O7.
Growing Australia's Innovative Medicines Industry Through Investment



Better health through research and innovation

Investment Overview

Constructive collaboration between industry and government is critical to the growth of Australia's innovative medicines industry.

Australia needs foreign investment because it is a key driver of economic growth and prosperity.

According to a recent analysis by PwC, our members contributed approximately \$9 billion to the Australian economy in 2016-17, which supported the employment of 23,000 Australians (direct and indirect). The medicines industry continues to be one of the largest exporters of manufactured goods with some of our members expanding their advanced manufacturing facilities and capabilities in Australia. Our members continue to be significant investors in Australian research and development, including 1000 clinical trials initiated in 2016-17 that helped 33,000 Australians get early access to emerging therapies.¹

To support this ongoing contribution to the Australian community and economy, Government needs to maintain not just a well-funded PBS, but also continue to support industry-focused policy settings, such as the R&D tax incentive. These are important enablers to encourage investment by our members into Australia's medical technology, biotechnology and pharmaceutical sectors.

Medicines Australia supports the Australian Government implementing the below measures, which align with the main objectives of Australia's policy for foreign trade, investment and development,² to:

- Create a stable policy environment that supports business trading and export opportunities, avoiding changes that could reduce Australia's competitiveness to attract investment in priority areas such as medical research;
- Grow export opportunities in both established and emerging markets, including through free trade agreements and other trade liberalising mechanisms;
- Increase co-operation and co-ordination of policies and programmes with the states and territories including through a long-term marketing plan for the Medical Technologies and Pharmaceuticals sectors;
- Benchmark Australia's advanced manufacturing and R&D capability and skills; and
- Restore direct forms of business R&D support to build skills as part of a long-term plan to encourage growth in the Medical Technologies and Pharmaceuticals sectors.

Challenge: Growing exports in both established and emerging markets.

Key Fact: In 2017-18, locally manufactured pharmaceutical products[‡] generated approx. \$1.6 billion in exports.³

‡ excluding medicaments (when included the total becomes \$3.6 billion) 4

There are exciting opportunities for Australia to grow its share of the pharmaceutical trade, with global demand for medicines forecast to increase at 3-6% compound annual growth rates to 2023.⁵ Making the most of this opportunity will help to drive economic growth, deliver more high-skill jobs, and provide Australians with improved access to medicines.

Even though Australia has a reputation for manufacturing safe, high-quality medicines and vaccines, imports of pharmaceutical products‡ continue to be significantly higher than exports (\$2.65 Billion difference in 2017-18).6 This is exacerbated by the continuing closure of traditional pharmaceutical manufacturing facilities in Australia,7 as technology has improved and because Australia struggles to compete with other nations on costs, including labour.

Example Case 1: AstraZeneca Operations, North Ryde

AstraZeneca (AZ), a multi-national science-led biopharmaceutical company, has continued to invest in its Macquarie Park manufacturing facility (a key manufacturing site within its global operations network), creating skilled jobs and driving growth in important export markets. The factory produced 580 million respiratory medicine units in 2018, a quantity which is expected to grow at year-on-year rate of 15% for the next 5 years. AZ is one of the most significant manufacturing and export operations in the Pharmaceutical Industry and in Australia, supplying medicines to 19 countries including Australia & New Zealand. The largest export is to China, treating more than 10 million patients.

Photo shows specialised production lines at the AstraZeneca North Ryde facility.



Image courtesy of Andrew Donald Design Engineering.

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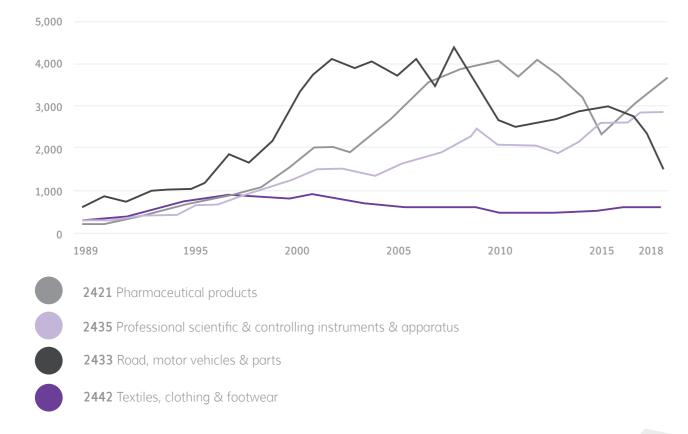
Despite the negative impact on the value of pharmaceutical exports observable in Figure 1, the trend for exports has increased since the low of mid-2015 and continues to grow. As an Australian produced export, pharmaceutical products continue to grow by approximately 16% over the past few years.8

