide a competitive advantage to a firm in good times and bad.

The report also provides a supportive/confirmative basis for firms to undertake or reassess their own risk assessments of their supply chains and evaluating possible mitigation strategies and determining implementation plans.

CHP Australia endorses the “data-with-experts” approach adopted in the framework, and concur with the conclusion drawn when the framework was piloted. The recognition of the broad functionality of our current supply chains, and the comprehensive filters applied to trade data, the framework allows for a more targeted approach to identifying and mitigating vulnerabilities, particularly in the space of highly concentrated imports and suppliers.

The highly regulated nature of medicines is a significant factor contributing to the demand for Australian made health products in other markets, but it does mean introducing greater flexibility into the supply chain is a time consuming and costly exercise. A medicine sponsor’s risk management plans for products must therefore be in place in readiness for a crisis.

Some medicinal standards particularly when applied to lower risk medicines in Australia, where those products are not regulated as medicines in other major markets, like sunscreens and complementary medicines, may become a limitation for supply during a crisis. Government may need to be ready to provide for a level of flexibility to provide for ongoing supply of some of these products. In a crisis situation, where there is high demand for a material, suppliers will take steps to maximise output by reducing varieties of grades and sizes of packs on offer. This minimises change over of a line and hence downtime. Under these circumstances there will be no appetite for meeting additional testing or selecting batches which meet a tighter specification to meet Australian specific requirement. An example of the flexibility necessary occurred during the initial stages of COVID crisis and global demand for hand sanitiser. A manufacturer of a therapeutic hand sanitiser was unable to obtain the pharmacopoeial grade of the specialty chemical to thicken the sanitiser to a gel. They could however access the technical grade and conducted testing to demonstrate its equivalence. They applied to the TGA for an exemption to use the material. TGA reviewed the material conducted their own tests and granted an exemption to use the non-pharmacopoeial grade.

CHP Australia supports the Commission’s view that a “responsive regulatory environment” is one area where governments could focus their effort to assist industry’s attempts to diversify their supply sources. We would encourage consideration also be given to ensuring the appropriate regulatory bodies are sufficiently resourced to facilitate the processing of variations



to market authorisations necessary to increase the flexibility and therefore robustness of the supply chain.

We are grateful to have had the opportunity to share our industry's insights and experiences with the Productivity Commission's study, and hope our comments add value to policymakers' deliberations and decision-making.

As the leading industry association representing consumer healthcare products, we would appreciate remaining involved in the development and implementation of the framework, and any resulting policy responses.

We look forward to reviewing the outputs of the pilot of the framework, and, where appropriate, can provide industry-specific, 'expert' information and advice on the list of chemicals identified vulnerable and essential.

Consumer Healthcare Products (CHP) Australia is available to discuss any issues raised in this submission and answer any additional questions the Productivity Commission may have about our industry.

If we can be of any assistance, please don't hesitate to reach out.

Yours faithfully,

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