
# AusBiotech submission in response to the *Industry Growth Program: Consultation Paper*

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## Introduction

AusBiotech welcomes the opportunity to submit a response to the Department of Industry, Science and Resources' consultation paper on the *Industry Growth Program* (the Program).

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 more than 105,000 Australians and consists of more than 1,425 biotechnology and medical technology 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 – the majority of which are pre-revenue.

It is important to note that the development of bio/medical technology differs from traditional business and other non-medical technology in both its development challenges and in its potentially world-changing technologies.

Its main unique characteristics include: being highly regulated; requiring costly and extensive clinical trial data before any product can be approved; and having longer than usual development times. It can typically take 7 – 15 years and up to $2.5 billion to bring one bio/medical product from early research to market, with little or no revenue.

When government programs do not take account of the unique characteristics of the biomedical development, the journey of medical products to patients is disadvantaged, because biotech companies developing them cannot compete on the same 'playing field'.

Australia's industry is well placed to participate in the global contribution to medial advancement but will need to develop a balanced community of companies at all stages/sizes – and funding is the key to moving these companies and their respective medical products along the pathway to market and patients. This will require that capital, and more of it, from a diversified and well-educated investor base is available for quality opportunities. This is why the Program's design is critical to the commercialisation of medical products.

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 digital health, and agricultural biotechnology sectors.

This submission represents AusBiotech members actively engaged in delivering social and economic benefits to Australia through the commercialisation of biotechnologies and medical technologies, and therefore relevant and interested in the medical science and enabling capability priorities outlined in the Program consultation.

Comments have been considered and formed in response to these two priority areas, and have been framed around the Department's feedback questions, as requested in the consultation paper.

## Key recommendations

1. The medical science sector's unique characteristics need to be overtly taken into consideration when determining eligibility criteria for SMEs in this 'space', lest the policy intent will not be met.
2. The intention for matched funding to be a criterion for grants, be rethought for the pre-revenue medical science sector. A pre-approved concession for the sector is recommended, lest the requirement become yet another barrier for SMEs. At any amount, it is high bar to entry for a

company relying on capital flow from investors and grants. Even the matching via prospective/new investment would be a significant barrier.

3. Technology Readiness Levels (TRLs) would assist in clarifying program intent and eligibility, however, without careful application, their use will be problematic, even within the same priority sector such as medical science. Again, the unique characteristics - and indeed the sub-sector characteristics – would need to be articulated.
4. It would be beneficial for Industry Partner Organisations to offer expertise where there are currently gaps in the market and where SMEs initially struggle to access, such as global IP strategies and investment attraction strategies.

### Eligibility of innovative SMEs

**What objective criteria should determine eligible innovative SMEs? For example, annual turnover of $20 million or less, employee cap and/or net asset cap?**

AusBiotech recommends that pre-market companies and those with turnover up to $20 million (if applied as in the R&D Tax Incentive) be considered an SME. Thes companies are typically also pre-revenue and pre-regulatory approval. However, it should be noted that an SME in this sector, will not be analogous to an SME in another sector. For example, a biopharma company that has received a once-off payment of $10 million and a prospective royalty stream upon development milestones, will not be equivalent in character to an IT company with a $10 million stream of revenue that is following year-on-year.

Bio/medical technology differs from traditional business and non-medical technology in both its development challenges and in its potentially world-changing technologies.

Around 80 per cent of Australia's biotech companies are classified as SMEs and are working to commercialise their research, with an important number developing new and novel technologies – the majority of which are pre-revenue.

The sector's main unique characteristics include being highly regulated, usually requiring expensive and extensive clinical trial data before any product can be approved, and having longer than usual development times. It typically can take 7 – 15 years and up to $2.5 billion to bring one bio/medical product from early research to market, with little or no revenue.

These differences are why, unless a policy takes these unique characteristics into consideration during the policy design phase, the sector can be severely disadvantaged. For example, annual turnover, FTE, and net asset caps are not appropriate eligibility criteria for the medical sciences.

Alternatively, if the eligibility for this sector is pre-market companies, then this would offer an opportunity to foster end-to-end ecosystem development. Collectively, the MRFF, Program and NRF programmes have the opportunity to support the transformation, scaling and growth of a balanced community of Australian biotechnology companies at all stages and sizes of the company life cycle, which can then in turn enable greater access to broader sources of funding and investment.

