

GROWING AUSTRALIA'S INNOVATIVE MEDICINES INDUSTRY THROUGH TRADE AND INVESTMENT

Medicines Australia aims to be part of a thriving global healthcare environment.

Constructive collaboration between industry and government is key to growing Australia's innovative medicines trade.

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



OBJECTIVES BRIEF 4: INVESTMENT

Medicines Australia would support the Australian Government implementing measures to:



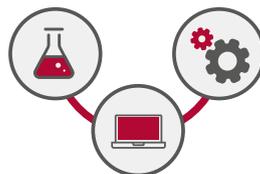
Grow export opportunities in both established and emerging markets, including through free trade agreements.

Develop a whole of Government plan for the medical technologies and pharmaceuticals sectors which balances trade, fiscal, health, innovation, employment and industry policies.



Align the policies and programmes of states and territories with the MTPConnect long-term plan for the medical technology and pharmaceutical sector and develop a global marketing plan to enhance its success.

Benchmark Australia's advanced manufacturing and R&D capability and skills.



Restore targeted 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.

Key fact:

The **Australian medicines industry** generates approximately **\$2.6 billion** in exports each year.

OVERVIEW

Global demand for medicines is expected to double in a decade.

Australia's policy for foreign trade, investment and development has four main objectives:¹

- **Trade:** pursue trade liberalisation through bilateral, regional and global trade agreements that provide new opportunities for Australian exporters and sustain a strong, rules-based architecture for global trade.
- **Growth:** support global growth and assist developing countries in the region to address internal constraints to economic growth, such as restrictive regulations, poor infrastructure and lack of capacity in the private sector.
- **Investment:** promote investment into Australia and Australian investment internationally.
- **Business:** advance the interests of Australian business overseas and the development of a stronger private sector in our region, as well as promote Australian tourism.

There are exciting opportunities for Australia to grow its share of the pharmaceutical trade, with global demand for medicines expected to double in a decade. Making the most of this opportunity will help to drive economic growth, deliver more high skills jobs, and provide Australians with improved access to medicines.



AstraZeneca exports to over 30 countries from its plant in Sydney's Macquarie Park.

MEMBER EXAMPLE:

ASTRAZENECA PLANT, MACQUARIE PARK NSW

AZ has expanded its local plant to enable production of more than 80 product variations including respiratory medicines. This investment has created jobs and new business opportunities, including cultivating a major export market.

Export sales in 2014 were \$329 million and are forecast to be \$560 million in 2016. It is projected to reach \$2 billion in annual exports by 2025. The AstraZeneca facility currently exports to 30 countries. 81% of this export volume is going to China – 445 million units to treat more than 10 million Chinese patients. The AZ plant also provides more than \$700 million of medicines to the Australian market.

1. The Australian Government, Department of Foreign Affairs and Trade, Public Diplomacy Strategy 2014-2016. Available at: <http://dfat.gov.au/people-to-people/public-diplomacy/Pages/public-diplomacy-strategy.aspx>

CHALLENGE: GROWING EXPORTS IN BOTH ESTABLISHED AND EMERGING MARKETS

Key fact:

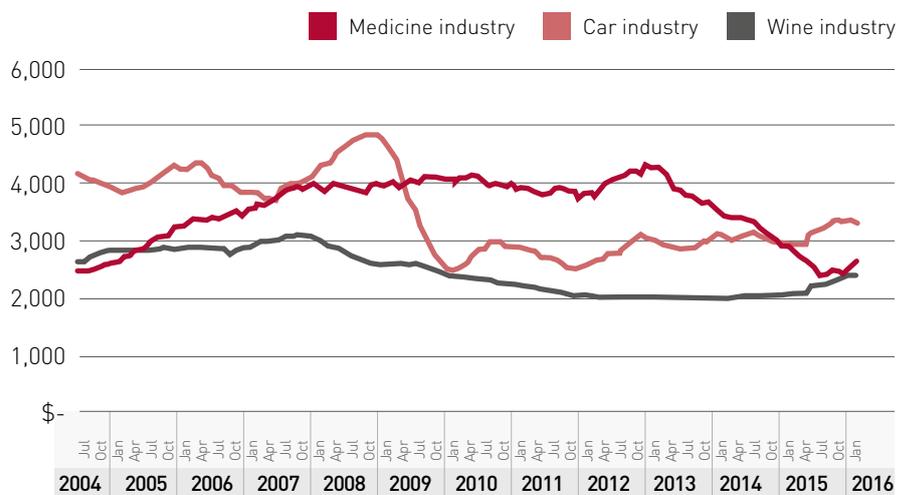
The right policy settings could see Australia potentially double its share of the global pharmaceutical market (currently approx. 1%) over the next decade.