There is growing demand for products from Australia's advanced manufacturing plants, such as AstraZeneca (see Example Case 1). Innovative pharmaceutical companies will invest to establish plants in response to a range of environmental, political, economic and regulatory characteristics of

a country. In 2016, Australia was ranked fifth of 54 nations in terms of biotechnology innovation by the Scientific American Worldview which is based on scores for productivity; intellectual property (IP) protection; intensity; enterprise support; education and workforce; infrastructure and research and development drivers; and policy and stability of government. Such facilities support highly qualified science, technology, engineering and mathematics (STEM) jobs, and associated economic benefits in Australia.

Figure 1: Pharmaceutical Products Vs. Other Manufactured Exports.

Exports (AUD) of Australian Manufactured Goods, 1989 to 2018.



Source: Australian Government Department of Foreign Affairs and Trade, 'Composition of Trade 2017-18', Country and TRIEC pivot table 1989-90 to 2017-18, accessed via https://dfat.gov.au/about-us/publications/pages/composition-of-trade.aspx

Solution: Attract direct foreign investment though positive and supportive policy settings.

Medicines Australia believes there is a valuable opportunity to further support the profile of Australia's innovative medicines industry internationally, and to promote Australia's brand to key markets and potential investors.

Support for a coherent nationwide plan, coupled with high profile delegations will increase our reputation as a 'goto' destination for medical research investment. Australia's high-class capabilities in R&D, such as clinical trials, and favourable business environment needs to be promoted to an international audience to encourage ongoing investment in Australia's local industry.

For the innovative medicines industry to grow, Australia must have a stable and transparent investment environment.

Reducing trade barriers, particularly barriers related to rules of origin and inappropriate customs, tariffs and harmonisation of regulatory standards across trading partners is required. Such trade policies must recognise the unique role of innovative pharmaceutical technologies to the health and economic prosperity of Australians.

Alongside trade policies, Australia needs supportive local industry policy settings to encourage investment in a competitive global market. Australian subsidiaries of global companies have been successful in competing for global clinical trials to be placed in Australia, but for this to continue, policy settings must be favourable. For example, the R&D tax incentives (R&DTI) for clinical trials to attract valuable medical research opportunities.

Intellectual property policy is particularly important in a global decision-making process, for example where research and development (including clinical trials) is conducted. A strong, effective and stable IP system is critical to fostering pharmaceutical innovation and encouraging investment. To maintain competitiveness Australia must strengthen regulatory data protection and ensure a strong, enforceable patent notification scheme. Moreover, transparency of initial lodgement of registration dossiers for all new medicines and brands to the Therapeutic Goods Administration (TGA) will enable originator companies to respond to potential patent infringements and avoid protracted legal disputes with the Commonwealth.



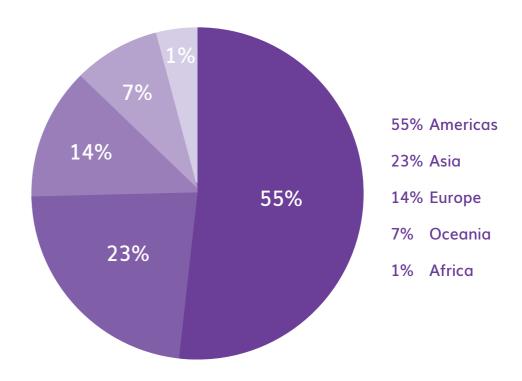
Challenge: Removing trade barriers (including through Free Trade Agreements).

Key Fact: In 2017-18, the majority of exports of locally manufactured pharmaceutical products[‡] were destined for APEC and OECD countries.¹⁰

A key component of the development of Australia's medicines industry-base is the development of new export opportunities. With domestic consumption accounting for approximately one percent of the global pharmaceutical market (by value), 11 it is important that manufacturers in Australia have sufficient access to global markets to help encourage growth.

During 2017-18, Australia exported pharmaceutical products to over 100 countries (although the top 20 accounted for over 95%).¹² The establishment of a number of Free Trade Agreements (FTAs) has opened up new markets, reduced trade barriers, encouraged further exports and increased competitiveness for the Australian innovative medicines industry. A number of these agreements are with countries with high growth economies in the Asia region, which are major export destinations for medicines and vaccines.

