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Developing Advanced Manufacturing in Australia
30 March 2023

Sanofi is an innovative global healthcare company. We provide life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.

In Australia, where we have been operating for over 40 years, our diverse portfolio of medicines and vaccines, includes:

- 60+ medicines funded on the Pharmaceutical Benefits Scheme (PBS).
- Seven vaccines funded on the National Immunisation Program (NIP), and a further ten available for use.
- Two therapies funded via the National Blood Authority (NBA)
- Six medicines funded on the Life Saving Drugs Program (LSDP).

We have a large pipeline of new therapies, underpinned by an enduring commitment to clinical research to transform the practice of medicine. This is exemplified by our partnership with the Queensland Government, University of Queensland, and Griffith University, announced in late 2022, to establish a Translational Science Hub; a total investment of AUD$280 across the partners.

The Translational Science Hub will connect world-class researchers in Queensland with Sanofi scientists in France and the US, creating a first-of-its-kind, global scientific community focused on mRNA technology and translational science. The goal of the hub will be to expand the use of the mRNA vaccine platform to treat a wider range of diseases.

Sanofi welcomes the inquiry by the House of Representatives Standing Committee on Industry, Science and Resources into developing advanced manufacturing in Australia. Our submission is focused on the opportunities for Australian advanced manufacturing that relate to medical science.

"Manufacturing is more than production. Manufacturing today comprises R&D, design, supply chain and logistics, mass customised goods, post-sales support, and services."[1]

Manufacturing today is being shaped by technological change, large scale economic forces, and supply chain disruptions. Advanced manufacturing utilises innovative technologies, including production activities that depend on information, automation, computation, software, sensing, and networking. It also tends to be linked to industries like medical, pharmaceutical, and aerospace.

Successful manufacturers are adopting smart technologies, such as cloud computing, artificial intelligence (AI), and advanced data analytics, to improve competitiveness. Technology-driven production is also helping to overcome labour

[1] Advanced-Manufacturing-a-new-definition-for-a-new-era.pdf (amgc.org.au) Accessed March 2023

shortages that are being experienced around the world. Finally, today's consumers are increasingly savvy, are better informed, and have higher expectations. They want personalised products, faster delivery systems, and sustainable and transparent practices.

Australia's comparative advantages:

Australia has many comparative advantages that position the nation favourably for advanced manufacturing. However, more can be done to optimise these. Strengths include:

- Access to world-class universities and research institutions, coupled with high education levels
- An international reputation for quality, safety, and reliability
- Strong trade relations and cultural ties with markets in the Indo-Pacific
- Political and economic stability
- A strong legal system that supports the creation and protection of intellectual property (IP) and licensing for the commercialisation of innovations.

In an increasingly competitive global landscape, continual improvement and investment in R&D is the only way for manufacturers to remain competitive. In the case of medicines and vaccines companies, they will prioritise R&D investment and skills development (i.e., advanced knowledge) in countries with policies that appropriately value innovation. This includes having harmonised processes for clinical trials, as well as efficient evaluation pathways that enable their populations to access new health technologies in a fast and equitable manner.

Australia should leverage our competitive strengths by creating high-value, distinctive solutions within global value chains. This is particularly pertinent for medical science where Australia has world-leading skills and experience, including in manufacturing.

With the right policy settings, Australia can create a dynamic and thriving domestic medicines and vaccines industry. This could include advanced manufacturing at the local level or as part of a regional network. From a vaccines perspective this could include:

- Raw materials and equipment manufacturing
- Bulk production
- Finished product
- An expanded role for regulatory approvals.

By leveraging our advanced knowledge in medical science, Australia can provide patients with early access to medicines and vaccines via clinical trials, for which there is likely to be no other solution available at that time. Not only do clinical trials help to deliver better health outcomes they have economic benefits via the creation of high-wage jobs and high-value manufactured products that can generate strong export income.

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A report by the Australian Commission on Safety and Quality in Health Care and the Australian Clinical Trials Alliance (ACTA) showed that for every $1 invested in clinician-driven clinical trials in Australia, benefits of $5.80 can be realised.[2] More broadly, we have seen first-hand over the course of the COVID-19 pandemic how a healthy population contributes to an economically strong nation via increased productivity, fewer hospitalisations and GP visits, and less reliance on social services.

Australia's comparative disadvantages:

Australia faces some headwinds to the growth of advanced manufacturing. These include:

- High labour costs
- Geographical remoteness which restricts access to global markets due to high transportation costs (exacerbated by current inflationary pressures)
- A small and dispersed domestic market
- Poor history of commercialisation
- Digital infrastructure and capabilities

Australian manufacturing businesses and researchers are excellent at solving problems but comparatively poor at commercialising these innovative solutions. According to the Global Innovation Index 2022[3], Australia ranked 19th for innovation inputs (lower than both 2021 and 2020). However, for innovation outputs Australia ranked 32nd (one position higher than 2021 but lower than 2020). Consequently, Australia produces less innovation outputs relative to its level of innovation investments. Australia's poor track record of commercialisation has global implications.

Currently the perception of Australia is that our technological strengths are in industries other than biomedical research, such as mining and agriculture. Because of this, Australia is often overlooked as a destination for medical R&D. As such, there is scope to promote the federal government's renewed commitment to deepen Australia's medical science and research capabilities, including sovereign manufacturing. Central to this is the need to foster end-to-end healthcare ecosystem development and sustainability. This can only be achieved if Australia's healthcare ecosystem is considered holistically, from the translation of medical science R&D into registered and reimbursed therapies, as well as manufacturing.

To fully realise the benefits of advanced manufacturing, Australian manufacturing capabilities need a significant digital boost. Digital supply networks and data analytics can stimulate critical advances in quality, speed, agility, and resilience in manufacturing processes. Cumulatively, these tools can help achieve significant increases in performance e.g., capacity, reduced lead times and conversion costs.

[2] https://www.safetyandquality.gov.au/about-us/latest-news/media-releases/clinical-trials-pay-safety-quality-and-economy. Accessed March 2023
[3] Global Innovation Index 2022, Australia. Available at https://www.wipo.int/global_innovation_index/en/2022/ Accessed March 2023

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Critical enablers for successful advanced manufacturing:

There are several elements that are needed to embed advanced manufacturing in Australia as it relates to the medicines and vaccines industry. They include:

1. A clear vision and national strategy for biopharmaceuticals, coupled with a robust investment mandate.
2. A diverse and highly skilled workforce with the necessary capability to conduct medical science R&D through to expertise in commercialisation.
3. Continuing education and training opportunities to ensure there is a sustainable and job-ready pipeline of talent.
4. A culture of collaboration between government, academic and industry stakeholders to implement and achieve the objectives of the national strategy for biopharmaceuticals.

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