Source: Medicines Australia 2015 Facts Book 4

Even though Australia has a reputation for manufacturing safe, high-quality medicines and vaccines, imports are significantly higher than exports.

Australian manufacturing is going through a period of significant transition which is having an impact on the Australian economy and on the level and types of exports generated. Traditional manufacturing facilities have been closing, including in pharmaceuticals, as technology has improved and because Australia struggles to compete with other nations on costs, including labour.

FIGURE 1: MEDICINES EXPORTS VS OTHER MANUFACTURED EXPORTS (\$ MILLIONS)



Source: ABS Multiple Years International Trade in Goods and Services, catalogue 5368.0



↑ Previous high: \$4.3 billion (Dec 2012)

↓ Previous low: \$2.2 billion (Aug 2015)

Despite these challenges, medicinal and pharmaceutical products became Australia's largest manufactured export category for five years from 2009-2014.

The value of medicinal and pharmaceutical exports has been declining since 2013, however, there are some indications that this trend may have turned around.

The trend for exports has begun to increase since the low of mid-2015 (although there has been quite a bit of seasonal variation) with indications that this figure may continue to grow in the months and years ahead. Some of this increase may be explained by the growing demand for products from Australian advanced manufacturing plants run by innovative pharmaceutical companies. These facilities also help to support highly qualified science, technology, engineering and mathematics (STEM) jobs in Australia.

2. The Australian Government, Australian Bureau of Statistics, (International Trade in Goods and Services (catalogue 5368.0). Available at: <http://www.abs.gov.au/AUSSTATS/abs@nsw/detailsPage/5368.0May%202016?OpenDocument>

CHALLENGE: REMOVING TRADE BARRIERS (INCLUDING THROUGH FREE TRADE AGREEMENTS)

Domestic consumption
accounts for just
1% of the global
pharmaceutical market.

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 1% of the global pharmaceutical market, it is important that manufacturers in Australia have sufficient access to global markets to help encourage growth.

Australia currently exports medicines to over 70 countries.³ The establishment of a number of Free Trade Agreements (FTAs) with Australia 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.

Many opportunities to grow exports have been facilitated through FTAs. Contrary to some previous commentary, FTAs have not resulted in more expensive pharmaceuticals for Australian consumers, or increased risk to patient safety.

A number of measures in the Australian Government's policy for **More Jobs and Growth through Increased Trade and Investment** aim to open new markets and reduce barriers to trade.

Medicines Australia will be interested in how the measures designed to connect businesses with new opportunities and reduce export documentation will operate in practice.

Medicines Australia welcomes the Australian Government's promise to commence and conclude trade agreements with the European Union, India, Indonesia, the 16 Regional Comprehensive Economic Partnership countries, the Gulf Cooperation Council, and Pacific Island countries through the PACER Plus agreement.⁴ The feasibility of further trade negotiations with Canada, Mexico and Colombia 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 what businesses work in particular markets, policies that encourage growth in major trading markets as well as emerging markets are welcome.

3. The Australian Government, Department of Foreign Affairs and Trade, Composition of Australian Trade, 2013. Available at: <http://dfat.gov.au/about-us/publications/Documents/cot-cy-2013.pdf>