Figure 2: Pharmaceutical product region of export, 2017-18.



Source: Department of Foreign Affairs and Trade. Trade statistical pivot tables: Country and commodity 2005-06 to 2017-18, last updated June 2019 using ABS catalogue 5368.0 (Jan 2019 data). Available at: https://dfat.gov.au/about-us/publications/pages/tradestatistical-pivot-tables.aspx

as an export destination for pharmaceutical 54163). This category, at approximately products (Table 1 and Figure 2) manufactured in Australia is due to antisera STIC-541 Medicinal and Pharmaceutical and other blood fractions and modified immunological products and vaccines for human and veterinary use (Standard

The predominance of the United States (US) International Trade Classification, STIC-\$820 million, represented over 95% of the Products exported to the US in 2017-18.¹³

Table 1: Top 20 countries for pharmaceutical product exports, 2017-18.

Country Rank	541 Pharm products (excl medicaments)	Proportion of total Pharma product exports
1	United States	54.2%
2	China	11.1%
3	New Zealand	6.6%
4	Germany	5.7%
5	Hong Kong (SAR of China)	4.1%
6	United Kingdom	3.6%
7	Netherlands	2.0%
8	India	1.3%
9	Repubic of Korea	1.2%
10	Singapore	1.1%
11	Malaysia	1.1%
12	Switzerland	1.1%
13	Japan	1.0%
14	Taiwan	0.8%
15	Vietnam	0.6%
16	South Africa	0.5%
17	Norway	0.4%
18	France	0.4%
19	Canada	0.3%
20	Brazil	0.3%

Note: Per Standard International Trade Classification (SITC), Category 541 Medicinal and Pharmaceutical Products includes vitamins, antibiotics, vegetable alkaloids, hormones, glycosides, antisera, vaccines, bandages, blood groups, other such as pharmaceutical waste.

Source: Department of Foreign Affairs and Trade. Trade statistical pivot tables: Country and commodity 2005-06 to 2017-18, last updated June 2019 using ABS catalogue 5368.0 (Jan 2019 data). Available at: https://dfat.gov.au/about-us/publications/pages/trade-statistical-pivot-tables.aspx

Medicines Australia's support of the principles underpinning free trade agreements is fundamentally about three key principles:

01

Ensuring all Australians have access to high quality, safe, efficacious and cost-effective medicines.

02

Ensuring Australia remains competitive internationally to incentive the growth of industry, and the Australian economy.

03

Recognising the value of our industry in advancing the overall health and well-being of Australians.

Medicines Australia welcomes the commencement and conclusion of trade agreements with the European Union, India, the 16 Regional Comprehensive Economic Partnership countries, the Gulf Cooperation Council, and Pacific Alliance. We commend the FTAs that have been concluded with the following countries, but not yet come into force: Hong Kong; Indonesia; Peru and PACER Plus (New Zealand and 8 Pacific Island countries). ¹⁴ The possibility of trade negotiations with the United Kingdom will be followed with interest.

Established markets are just as important as emerging ones, and individual companies will ultimately decide where they establish and build their export market. While it is not the responsibility of the Australian Government to determine which businesses work in particular markets, policies that encourage growth in major trading markets and emerging markets are welcome.

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Solution: Establish FTAs that include a pharmaceutical chapter with major trading partners.

Successful trade agreements depend on the inclusion of a pharmaceutical chapter that incorporates and supports the following:

- Acknowledgement of the unique role of innovative pharmaceutical technologies to Australians' health and economic prosperity
- Commitment to a strong and competitive intellectual property (IP) system that recognises and rewards our niche strengths in research and advanced manufacturing, and is consistent with international IP norms

- Harmonisation of regulatory standards across key trading partners
- Inclusion of policy incentives and streamlined processes to attract direct and indirect investment in R&D and the avoidance of policies that detract from innovation
- Mechanisms to continuously monitor, strengthen and improve trade relations.

Challenge: International competition for investment.

Key fact: During 2015, Australia spent \$1.1 billion on clinical trials, 75% of which was attributable to international inbound investment.¹⁵

Access to equity is of particular importance to the innovative medicines industry at two key points requiring significant capital investment decisions, namely research and development (R&D) and location of manufacturing operations. There is intense global competition for this investment and both federal and state government involvement is essential to promote Australia as a premier destination for both.