Currently, incentives and structural supports along the pipeline are patchy, inconsistent and uncoordinated and there is a valuable opportunity for the Program to support SMEs that are earlier in their journey, as well as those companies that are further along in their commercialisation progression but still pre-market. This offers a spectrum of diversity and growth opportunities within the 'medical science' portfolio.

**What level of grant matching is appropriate? Should there be a variation for earlier stage Technology Readiness Levels (TRLs) programs and the size of the grant?**

A pre-approved concession to remove the need for matched funding for the sector is recommended, lest the requirement become yet another barrier for SMEs. At any amount, it is high bar to entry for a company relying on capital flow from investors and grants. Even the matching via prospective/new investment would be a significant barrier.

The reliance on venture capital and the 'market failure' in Australia's venture capital, means that many of our companies need to go overseas for capital and this in turn undermines our ecosystem. There are many worthy companies developing great technologies that struggle to access capital, irrespective of where they are in their development pipeline. This was strongly reiterated during AusBiotech's member roundtables when discussing the Program, where CEOs noted it was difficult to capital raise both small and large amounts.

With inbound international capital remaining limited, 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.

It is estimated that to build, diversify and address gaps in access to capital across the variety of biotechnology industry organisations, Australia needs to significantly increase the flow of capital to the sector by $1 billion annually.

As biotechnology companies are facing impediments in capital raising irrespective of the amount needed, company structure (ie, private or publicly-listed), and the progression point within the pipeline, it is recommended that the Program's policy design consider concessions based on the sector, rather than linking it to the aforementioned characteristics.

Given the challenge in attaining matched funding, if this is to persist as a requirement for the sector, it would be valuable to note that a conditional agreement of funding would be beneficial for companies trying to attract matching, in order to motivate the capital raising, including companies on the public market. Companies face a 'chicken or egg' scenario, and a conditional funding offer would present greater certainty to investors, particularly with early-stage companies. This would also overcome timing barriers for companies that are between planned capital raises but have meritorious projects that may grow a company's workforce or attract investment.

## Eligibility of projects

**Should Technology Readiness Levels (TRLs) be used to determine eligibility of a project? If so, what are appropriate TRLs for commercialisation and/or early-stage growth phases?**

Technology Readiness Levels (TRLs) are used as standardised numerical indicators of the level of technology maturity and would assist in clarifying program intent and eligibility, however, without careful application then their use will be problematic, even within the same priority sector such as medical science. Again, the unique characteristics - and indeed the sub-sector characteristics – would need to be articulated.

Different technologies, such as digital health vs medical technology vs biotherapeutics, require different regulatory and development pathways and timelines. These are noted in the schematics below. Therefore, standardising the eligibility criteria through the broad use of TRLs will create a programme of comparing 'apples with oranges' and therefore intended companies will be unable to

access the program and it will not successfully deliver on its aim of supporting Australia's small to medium enterprises in expanding their national and global footprint.

The conflation of medical science is already being reported by industry leaders speaking to investors, where medtech – which was previously seen as a 'faster to market' medical science (and therefore return) than biotherapeutics – is now being perceived as 'longer term' investment compared to digital health companies.

Should TRLs be utilised within the Program, then it is essential that the three segments of the medical science industry are separated out with clear guidance, and assessed and managed accordingly – and then compared to other priority areas.

***Different technologies, such as digital health vs medical technology vs biotherapeutics, require different regulatory and development pathways and timelines.***

| | 0-2 years | 2-4 years | 4-6 years | 6-8 years | 8-10 years | 10-12 years | 12-14 years |
|---|---|---|---|---|---|---|---|
| Regulations | Patent Application | Clinical trials application | | | Regulatory Approval | | Regulatory approval |
| Trials | Basic Research/ Proof of Concept | Phase 0 Toxicology and animal testing | Phase 1 a & b Dosing trials | Phase 2 a & b Small cohort trials | Phase 3 Large cohort trials | | Phase 4 Post-marketing studies |
| Product & Commercial Milestones | | | | | Prepare data package | Submit data package and apply for re-imbursement | Market Launch |

*Table 1: Schematic showing typical development pathway, specific to a bio-pharmaceutical*

| | 0-1 years | 1-2 years | 2-4 years | 4-5 years | 5+ years |
|---|---|---|---|---|---|
| Regulations | | | Standards testing and technical file compilation | Regulatory Approval | |
| Trials | Phase 0 Analysis<br>Proof of principle test beds (Unit testing) | Phase 1 Feasibility<br>Concept demonstrator prototypes | Phase 2 Development (Detailed design and design<br>Alpha and Beta prototypes - integration testing transfer) | Phase 3 Implementation<br>Pilot production units (Product and process validation) | Phase 4 Monitoring<br>Market launch & commence regulatory authority audits |
| Product & Commercial Milestones | | Confirm feasibility | Design finalised | | |
| | ISO 13485 compliant process | | | | |

