AusBiotech submission in response to the *Understanding our RNA potential: Discussion paper*

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Introduction

AusBiotech welcomes the opportunity to submit a response to the Department of Industry, Science and Resources' discussion paper on *Understanding our RNA potential*.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry, which includes biotherapeutics, medical technology (devices and diagnostics), and agricultural biotechnology sectors.

Australia has a substantial life sciences and biotechnology sector, which is consistently ranked as one of the top countries for biotechnology innovation globally when adjusted for population. Industry employs almost 100,000 Australians and consists of more than 1,425 biotechnology companies. Around 80 per cent of these industry companies are classified as small to medium enterprises (SMEs) and are working to commercialise their research, with an important number developing new and novel technologies, including RNA technologies.

The submission represents AusBiotech members actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies.

Key recommendations

- Undertake national capabilities mapping, in order to appropriately prepare for Australia's RNA future, and to track its progress.
- Build, diversify and address gaps in access to capital across the industry by introducing a Small Business Innovation Research (SBIR) programme, modelled on that which has been successful in the USA, thus significantly increasing the flow of capital to the biotech sector.
- RNA technology shows great potential, however, there is an urgent need for agreed regulatory guidance materials and to harmonise globally, where it makes sense.
- For Australia to be globally attractive, it needs to consider a targeted tax amendment in its multinational tax regime; these policy levers not only anchors the manufacturing, but fosters further R&D.

Capability mapping to drive benefits to Australia and Australians

Taking a national approach to capability mapping will support the collaboration and cooperation between companies, and streamline efforts and investment opportunities, thereby enabling the RNA industry to thrive and drive benefits to Australia's economy and health of its people.

Australia is home to world-leading scientists and healthcare professionals, has high-quality medical and agricultural research and healthcare infrastructure, a stable political and regulatory environment, and a strong intellectual property (IP) regime. Its thriving life sciences and biotechnology sector is consistently ranked as one of the top countries for biotechnology innovation globally when adjusted for population. Included in these accomplishments, is the country's impressive RNA track record, and it is only anticipated to continue growing.

RNA's potential has most recently been recognised through the 2023 Nobel Prize in Physiology or Medicine, having been jointly awarded to Katalin Karikó and Drew Weissman for their discoveries concerning nucleoside base modifications that enabled the development of effective mRNA vaccines against COVID-19. Locally, investment has recently being seen through multinational partnerships being penned with Sanofi and Moderna; the establishment of the NSW RNA Pilot facility; and further industry investment taking place across the country.

However, Australia is underprepared to capitalise on the opportunities RNA can deliver as there is currently no clear visibility of the capabilities within the country in order to appropriately and proactively prepare for Australia's RNA future, and to track its progress.

AusBiotech recommends that national capability mapping is undertaken, similar to that of the AusBiotech-led Regenerative Medicines Consortium Project. Taking a national approach to mapping the stakeholders, location, company size (amongst other metrics), technologies and phases, will support the collaboration and cooperation between companies, and streamline efforts and investment opportunities, thereby enabling the RNA industry to thrive and drive benefits to Australia's economy and health of its people.

Additionally, having clarity on the size and shape of the local industry will help business cases be built for why Australia is a destination of choice for multi- and inter-national companies.

With a vision to foster the development of the Australian ecosystem to a self-sustaining state, and to position Australia as a global leader, it is crucial to establish a robust Australian capability in RNA manufacturing; prioritising quality, and reliability.

In harnessing Australia's strategic location within the Asia-Pacific (APAC) region, this reach can be expanded to encompass international markets. This capability should be actively promoted to two key stakeholders:

1. International product developers: Continuing to collaborate with these companies can strategically enhance our infrastructure while supporting local research and development (R&D). This can be achieved through government-funded industry-operated facilities with the capability and capacity to support the whole product development pipeline; from translation and first-in-human clinical trials, early to late phase clinical trials, through to commercial product supply.
2. Foreign markets: Sovereign manufacturing capabilities should be scaled to supply regional and global markets, and expertise in accessing and navigating these markets must be developed. This is in recognition that Australia's healthcare population is small (~1% of global) and a larger market opportunity must be realised to ensure a self-sufficient RNA ecosystem.