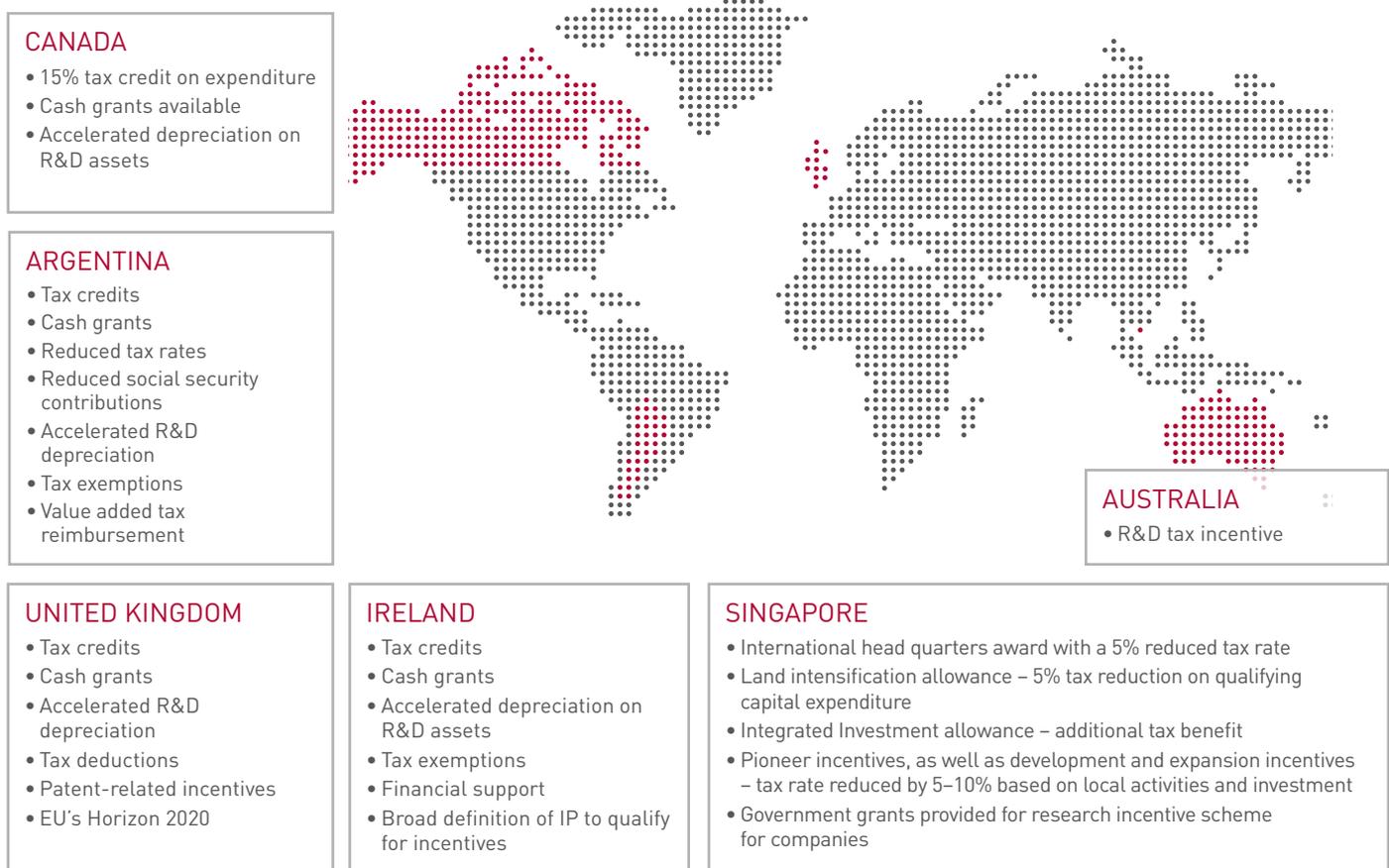
4. Liberal Party of Australia, the Coalition's policy for more jobs and growth through increased trade and investment, May 2016. Available at: <https://www.liberal.org.au/coalitions-policy-more-jobs-and-growth-through-increased-trade-and-investment>

CHALLENGE: INTERNATIONAL COMPETITION FOR INVESTMENT

For our medicines exporting capacity to increase, Australia needs to ensure that barriers to attracting investment are not blocked unreasonably.

Investment capital is globally mobile, and the competition with other comparable western and developed Asian markets is very significant. High-quality manufacturing countries such as Australia can still win investment in advanced manufacturing if appropriate incentives are in place.

FIGURE 2: INTERNATIONAL COMPETITORS' INCENTIVES FOR ADVANCED MANUFACTURING AND R&D^{5,6}



Source: Adapted from EY, 2013-2014 Worldwide R&D incentives reference guide, and Singapore Government, Incentives for businesses.

Australia faces a highly competitive international investment environment. Many factors drive this competition, with the level of foreign investment likely to continue to decline without a greater focus on company tax rates, manufacturing incentives and supportive industry policy.