*Table 2: Schematic showing typical development pathway, specific to a medical device*

**How should we determine which projects have the most potential for future growth and market impact?**

Non-financial objectives outlining impact metrics would be constructive. Non-financial objectives for our sector could include patient access to clinical trials; health economics such as anticipated patient outcomes; and skills and learning development for industry and healthcare talent.

It is recommended that the way 'value add' be defined and measured enable home-grown biotechnology companies to expand their local workforces as this return on investment would deliver vital skills and training for the future workforce of Australia and offer a competitive advantage over countries such as the USA, Canada, and the UK.

**Should it be necessary that the applicant has the legal ownership, or effective ownership, of the know-how, intellectual property or other similar results arising from the project?**

For the Program's medical science priority sector, legal or effective ownership of IP is a sensible eligibility criterion, as it supports the value creation of new technologies and their pathway to patients.

Intellectual property protection is the fundamental source of value that is used by Australian biotherapeutic and medtech companies to attract the substantial, multi-million dollar investment it takes to bring treatments, cures, tests and devices to the patient. It's a strength of the Australian business environment, and the research and development being undertaken across the nation is recognised globally as world-class.

Data from IP Australia's *Australian Intellectual Property Report 2023* highlighted that healthcare dominated other fields "for the volume of standard patent applications received each year... Applications for pharmaceutical patents have been on a growth trajectory since 2016 [and] medical technology and biotechnology also increased their share of overall filings."

**Is 'need for funding' (i.e. why applicants are unable to access sufficient funding for the project from other sources) a useful merit criterion for assessing grant applications? If so, how should this be measured?**

There is an ever-present and critical need for funding for SMEs in this sector. Even at the full grant of $5 million, companies will 'need' significantly more funding. Therefore, the 'need for funding' is given, and would not be a beneficial differentiator between medical science grant applications.

With capital the lifeblood of the sector, rapidly increasing start-up and spinout company numbers, and a dearth of venture capital in Australia compared to other major countries, the thirst for capital is key.

It is estimated that to build, diversify and address gaps in access to capital across the variety of biotechnology industry organisations, Australia needs to significantly increase the flow of capital to the sector by $1 billion annually.

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.

## Diversity and inclusion

**What are the potential barriers to accessing the Industry Growth Program?**

A vibrant industry starts with people. Building a diverse and inclusive Australian biotechnology workforce with the collective creativity to adapt, respond, and innovate is core to a thriving ecosystem.

Women have steadily been working towards equal participation, and having their contributions recognised in the biotechnology sector. However, recent figures show that efforts to support women across the sector are reaping results but still fall short of equity.

Whilst the 2023 IP Australia report[1] notes that in 2022 women inventors were named on around half of PCT applications in biotechnology (61 percent), and pharmaceuticals (59 percent), they remain under-represented across the biotechnology industry[2], representing a stagnant 32 percent of the industry's workforce; 25 percent of executives, 15 percent of board directors, and only 11 percent of CEOs.

**How can we help overcome these barriers to expand the reach of the program?**

The issue of gender inequality is complex and systemic, and requires a national plan and concurrent and concerted efforts in order to improve the barriers faced.

At a minimum, the Program should publicly report on the gender of founders and CEOs as well as the level of Indigenous Peoples' participation and success in the Program in order to recognise conscious or unconscious bias present in the Program. The results of these reports will enable the Executive Director to consider how to improve the initiative's accessibility to best support participation and therefore improve diversity outcomes. Ideally, these actions should be tied into this role's performance measures, thereby demonstrating the commitment to inclusion and accessibility.

## Industry partner organisations

**What core capabilities and resources would be most useful from industry partner organisations to improve commercialisation and early-stage growth performance for participants of this program?**

There are already numerous accelerators and incubators supporting the life sciences sector through consultation and commercialisation advice to guide project development and assessment. For the Program to offer additive value and best use of public funds, it is recommended that the industry partner organisations offer support that targets areas often overlooked by SMEs when capital raising, and that are less available through these existing initiatives.