With a clear map of the capabilities and activity taking place domestically, Australia can make informed decisions on longer-term skills development and options for shorter-term talent migration. Similar to other industries, biotechnology is faced with a shortage of skilled talent; unique to this sector though is that biotechnology has seen a 60 percent growth during the past five years[1]. This means that not only is the sector already facing headwinds, but these are compounded due to the impressive growth of the sector that is expected to continue in an upwards trajectory.

Additionally, current tertiary training does not correspond to having a job-ready workforce. Through capability mapping, education providers will have a map to best understand the industry landscape and develop the targeted courses and speciality degrees that students need and that encompasses the cutting-edge knowledge and skills required in RNA development. This includes targeted courses and training to increase understanding and skills in GXP compliance, such as good clinical practice (GCP), good manufacturing practice (GMP), good laboratory practice (GLP) and good pharmacovigilance practice (GVP).

Greater investment in Australia

To build, diversify and address gaps in access to capital across the industry, thus significantly increasing the flow of capital to the biotechnology sector by $1 billion annually[2], it is recommended

[1] AusBiotech's *Australian Biotechnology Sector Snapshot 2022*
[2] Biotechnology Blueprint, 2022

that Government and industry work to introduce a Small Business Innovation Research (SBIR) programme, modelled on that which has been successful in the USA.

Investor diversity is needed

While recent years has seen welcome growth in Australia's venture capital industry, the pools of genuinely patient and risk-tolerant capital remain too shallow to sustain available growth and commercialisation opportunities. Inbound international capital is still limited, and there are concerns about a lack of diversity in the local investor base. This has meant that companies face continued challenges accessing private capital both at early (preclinical) and later stages (Phase II and beyond), often leading them to seek inappropriate commercialisation strategies, such as premature public listing on the ASX. Further, deeper analysis of the make-up of the sector shows that the vast majority (~70 percent) of companies are very early stage, pre-revenue and pre-clinical and ~80 percent are not yet able to be accessed by patients and are pre-revenue.

SBIR programme

The Small Business Innovation Research (SBIR) programme is a successful programme, initiated in the USA, that encourages domestic small businesses to engage in Federal research/research and development (R/R&D) with the potential for commercialisation.

Through a competitive awards-based programme, SBIR enables small businesses to explore technological potential and provides the incentive to profit from its commercialisation. By including qualified small businesses in the nation's R&D arena, high-tech innovation is stimulated, and the country gains entrepreneurial spirit as it meets its specific research and development needs.

The US's SBIR programme provides awards for Phase I, $50,000 - $250,000 for six months and Phase II to continue the R/R&D efforts initiated in Phase I, with $750,000 for two years. Funding is based on the results achieved in Phase I and the scientific and technical merit and commercial potential of the project proposed in Phase II.

The NSW SBIR programme is an initiative of the NSW Government programme that provides competitive grants to small and medium-sized enterprises (SMEs) to find and commercialise innovative solutions to well-defined problems for NSW Government agencies.

The establishment of the SBIR programme in NSW was recommended as the first Priority Action of the *Turning ideas into jobs: Accelerating research & development in NSW Action Plan*. The programme is modelled on similar programmes at the Commonwealth level (the Business Research and Innovation Initiative) and in the United Kingdom (the Small Business Research Initiative) and the US's SBIR programme.

The NSW SBIR programme is designed to:

- Leverage the capacity of NSW-based R&D in SMEs to address the needs of the NSW Government
- Grow the number of innovative products, services and jobs in NSW.

