

3 April 2023

House Standing Committee on Industry, Science and Resources
PO Box 6021
Parliament House
CANBERRA ACT 2600
Email: isr.reps@aph.gov.au

Re: Inquiry into Developing Advanced Manufacturing in Australia

Dear Mr Mitchell,

Thank you for the opportunity to make a submission to the House Standing Committee on Industry, Science and Resources Inquiry into Developing Advanced Manufacturing in Australia. AstraZeneca supports the Committee's aims of further supporting Australian industry, creating jobs and reviving our ability to manufacture world-class products domestically.

AstraZeneca employees approximately 83,000 globally and manufactures in 15 countries including Australia. We are one of the largest pharmaceutical manufacturers in Australia, and our Australian facility, based in North Ryde, Sydney, is a world-class facility known for delivering outstanding supply performance, and regarded as one of the most cost-efficient and successful manufacturing sites in the AstraZeneca global network.

AstraZeneca is a willing industry partner, open to opportunities to collaborate with government and industry to drive local manufacturing. We have a proven track record, having collaborated with CSL to manufacture our COVID-19 vaccine, Vaxzevria, locally, demonstrating that Australia is capable of producing high quality medicines.

AstraZeneca's Australian Manufacturing

AstraZeneca's North Ryde facility is an aseptic manufacturing site, primarily manufacturing Pulmicort Respules and local anaesthetic products. This facility produced 200 million Respules in 2022, with projected growth of 30% over the next five years. This facility supplies medicines to 18 countries across southeast Asia, Europe, China and Japan.

Current demand projections for this facility for the next 2-3 years will be projected to be well below our total capacity due to changing demand of our medicine in different markets. As a result, there is potential for additional market transfer to this site. This site employs approximately 300 people, including operations and quality assurance staff.

Pharmaceutical Manufacturing in Australia

The majority of medicines in Australia are imported. The COVID-19 pandemic highlighted many of the fragilities of Australian supply chains for medicines, with shortages for vital medicines experienced throughout the pandemic. Shortages were the result of multiple factors including

disruptions to supply chains, as well as stockpiling in other countries. Global health crises, trade disputes, political disputes, labour shortages or civil unrest could all result in shortages of critical medicines in the future.

Pharmaceutical manufacturing faces several challenges in Australia. However, there are also a number of key advantages to manufacturing domestically which could be better leveraged, such as our globally recognised regulation, strong IP protection, highly developed medical innovation ecosystem, highly regard clinical trial network and expansive health and research infrastructure, highly skilled workforce, and proximity to growing Asian markets.

Recommendation 1: Develop a National Strategy for Sovereign Pharmaceutical Manufacturing Capability

AstraZeneca supports initiatives that support sovereign manufacturing capability for medicines and vaccines that millions of Australians rely on every day. However, any such approach requires a national strategy and coordination.

The Strategy must consider the critical nature of products, with the basic capability to manufacture the most critical products, potentially taken from those outlined by the World Health Organisation as the most effective and safe medicines to meet the most important needs of a functioning healthcare system.

By clearly prioritising critical products, a National Strategy would encourage stronger pathways and investment in facilities.

The Strategy must include a coordinated approach, in close collaboration with pharmaceutical companies, research and clinical organisations, the biotech industry, and states, to ensure that states do not compete or duplicate effort. Manufacturing networks must cover all key platforms, including small molecule synthesis, cell based-microbial or mammalian, and new technologies such as RNA and DNA.

Recommendation 2: Support for sourcing of active ingredients and cold chain storage

Imported and domestically produced products are heavily reliant on imported active ingredients. Any sovereign manufacturing capability must include support for sourcing active ingredients, otherwise supply chains will remain exposed to international shocks.

Cold chain storage is becoming more common (i.e., RNA technology), however it remains logistically challenging and costly. Cold chain storage requires active and passive packaging solutions and significant technological investment (such as data loggers and sensors), which can be expensive. Supporting investment to enhance Australia's cold chain storage capacity will help support and encourage local manufacturing.

Recommendation 3: Support to enable transfer and evolution of existing Australian pharmaceutical manufacturing sites to ensure they are operating close to full capacity, including skills and training development

Australian pharmaceutical manufacturing sites require support to ensure they can operate at full capacity. The COVID-19 pandemic demonstrated how agile the Australian economy can be when necessary, i.e. with manufacturing facilities ability to pivot to producing medical supplies and hand

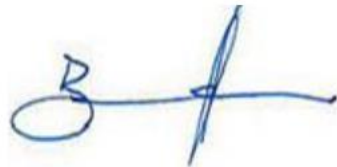
sanitiser, when required. Pharmaceutical manufacturing facilities require support to enable them to repurpose existing capacity and to scale in response to global supply chain challenges.

Government must ensure that policies and initiatives support existing TGA licensed facilities, as well as greenfield sites.

For example, AstraZeneca's North Ryde facility is currently operating below capacity. In order to explore other commercially viable options for the future, strategic insights from the government – such as new medical technology to invest in – as well as support in the form of taxation concessions or subsidies, and government investment in training and developing a highly skilled workforce.

This Inquiry presents an opportunity for the Government to establish further policies and initiatives to safeguard Australia's access to critical and lifesaving medicines, whilst also leveraging economic benefit and driving employment growth. AstraZeneca welcomes the opportunity to continue to collaborate with the Standing Committee on this topic.

Yours sincerely,

A handwritten signature in blue ink, appearing to be 'B McDonald', with a stylized flourish at the end.

Benjamin McDonald
Country President
AstraZeneca Australia and New Zealand