



Consumer Healthcare
Products Australia

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10 September 2021

Senate Standing Committees on Economics
Department of the Senate
PO Box 6100
Parliament House
Canberra ACT 2600

RE: Australian Manufacturing Inquiry

Dear Committee Secretariat,

Consumer Healthcare Products (CHP) Australia appreciates the opportunity to contribute our industry's experiences and perspective on Australian Manufacturing.

Consumer Healthcare Products (CHP) Australia is the leading industry voice representing the manufacturers and distributors of consumer healthcare products, including nonprescription medicines. Additionally, we represent businesses that support the consumer healthcare products industry.

To assist the Committee in their deliberations, this submission seeks to provide Senators with a greater understanding of Australia's current domestic medicines manufacturing operations and capacity, opportunities, and avenues for greater Government support.

Nonprescription Medicines Manufacturing in Australia

9 out of 10 Australians use nonprescription medicines regularly¹, including analgesics, hand sanitisers, cold & flu products, nicotine replacement therapies, vitamin and mineral supplements, hay fever and allergy relief, sunscreens and many more.

Annually, our industry generates approximately \$8 billion in domestic sales, \$2 billion in export revenue and employs over 10,000 Australians².

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 and exports growth.

That said, because of Australia's high standards of regulation for complementary medicines, the majority of these health products are manufactured and packaged domestically. This regulatory environment for listed medicines³, and consumer trust in the quality and safety of Australian

¹ Consumer Behaviour Factbook (March 2015) Macquarie University

² 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

³ Listed products (AUST L) are medicines considered low risk by the TGA, and usually with a long history of use, such as vitamin and mineral products or sunscreens. They are assessed by the TGA for quality and safety, and product sponsors companies are required to hold information to substantiate all of their product's claims.



made health products, has led to significant demand for these products in other markets, China but increasingly also in India and the Middle East.

However, even with the high value export market opportunity for Australian made health products, the higher costs of domestic operations have meant the extent of potential and growth in this market is yet to be realised.

The recent constraints and pressures on the global supply chain have emphasised the rapid response value of our domestic manufacturing capabilities, a capacity greatly enhanced by nimble contract manufacturers who make up a large proportion of domestic operations. Throughout the pandemic, Australia's local medicines manufacturing's flexibility and responsiveness has assisted in responding to the evolving needs of government procurement for both the healthcare system, and consumers.

If given appropriate support, the nonprescription medicines manufacturing sector has the capacity to provide new and ongoing economic growth for Australia, capitalising on the expanding export market for Australian made health products.

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

Australia does not have the capacity to support medicines self-sufficiency and, for the foreseeable future, access to the vast majority of medicines Australians use every day to maintain productivity and healthy lives will be dependent on a resilient and effective international supply chain.

Reinforcing supply chain resilience

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

Based on CHP Australia's work and experiences as part of the TGA's Medicines Shortages



Working Group, we believe that when the international community productively works together to address supply pressures, the global supply chain is robust, resilient, and effective.

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 sovereign risk and highlighted vulnerabilities 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. CHP Australia is supportive of the framework outlined in the Productivity Commission's report for identifying those goods/components subject to supply chain disruptions and used in essential industries and to produce critical goods and services, without which, there would be a significant impact on the economy, security and the wellbeing of the nation.

However, 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.

As such, we welcome the Commission's 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 would need to be justified. We recognise and support a 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)"*.

The highly regulated nature of medicines is a significant factor contributing to the demand for Australian made health products in other markets, but it also means that introducing greater flexibility of sourcing into the supply chain must be first confirmed as not impacting the safety, quality and efficacy of the medicine and in some cases requires an application for approval to change the registered details of a medicine. It 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.

We would strongly 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.

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 an 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.

Finally, a key and ongoing vulnerability in the COVID-19 supply chain, repeatedly raised by both our manufacturing and importer/ distributor members, is the reduced reliability and increased cost of sea and air freight. The direct costs of freight have tripled and, in some cases, even quadrupled. Additionally, fluctuations in available freight capacity, and lack of predictability in shipping times have necessitated manufacturers and distributors, during a period of record high prices, significantly increasing their inventory holdings to support the continuous supply of medicines.

Given the necessity and value of Australia's health and infection containment protocols, CHP Australia appreciates this issue will likely only be resolved by the resumption of international travel. However, 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.

Conclusion

We are grateful to have had the opportunity to contribute our industry's insights and experiences to the inquiry.

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

If the committee would like to discuss any of the matters raised in greater detail, please don't hesitate to contact our Public Affairs Manager, [REDACTED], on [REDACTED]
[REDACTED]

Yours sincerely

Dr Deon Schoombie
Chief Executive Officer