The SBIR programme is managed by the Office of the NSW Chief Scientist & Engineer, within Investment NSW, with the support of other NSW Government agencies, and supports:

- **Phase 1 – Feasibility study:** An SME submits a proposal to solve one of the seven SBIR programme challenges. The proposals are assessed, with each successful applicant receiving a grant of up to $100,000 to conduct a feasibility study over a period of three months.
- **Phase 2 – Proof of concept:** Successful feasibility study grantees are invited to apply for the proof-of-concept phase. Applications are assessed and each successful proof-of-concept grantee will receive up to $1,000,000 to develop a proof of concept over a period of up to 15 months.
- **Phase 3 – Procurement:** NSW Government agencies will consider purchasing successful solutions.

Continuing and scaling the SBIR programme has been identified by the Australian biotech industry as a key opportunity to foster and encourage an enduring collaboration-to-commercialisation partnerships between Australian universities, industry, and funders, in the decadal strategy, the *Biotechnology Blueprint*.

Industry would be pleased to work with Government on co-developing a set of desired principles for industry programmes aimed at SMEs, as it continues and expands the support and funding for early, clinical-stage companies to source seed funding (through a stage-gated approach) and broadens accessibility.

Given the great "*potential to drive innovation and growth in biotech, medicine and agriculture*", it would be fair to expect that RNA technology would be applicable across numerous government challenges.

Regulatory reform to reflect the potential of RNA

RNA platform technology shows great potential, however, there is an urgent need for agreed regulatory guidance materials and to harmonise globally, where it makes sense.

Developing traditional viral vaccines and therapeutics has typically taken years and included processes that can take considerable time to validate. With the commercialisation of RNA technologies, design and production time is significantly shortened as, once the platform is established, no infectious virus is required. With the maturation of this technology, a clear gap in platform regulation has become evident and needs to be filled.

Since the first regulatory approvals and deployment of mRNA vaccines in late 2020, they have proven to be highly effective in the treatment COVID-19. Many other mRNA vaccines are now under development, for example, for other respiratory and tropical and other infectious diseases, rare metabolic diseases and oncology. mRNA therapeutics are also being developed for treatment of a range of diseases.

A major factor behind the explosion of research and success in development of mRNA vaccines and therapeutics is that the products are developed from a common platform technology underpinning their design and development. This can streamline both the development and regulatory evaluation of these products, although regulatory guidance is needed on which aspects of the product, and its regulatory review will be more common between products and which aspects are expected to be product specific.

For Australia to maintain a competitive research, development, regulatory and commercialisation environment, there needs to be a clearer description and agreement of the implications of platform technology for these enabling processes, and a willingness to capitalise on the benefits of platform technology to enable efficient translation of products through the development and regulatory phases to commercial products.

Additionally, the global harmonisation of regulatory requirements for RNA vaccines, as far as possible, is recommended. Adopting a harmonised approach will streamline the approvals processes and reduce unnecessary regulatory burdens on industry sponsors; it is essential to avoiding unnecessary errors, duplication and costs within the healthcare supply chain and will facilitate international trade.

Creating a globally-competitive environment through a targeted tax amendment

For Australia to be globally attractive, it needs to consider a targeted tax amendment in its multinational tax regime; these policy levers not only anchors the manufacturing, but fosters further R&D.

Australia's development as a knowledge economy means that our (intangible) assets are becoming more globally-mobile than ever before. Companies, small and large, can move the advantages of their IP around the world to enjoy the most favourable tax treatments and incentives. The spillover benefits of managing, developing and monetising IP, such as jobs, manufacturing, exports, clinical trials and associated service businesses go too.

To foster the development of the Australian ecosystem to a self-sustaining state, and to position Australia as a leader in the APAC region, it is crucial to establish a robust Australian capability in RNA manufacturing, prioritising quality, and reliability. In harnessing Australia's strategic location within the Asia-Pacific (APAC) region, this reach can be expanded to encompass international markets.

Advanced manufacturing, such as RNA technologies, often yields high value/low volume products, thereby somewhat overcoming Australia's geographic barriers from its major markets in the northern hemisphere. Additionally, as advanced manufacturing is relatively wage/salary agnostic it can operate competitively in developed countries.

Nevertheless, the rivalry among developed countries for advanced manufacturing is fierce.