5. EY, 2013-2014 Worldwide R&D incentives reference guide. Available at: <http://www.ey.com/GL/en/Services/Tax/Worldwide-R-D-incentives-reference-guide---Country-list>

6. Singapore Government. Incentives for businesses. Available at: <https://www.edb.gov.sg/content/edb/en/why-singapore/ready-to-invest/incentives-for-businesses.html>

Australia faces increased international competition for investment. Many factors drive this competition, including access to skills and training needs.

Like other high-tech industries, growth in the medicines industry in Australia is being hampered by the persistent shortage of skilled workers. The workforce needs of the industry were the subject of a detailed study by the Pharmaceuticals Education Council (PEC), which brought together both industry representatives and senior academics from Australian universities.⁷

The report identified gaps across the value chain, and especially noted that many recent university graduates lack basic research, project management, clinical trial design, interpersonal, marketing and negotiating skills. Medicines Australia surveys have also found that bio-pharmaceutical companies in Australia routinely turn overseas to find skilled and experienced workers who can help them to meet shortages in several key areas such as clinical trial management and business development.

Unfortunately given the already high cost of doing business in Australia, it is difficult for companies to substantially invest in up-skilling their workforce.

Some medicines companies (PWC, 2014) expect to outsource functions like IT, supply chain, CROs and finance into the Asia Pacific region in the next five years. Despite significant local challenges, Australia is considered by the majority of companies to be ranked high or mid-range in new product launches, compared with other developed markets.

7. Pharmaceuticals Education Council, 2009, Report on Skills Gaps in the Pharmaceutical and Biopharmaceuticals Industries in Australia.



SOLUTION: BENCHMARK AUSTRALIA'S INCENTIVES AT ALL STAGES OF THE MEDICINES INDUSTRY VALUE CHAIN

In addition to targeted measures of support, 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.

Australia does offer 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.

Targeted measures of support to the medicines industry including business R&D grants could not only allow companies to train their workforce but, in doing so, also add to Australia's general pool of skilled labour.

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 is an important factor in influencing decisions on where to invest, as well as regulatory issues, intellectual property arrangements, operational costs, tax incentives and infrastructure.

While the R&D tax incentive scheme in Australia has been established and been successful, the policy has not provided sufficient incentives for larger companies to establish in Australia. R&D schemes in Australia have also not yet been able to address the low levels of collaboration between universities and business.

Despite world-class research capabilities, the complex and time-consuming regulatory process for the approval and initiation of clinical trials is frequently cited as an ongoing barrier to attracting investment in Australia.

Australia can benefit from the international experience. The trade portfolio could assess, in the Australian context, investment incentives that other countries have introduced to build their medical technologies and pharmaceutical industries and target them to Australia's needs.

As a first step, benchmarking investment incentives provided by our competitors overseas could help to inform how improvements could be made in Australia to improve our competitiveness at all stages of the industry value chain (discovery R&D, preclinical development, clinical trials and manufacturing). This benchmarking will then help inform the future development of targeted incentives to encourage further foreign investment by the innovative pharmaceutical sector.