This may include: IP strategy development that applies a global mindset and lens (thereby supporting a globally-competitive approach to success); improving investor communications (including pitch deck review or development); and support to get the right Board around the company in preparation for its growth stage and phase.

**What services and support should industry partner organisations provide to participants?**

What is critical about life science companies is their interrelationships, including with highly-specialised expert services. No single part of the life sciences sector can thrive without the others.

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[1] 2023 Australian IP Report: https://www.ipaustralia.gov.au/tools-and-research/professional-resources/data-research-and-reports/australian-ip-report-2023

[2] AusBiotech's Australian Biotechnology Sector Snapshot 2022: https://www.ausbiotech.org/documents/item/707

The time and investment required to develop, for example, a new medicine is such that no single entity identifies the successful molecule and then develops it through the clinical trial process to commercialisation. The sector has become increasingly interdependent such that numerous organisations will now all work on a product to achieve this outcome. This means that the sector has become increasingly reliant on its own ecosystem, and the unique skills required to service its unique and complex characteristics.

The Industry Growth Program's Advisor RFT notes it is seeking a total of 20 advisors that will cover the whole of Australia and more than one priority sector. Many life science innovators may already have some (or all) of those service relationships filled with outstanding experts; therefore, rather than having to utilise the appointed 20 advisors, industry proposes that the programme include provision of professional services within the Program for companies to assign their own advisors, thereby redirecting some of the funds into the financial support being offered by the Program. This would be in line with some MRFF programmes and the previous Commercialisation Australia programme.

Given these strong existing relationships, typically biotech companies' strongest barrier to traversing the valley of death is access to capital. This is in contrast to other sectors and the assumption of the consultation paper: "Many innovative SMEs lack the necessary expertise, experience, networks or resources to overcome the challenge of progressing from proof-of-concept and prototyping stage."

With a pool of 20 mandated advisors, it is assumed that those chosen will have sufficient knowledge of the biotech sector and its sub-sectors, to assess what's 'most promising', and therefore to invite a further application for grant funding. To give all sectors confidence in investing into these often-time-consuming application processes, it would be valuable to develop tailored guidance outlining the assessment criteria, governance roles and responsibilities, and the timelines for each activity within the process, as well as the hold period between. For example, how many months to receive advisory services prior to a grant invitation being issued.

Additionally, AusBiotech plays a key role in providing a platform for connection with potential investors, such as AusBioInvest held annually, and the expansion of this program globally would be beneficial on numerous levels. This is true also for investor education, where AusBiotech has created multiple resources for investors and seeks to expand their reach.

### Program governance and grant assessment

**Are there other skills and expertise that should be represented on the committee?**

The biotechnology industry is unique and distinctive by virtue of the way it uses the latest advances in biomedical science to deliver potentially life-changing and life-saving therapies, vaccines, diagnostics and devices that have application in markets around the world. It is intrinsically global, and Australia's industry is strongly connected to the worldwide biotechnology sector through development partnerships and trade relationships.

This uniqueness cannot be overlooked, and having global experience in product development on the committee would be advantageous.

## Program design to meet intended outcomes

**How should we measure the success of the Industry Growth Program, for the economy and for participating businesses?**

AusBiotech's *Biotechnology Blueprint*[3], the decadal strategy developed by industry, for industry, outlines 27 metrics to track the progression towards delivering on its ambitions. There is a necessity for all stakeholders to collaborate for success, and to actively pursue aligned approaches.

The aim of the Program is to grow medical science companies' workforce and to attract investment. To measure this, it is recommended to track:

- Capital raised (private, public and government) (Blueprint metric M1.6): This is a leading indicator of future growth and a measure of support for industry. Post-funding reporting could also capture series A and B funding.
- Development progression made (e.g., percentage of companies that progressed to next phase in clinical trials) (Blueprint metric 3.7): Progression through the development pipeline is a short-term measure of commercialisation success.

## Alignment with other initiatives

**How can the program complement other university, industry and government initiatives?**

A barrier to greater private sector investment is the number and access of biotech-literate investors in Australia. Due to the sector's unique characteristics, investors without experience in biotechnology investment tend to shy away from the sector due to the nature of its different risk profile and complex 'product'/science.

Government could play an important role in supporting the attraction of new investors and building investments from existing investors through the consideration of incentives (including long term tax or income incentives) for angel and private investors to overcome different risk profile and time to market, and by building a partnership between industry and government to develop a capital-raising education programme.

[3] Biotechnology Blueprint: https://www.ausbiotech.org/documents/item/703