Research and Development

Over the past two decades the type of clinical research being conducted in Australia by innovator pharmaceutical, biotechnology and medical device companies, has moved away from the later stage confirmatory trials requiring large numbers of patients. Despite this, local clinical studies are growing at a rate of 5% per annum faster than the global average.¹⁶

Our world-class healthcare system, high quality medical research infrastructure, skilled workforce of scientists and healthcare professionals, including internationally regarded clinicians, is uniquely placed for the more complex earlier phase R&D work. Conversely, Australia's relatively small population and large landmass mean investigation sites must be distributed nationally and this adds to the total cost per patient recruited.

Successive Australian Governments have actively worked to reduce regulatory barriers, for example via the Clinical Trials Notifications scheme (Figure 3).

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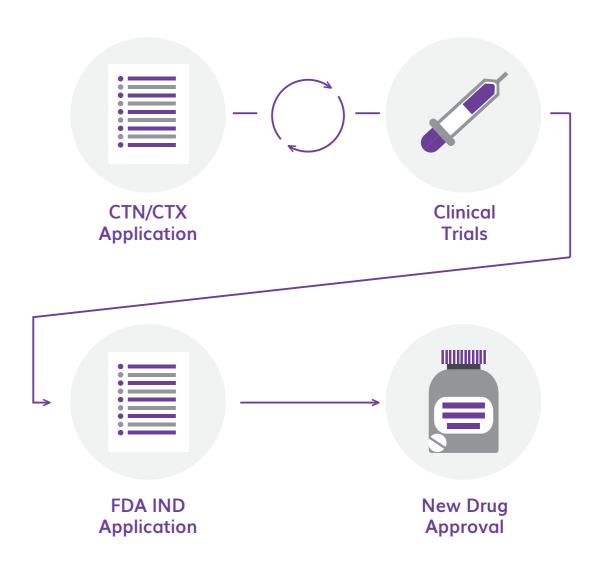
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Figure 3: Accelerated Path to Market using Australian generated clinical data.

Australia's Clinical Trial Notifications (CTN) scheme is a global benchmark for best practice in reducing the regulatory burden on clinical trial sponsors while maintaining quality research.

Source: Australian Trade and Investment Commission, Invest in Australia Clinical Trials Fact Sheet, April 2018.



The R&D Tax Incentive Program, that offers tax offsets for eligible R&D expenditure, is a critical component of Australia's attractiveness to investment in this area. Per Table 2, this is the only type of internationally recognised incentive noted as being available in Australia.

Unfortunately, this lever has also been diluted with the rates of the R&D tax offset incentive reduced by 1.5 percentage points (from 45% to 43.5% for the refundable rate, and from 40% to 38.5% for the non-refundable rate), from 1 July 2016.¹⁷

Table 2: Australian R&D incentives, May 2018.

	AUD	BEL	CAD	СН	IN	IRE	IL	NED	NZD	SG	KR	СН	UK	US
Accelerated depreciation on R&D assets														
Cash grants														
Expedited government approval process														
Financial support														
Income tax withholding incentives														
Infrastructure/land preferential price														
Loans														
Patent-related incentives														
Reduced social security contributions														
Reduced tax rates/preferable tax rates														
Tax allowance														
Tax credits (R&D, investment)														
Tax deduction (including super deduction)														
Tax exemptions														
Tax holiday														
VAT (GST) reimbursement														

Source: EY. Worldwide R&D Incentives Reference Guide 2018.

Manufacturing: As noted earlier, high quality manufacturing countries such as Australia can win investment in advanced manufacturing if appropriate incentives are in place.

Solution: Benchmark Australia's incentives at all stages of the medicines industry value chain.

Medicines Australia encourages the broadening of Government initiatives to further improve Australia's attractiveness for inbound investment.

Australia offers distinctive skills, knowledge and expertise in health and medical research. However, there is an urgent need for the Australian Government to accept that incentives, whether fiscal, financial or other measures, are a reality of the global medicines industry. Incentives need to be sufficiently targeted and flexible and of a sufficient scale to attract greater levels of foreign investment.

The wider business environment must also be taken into account as investment incentives are by no means the only consideration of international investors when deciding the location of a R&D facility or advanced manufacturing base.