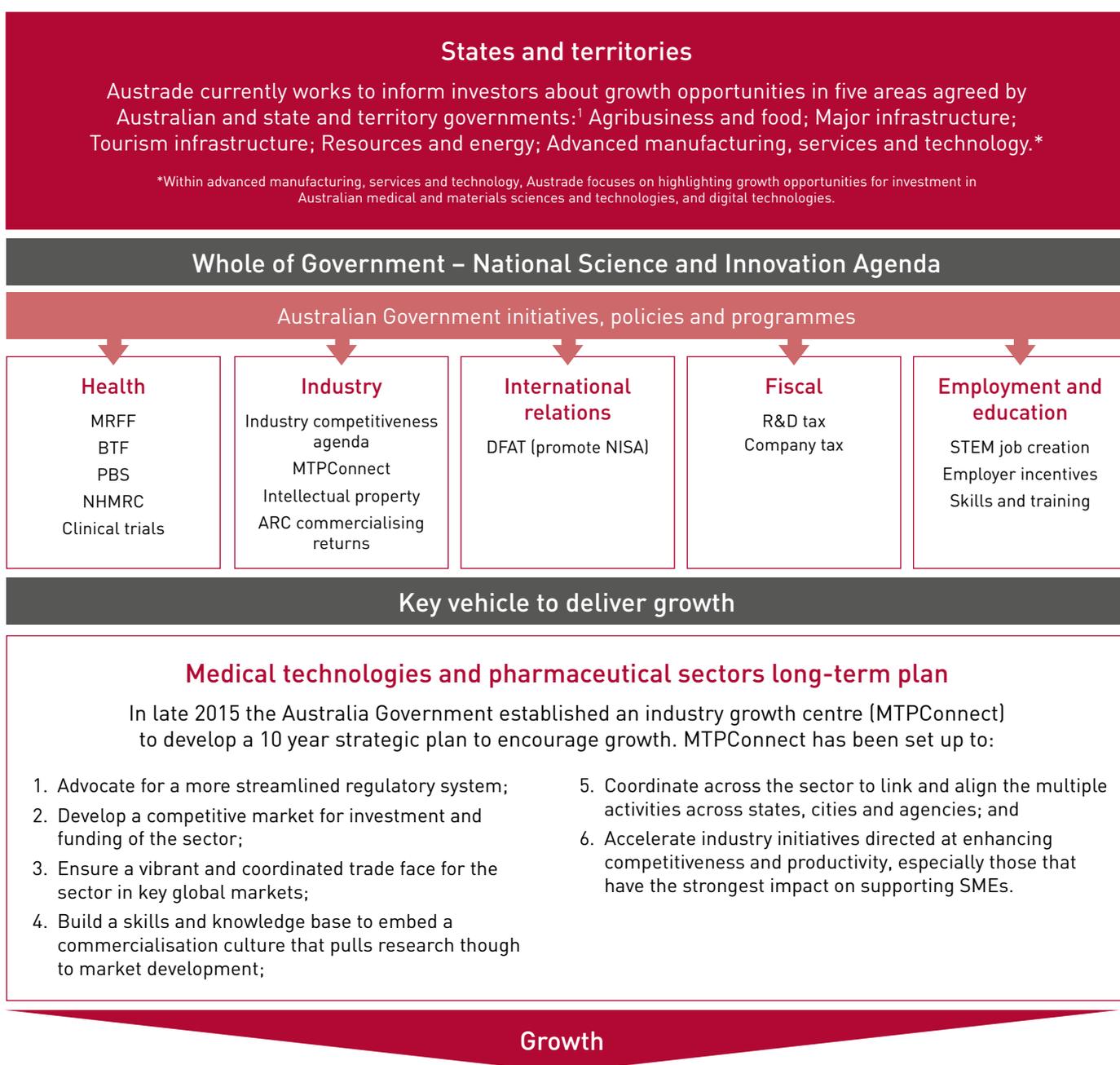
CHALLENGE: ALIGNMENT OF STRATEGIES WHICH IMPACT ON THE MEDICINES INDUSTRY

While most of the health policies that relate to medicines (such as administration of the Pharmaceuticals Benefit Scheme) are the responsibility of the Australian Government, other policies and plans can also impact on the medicines industry and the attractiveness of Australia as a destination to invest.

Free trade agreements have provided a demand-side incentive to increase advanced manufacturing through increased access to new markets. Without further domestic supply-side policy support for the manufacturing industry these opportunities cannot be harnessed.

As Figure 3 below demonstrates, various policies and programmes in the trade, fiscal, health, innovation, employment and industry portfolios have to varying degrees impacted the medicines industry.

FIGURE 3: OVERVIEW OF POLICIES AND PROGRAMMES THAT IMPACT ON THE MEDICINES INDUSTRY



With the right policy settings, the medicines industry has the potential to be a key innovative sector for Australia's future. To achieve this, there needs to be greater cooperation and coordination between the trade, health, innovation and industry portfolios.

Within advanced manufacturing, services and technology, Austrade focuses on highlighting growth opportunities for investment in Australian medical and materials sciences and technologies, and digital technologies.

Growing advanced manufacturing capabilities could help Australia to maintain a healthy balance of trade in medicines in the future. It is also recognised that for the objectives of the national medicines policy to be realised, the long-term sustainability of the PBS needs to be maintained.

On average it takes an investment of around \$1.5–2.6 billion to develop and bring a new medicine to market.^{8,9} A reasonable return on investment allows innovative based medicines to continue to develop and manufacture safe and effective medicines.

A high degree of coordination and cooperation between the Australian Government's trade, health, industry and innovation portfolios will help the medicines industry to flourish. With the right policy settings, the medicines industry has the potential to be one of the key innovative industries for Australia's future, as identified by the Australian Government in their **Industry Competitiveness Agenda**.

