Medicines Australia submission to the House of Representatives Standing Committee on Industry, Science and Resources inquiry on Developing Advanced Manufacturing in Australia

1. Medicines Australia welcomes the opportunity to respond to the House of Representatives Standing Committee on Industry, Science and Resources' inquiry into developing advanced manufacturing in Australia. We would be pleased to provide oral evidence as part of the inquiry.

2. The COVID-19 pandemic has clearly demonstrated the link between Australia's health and economic wealth and the value of investment in health innovation. For example, a recent peer-reviewed study demonstrated that COVID-19 vaccines are estimated to have reduced the impact of the pandemic on the Australian economy to an estimated $214 billion, resulting in a positive incremental benefit of $181 billion.[1] We welcome the increased policy focus on health innovation to ensure that the lessons from the pandemic are learned so that Australia is not only better prepared for the next health emergency, but so that all Australians can consistently enjoy the world's best health outcomes.

Attracting and building advanced manufacturing requires a holistic view of healthcare innovation

3. As the peak body for the innovative pharmaceutical industry, Medicines Australia is committed to driving policy outcomes in partnership with government, health sector organisations and the community which will ensure Australians have universal, affordable and fast access to treatments that keep pace with advancements in medicine. Building a strong Australian life sciences ecosystem is an important part of realising this mission. The Government's $1.5 billion investment in medical science via the $15 billion National Reconstruction Fund (NRF) is an important initiative designed to help the sector move up the value chain to become more productive and address supply chain vulnerabilities. We are pleased to be part of the NRF Medical Science Industry Working Group to progress this agenda in partnership with the Government.

4. It is vital to note that advanced manufacturing in life sciences cannot be done in isolation. A sustainable advanced manufacturing sector requires a sustainable life sciences ecosystem to support it. A life science ecosystem encompasses a range of stakeholders, such as researchers, entrepreneurs, investors, regulatory bodies, healthcare providers, and patients, who collaborate to bring new therapies, diagnostics, and medical technologies to market. The significant challenge – and opportunity – for the Australian life sciences ecosystem is to translate local research into clinical and commercial outcomes that benefit patients and the Australian economy.

5. In recent years, there have been positive developments which demonstrate that progress is being made towards capitalising on the opportunity that a thriving life sciences ecosystem would offer. These include recent investments, such as Sanofi partnering with the Queensland Government to establish a $280 million Translational Science Hub and Moderna building an mRNA manufacturing facility in Victoria in collaboration with the Federal and State

[1] Fox, Nathan, Philip Adams, David Grainger, Jennifer Herz, and Carolyn Austin. 2022. "The Value of Vaccines: A Tale of Two Parts" Vaccines 10, no. 12: 2057. https://doi.org/10.3390/vaccines10122057

Governments. These investments are complemented by public investments made by the Government, such as the commitment to earmark $1.5 billion for medical science via the NRF.

6. While Australia is recognised as a global destination for clinical trials, more must be done to increase Australia's international competitiveness. Delivering a multi-centre trial in Australia across state and territory borders continues to involve significant duplication of effort, complexity and inconsistency in approach. The National One Stop Shop is an initiative currently being considered for funding by the Government which would make it easier for patients, researchers, industry representatives and sponsors to find, conduct, participate and invest in high quality and ethical research in Australia. The National One Stop Shop is a rare opportunity to address Australia's long-running lack of harmonisation in the clinical trials landscape, which would boost our international competitiveness and strengthen our life sciences ecosystem. A public investment in the National One Stop Shop would complement the objectives of the NRF.

7. Furthermore, the Government's vision to "achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment" in the newly updated National Medicines Policy sends a strong message that Australia is committed to realising the economic, social, and health benefits that can result from a vibrant and innovative life sciences industry. The Strategic Agreement between the Government and Medicines Australia supports the vision of the National Medicines Policy with the shared goal to reducing time to access for Australian patients so that they can access new health technologies as early as possible.

Global investment in Australian advanced manufacturing requires a clear market access pathway

8. A key part of the Strategic Agreement between the Medicines Australia and the Commonwealth is the independent Health Technology Assessment (HTA) Policy and Methods Review, which is the first of its kind in nearly 30 years. If Australia is to remain amongst the group of countries prioritised for first wave launch of healthcare innovations, it is essential that the Review delivers bold reform which will result in faster access to innovative medicines for Australian patients. Such reforms must be accompanied by government policy which demonstrates a willingness to invest in new and innovative medicines and vaccines and to maintain a viable and sustainable market for healthcare innovation.

9. Reforming Australia's HTA system is a vital aspect of growing a sustainable life sciences ecosystem because companies make investment decisions based on a country's willingness to invest in bringing innovative technologies to their populations in a timely manner. Without a clear market access pathway in Australia, global companies are unlikely to invest in new, or upgrade existing, advanced manufacturing facilities.

Global investment in Australian advanced manufacturing requires a stable policy environment

10. Investments in advanced manufacturing are long-term and therefore require a stable and globally competitive policy environment. This includes political and economic stability, strong and reliable trade relations, a strong legal and regulatory system that supports innovation, and an internationally competitive tax environment. An Australian patent box scheme, which would offer concessional tax treatment to profits derived from intellectual property (IP) on innovative health products, would further incentivise both global and local companies to commercialise IP in Australia.

Public-private partnerships as a model to drive advanced manufacturing

11. In addition, to remain globally competitive, Australia must consider public-private partnerships (PPPs) as a key model to attract local and international partners, promote job creation, increase productivity and capability, and align with the Government's policy priorities. PPPs leverage private and public investment and bring together a wide range of capabilities to drive innovation. Success factors for PPPs include equal engagement and investment from stakeholders and government, long-term commitment, and harnessing the capabilities of industry, government, and academia. This ensures that issues of scale, financial sustainability, and knowledge and technology access are addressed throughout the manufacturing process.

12. To maximise the value of PPPs, the partnerships should focus on the high value add components of the production chain towards either end of the 'manufacturing smile curve' (which show the value added along a production cycle). [2] These components of manufacturing include pre-production (R&D, design) and post-production (sales and services), rather than traditional production. To realise the benefits of advanced manufacturing and build its knowledge economy, Australia should leverage knowledge creation and collaborative partnerships in areas of the value chain that do not require traditional production. We would welcome discussions with the Government to further develop PPPs as a model to drive advanced manufacturing and leverage global investment.

Establishing a government-industry Life Sciences Council to collaboratively drive health innovation

13. In summary, for Australia to attract and build advanced manufacturing in the life sciences, policymakers must take a holistic view of health innovation. Advanced manufacturing cannot be done in isolation, and to successfully build a thriving life sciences ecosystem, Australia must capitalise on the HTA Policy and Methods Review to create a clear market access pathway, ensure Australia has a stable and globally competitive policy environment, and consider PPPs as a key model to attract global companies.

14. To improve the collaboration and coordination between governments and industry, Medicines Australia recommends that the Government forms a high-level government-industry Life Sciences Council. The Council would drive government-industry partnership and importantly, send a positive message to global companies that Australia is committed to improving social, health and economic outcomes through a vibrant life sciences sector and stable policy environment.

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[2] Australian Department of Industry, Science, Energy and Resources submission to the Senate Economics References Committee inquiry into The Australian Manufacturing Industry. 2021, Page 2: https://www.aph.gov.au/DocumentStore.ashx?id=8a896104-d2e9-4da6-9b94-f2496608f91c&subId=715226