The highly mobile nature of IP means entrepreneurs can readily choose the location in which they commercialise research outcomes. As a result, taxation-based incentives are a subject of significant global interest because lower tax rates mean companies can offer more competitive product pricing and more sustainable production.

Although the political realities of changing the corporate tax rate are accepted, while Australia maintains one of the world's highest corporate tax rates, it will simply not be competitive in global markets. In 2022, the average top corporate rate among EU countries is 21.16 per cent and 23.57 per cent in OECD countries. In the US it is 21 per cent. Currently, the Australian company tax rate sits at 30 per cent; it is still one of the highest in the developed world.

Global policy makers are actively utilising micro and macro-economic levers to poach and fiercely compete for skilled job-creating capital investments and Australia is not a particularly attractive business environment for the commercialisation of medical research compared to peer nations such as Singapore, the UK, US, Switzerland, France, etc.

Manufacturing is one of the major sources of innovation in Australia. While the sector makes up just 8 percent of the economy, it is responsible for a quarter of all investment in R&D. Innovation and manufacturing are different sides of the same coin. A constant push-pull operates, whereby innovation in product design encourages innovation in manufacturing processes, and vice versa. For this reason, the Harvard Business School advises against the separation of R&D and manufacturing.

To create a more globally-competitive environment, for the emerging RNA industry as well as the broader biotech industry at large, Australia needs to amend its existing Controlled Foreign Companies (CFC) tax obligations that discriminate against locally-owned versus foreign-owned advanced manufacturing in Australia.

CFC legislation creates real world consequences for the competitiveness of Australian-based multinationals compared to foreign counterparts. These rules can also provide a disincentive to manufacture product in Australia, where the related IP is owned offshore, rather than at one of our overseas manufacturing plants.

Importantly, this disincentive is not imposed on foreign-owned companies seeking to manufacture similarly structured products in Australia.

At the time of the CFC rules introduction, there were few Australian-owned advanced manufacturing operations; however, this has changed and it should be noted that the CFC law is redundant due to the wide-ranging transfer pricing provisions in the Act operating to ensure that the profit returned in Australia appropriately rewards the manufacturing activity undertaken in Australia.

A small, targeted amendment to the CFC rules (s.447 of the Income Tax Assessment Act 1936) would ensure that Australia's competitiveness was stronger and more responsive to modern manufacturing activities within a global value chain. The impact would be one way: to bring jobs onshore.

This targeted amendment is a long-term mechanism to support the biotech industry of the future: taxing more companies at a lower tax rate over an extended period, is a better return than the present situation where there are minimal companies at a higher tax rate.

In September 2008, the Board of Taxation issued a report to the Assistant Treasurer and Minister for Competition Policy and Consumer Affairs, which was then accepted by Government. The report gave a practical example of how these rules place Australian investors at a competitive disadvantage compared with another investor in the same country with the same business structure.

Draft legislation was developed and circulated in 2011 to overcome this barrier, however, it is unclear why the draft bill did not proceed to Parliament. As such, multinational manufacturing companies continue to be specifically disadvantaged and disincentivised to manufacture products in Australia when the IP is owned by certain offshore owned entities.

Australia needs innovation to continue productivity growth and encourage new industries such as biotechnology, to supplement its declining industries, such as automotive manufacturing. If Australia's tax system does not provide a conducive environment with competitive incentives, these technology ventures are undermined and Australia's best ideas and the resulting economic benefits are then developed, manufactured and managed in other countries.

If Australia is serious about being internationally competitive, it needs to create an internationally competitive business environment that is conducive to the entire research, development, and commercial pipeline, with tax incentives that keep up with the provisions of our major trading partners.

As a nation, we cannot afford to lose our remaining manufacturing skills and capabilities. Innovation and manufacturing need to be nurtured, so that they can once again excel and form robust pillars of the Australian economy.

Let Australia be proactive and enact policy changes that support the companies that are contributing to our broad-based economy with new and sustainable innovations.