Pricing and reimbursement are important factors in influencing decisions on where to invest, as well as regulatory issues, intellectual property arrangements, operational costs, tax incentives and infrastructure.

As a first step, benchmarking investment incentives provided by our competitors overseas could help inform improvements at all stages of the industry value chain (discovery R&D, preclinical development, clinical trials and manufacturing), to encourage further foreign investment by the innovative pharmaceutical sector.

Challenge: Better alignment of strategies which impact on the innovative medicines industry.



Key Fact: The World Intellectual Property
Organisation ranked Australia 20th on the
2018 Global Innovation Index.¹⁸

New medicine development pathways are long and capital intensive. They require, on average, 12 years to bring a new product to market at a risk-adjusted average cost of up to US\$2.6 billion.^{19 20} Commercialisation on a global scale is necessary to deliver the required return on investment. Thus, even though innovation can start at a local level, most often out-licensing or divestment to a global partner is needed during pre-clinical

or clinical development. Such partners provide the infrastructure, resources and capabilities to fully commercialise the product.

The innovative medicine research community comprises consumers and patients, universities, other research organisations, small and large local and multinational companies, investors, service providers, industry organisations, infrastructure providers, governments, regulators, policymakers, funders and those involved in healthcare delivery, such as state health departments and private medical practice.

Such diverse stakeholders are connected via complex webs and may occupy all levels of government and various departments within. As such, the Australian Department of Industry, Innovation and Science plays the critical role in creating linked programs and aligning other government and nongovernment entities to deliver one of its key outcomes:

'Enabling growth and productivity for globally competitive industries through supporting science and commercialisation, growing business investment and improving business capability and streamlining regulation'.²¹

Policies and programmes in the trade, fiscal, health, innovation, education, employment and industry portfolios to varying degrees impact on the innovative medicines industry.

The National Medicines Policy recognises that a sustainable pharmaceutical industry is important for the long-term health of Australians.²²

In response to these needs, in November 2015, the Federal Government established MTPConnect as an independent, not-for-profit organisation to drive connectivity, innovation, productivity and competitiveness in Australia's medical technology, biotechnology and pharmaceuticals sector.²³ The MTPConnect priorities and objectives are illustrated in Figure 4 and aim to interconnect relevant stakeholders to benefit the sector at all levels of the value chain.

In addition, some State governments are developing long term plans to assist in the transition from the mining construction boom to the new economy. For instance, the Victorian Government released a Medical Technologies and Pharmaceutical Sectors Strategy as part of a broader plan to grow future industries which includes trade and promotion activities.²⁴ Innovative pharmaceuticals are viewed as strong prospects for Queensland, and growth of these products is expected as the population ages and Asia's middle class grows.²⁵

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Figure 4: MTPConnect Priorities and Objectives for 2019.

	Improving coordination and collaboration	Improving management and workforce skills	Identifying opportunities to address regulations	Improving access to global supply chains and markets
P1. Align investment in Knowledge Priorities identified based on current and future market funds				
P2. Create a highly productive commercialisation environment from research to proof-of-concept and early clinical trials				
P3. Transform the SME sub-sector to support the growth of smaller companies into larger, more stable and successful companies				
P4. Strengthen Australia as a attractive clinical trial research destination				
P5. Support the development of digital healthcare solutions: devices and data analytics				
P6. Position Australia as the preferred partner for international markets				
P7. Support advanced manufacturing as a part of the Australian innovation ecosystem				

Greater focus on addressing particular Growth Centre objective

Good focus on addressing particular Growth Centre objective

Less focus on addressing particular Growth Centre objective

Solution: A coordinated long term plan for the Medical Technologies and Pharmaceuticals sectors.

Medicines Australia is supportive of a whole-of-government (including States and Territories) approach to the Medical Technologies, Biotechnology and Pharmaceutical sectors that balances trade, fiscal, health, innovation, education, employment and industry policies.

Medicines Australia encourages ongoing government support of MTPConnect, the National Health and Medical Research Fund Council, Medical Research Future Fund, Biomedical Translation Fund, CSIRO and Co-operative Research Centres as vehicles to develop and ensure the long-term viability of Australia's innovative health sector.



Source: MTPConnect. Medical Technology, Biotechnology & Pharmaceutical Sector Competitiveness Plan June 2019. Available at: https://www.mtpconnect.org.au/images/2019%20MTPConnect%20Sector%20Competitiveness%20Plan.pdf

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