8. Mestre-Ferrandiz, J., Sussex, J. and Towse, A. [2012] The R&D Cost of a New Medicine. Office of Health Economics. Available: <https://www.google.com.au/l?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0ahUKEwjlrLnLuYb0AhXEi5QKHVEUA1wQFggbMAA&url=https%3A%2F%2Fwww.ohe.org%2Fpublications%2Frd-cost-new-medicine&usg=AFQjCNGskxaS9gufusMM07YJEI59Q7A8Cw&bvm=bv.127984354,d.dGo>

9. DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016;47:20-33.



SOLUTION: A COORDINATED LONG-TERM PLAN FOR THE MEDICAL TECHNOLOGIES AND PHARMACEUTICALS SECTORS

Australia has some key advantages for the location of medical technologies and pharmaceuticals activities, such as excellence in its public and university medical research infrastructure, clinical research capabilities, excellent access to the regions, and low sovereign risk.

Opening up access to new exports markets through trade agreements is an important policy priority, however more can be done to tackle barriers at home. Barriers such as lack of information, skills shortages, inadequate access to finance, and freight costs are all issues that impact trade and export promotion policy.¹⁰

The Australian Government, through MTPConnect, is developing a long-term plan for the medical technologies and pharmaceutical sectors. Medicines Australia is supportive of a whole of government approach to the medical technologies and pharmaceuticals sectors which balances trade, fiscal, health, innovation, employment and industry policies.

There is an exciting opportunity for the Commonwealth Science Council to consider the plan, as part of the whole of government approach to innovation and science, through the **National Innovation and Science Agenda**.

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 has recently released a **Medical Technologies and Pharmaceutical Sectors Strategy** as part of a broader plan to grow future industries which includes trade and promotion activities.

Innovative pharmaceuticals are viewed as strong investment and growth prospects for Queensland, and growth of demand for these products is expected as the population ages and Asia's middle class grows.¹¹

Given these recent developments, it is timely that the Australian Government increase its efforts to align its trade and industry development policies and programmes with those of the state and territory governments.

In addition to establishing MTPConnect, the Australian Government could ensure that 'Brand Australia' better coordinates its medical technologies and pharmaceutical activities (beyond events) with state-based trade and investment agencies.

A competitive advantage for domestic manufacturing in the areas of niche products, quality and standards, and services suggests the need for focussed effort on high-end manufacturing in these disciplines.

A long-term marketing strategy developed by Austrade with the agreement of the states and territories could position Australia as a preferred country to invest in. A long-term marketing plan could complement the work being done by MTPConnect.

The marketing strategy could also place a significant emphasis on clinical trial investment, through the promotion of a simple, consistent approvals framework, and incentives to commercialise.

10. Australian Labor Party, Positive policy: Generating Jobs through Trade and Investment, 2016. Available at: http://www.100positivepolicies.org.au/generating_jobs_through_trade_and_investment

11. Office of the Chief Scientist in Queensland, Advanced Manufacturing: Implications and opportunities for Queensland, February 2016. Available at: <http://www.chiefscientist.qld.gov.au/images/documents/chiefscientist/pubs/reports-other/advanced-manufacturing-2016.pdf>

EXECUTIVE SUMMARY

A COMMON GOAL

Encourage foreign investment to drive economic growth and prosperity in Australia.

KEY CHALLENGES

- Growing exports of pharmaceuticals in both established and emerging markets – even though Australia has a reputation for manufacturing safe, high-quality medicines and vaccines, imports are significantly higher than exports.
- Removing trade barriers (including through free trade agreements) in both established and emerging markets.
- International competition for investment – securing Australia's fair share of foreign investment to grow our participation in R&D and clinical trials is hampered by the shortage of local skilled workers across the pharmaceutical value chain.
- Alignment of multiple strategies which impact on the medicines industry.
- Free trade agreements have provided a demand-side incentive to increase advanced manufacturing through increased access to new markets, however these opportunities cannot be harnessed without domestic supply-side policy support.

KEY SOLUTIONS

- Medicines Australia welcomes the Australian Government's promise to commence and conclude trade agreements with the European Union, India and Indonesia. The feasibility of further trade negotiations with Canada, Mexico and Colombia will be followed with interest.
- Benchmark Australia's incentives at all stages of the medicines industry value chain. 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.
- Support MTPConnect in the development of a long-term plan for the pharmaceutical and medical technologies sector in Australia. Consider a marketing plan to complement the strategy developed by MTPConnect.