

2 July 2015

Mr Ken O'Dowd MP  
Chair, Joint Select Committee on Trade and Investment Growth  
C/o Committee Secretary  
PO Box 6021  
Parliament House  
CANBERRA ACT 2600

Via email: [jsctig@aph.gov.au](mailto:jsctig@aph.gov.au)

Dear Mr O'Dowd

Thank you for the opportunity to make a submission to the Joint Select Committee on Trade and Investment Inquiry into the Business Experience in Utilising Australia's Free Trade Agreements. Medicines Australia also appreciates being able to highlight the impact of Free Trade Agreements (FTAs) on the innovative medicines industry in the context of the potential signing of the Trans Pacific Partnership (TPP) agreement.

FTAs can facilitate the streamlining and harmonisation of international regulatory and Intellectual Property (IP) systems and can meaningfully reduce trade barriers. These are important factors, not just for growing Australia's pharmaceutical industry, but for expanding access to medicines and vaccines across our region. However, implementation of FTAs must include consultation and commitment from the governments involved to ensure the potential of these agreements is realised. Further, the Australian Government should go beyond trade agreements in stimulating research and investment.

## Introduction

Medicines Australia represents the research-based innovative medicines industry in Australia. Today, over 50 pharmaceutical companies and around 400 locally-owned medical biotechnology firms, operate in Australia. Together, they employ approximately 40,000<sup>1</sup> highly-skilled Australians (with at least 14,000 jobs<sup>2</sup> largely from within our member companies), invest more than a combined \$1 billion per year in research and development<sup>3</sup> and generate nearly \$2.9 billion in exports each year<sup>4</sup>. Our member companies supply up to 86% (by value) of the therapies available on the Pharmaceutical Benefits Scheme (PBS) – medicines and vaccines that help millions of Australians live healthier, longer, more productive lives.

As the Asia Pacific region is poised for growth, there are a number of economic and regulatory opportunities for the Australian pharmaceutical industry. Some of these opportunities may be facilitated through the FTAs that have been instigated. Contrary to some previous commentary<sup>5</sup>, FTAs have not resulted in more expensive pharmaceuticals for consumers, or increased risk to patient safety. Rather there has been increased

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<sup>1</sup> Comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution: Department of Innovation, Industry, Science and Research, Pharmaceutical Industry Fact Sheet, available at:

[www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx](http://www.innovation.gov.au/Industry/Pharmaceuticals/Pages/AustralianPharmaceuticalsIndustryFactSheet.aspx)

<sup>2</sup> IBIS World, Melbourne, 2014, Pharmaceutical Product Manufacturing in Australia: Market Research Report

<sup>3</sup> Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

<sup>4</sup> Australian Bureau of Statistics 2015, 'International Trade in Goods and Services': March 2015

<sup>5</sup> Drahos, P. et al. 2004. The FTA and the PBS: A submission to the Senate Select Committee on the US-Australia Free Trade Agreement.

competitiveness leading to a greater range of medicines being available for Australians<sup>6</sup> while at the same time Governments have implemented a range of reforms to achieve billions in savings from the PBS<sup>7,8</sup>. Despite increased market opportunities through recent FTAs, there has been little further support domestically to encourage investment in the innovative medicines industry.

### **Current Opportunities and Challenges**

With supportive policy settings, our industry has the potential to be one of the key innovative industries for Australia's future, as identified by the Government in their Industry Competitiveness Agenda<sup>9</sup>. The next decade will provide enormous opportunities, with the Asia Pacific region set to drive huge demand for medicines. This growth is driven by a growing middle class and expanding health systems<sup>10</sup>. Australia is uniquely placed to meet this demand, with FTAs with the Association of South East Asian Nations (ASEAN), China and Japan. We are strategically located, with a highly-skilled workforce and a long-standing reputation for manufacturing safe, high-quality medicines and vaccines.

Australia currently exports medicines to over 70 countries. The right policy settings could see Australia potentially double its share of the global pharmaceutical market (currently approximately 1%<sup>11</sup>) over the next decade. Medicines Australia welcomes opportunities to work with Members of Parliament in any efforts that can help realise this economic opportunity for Australia.

Despite this opportunity, there are several challenges facing the industry that are making it more difficult to achieve this aforementioned potential growth. In fact, the local industry has been in decline now for a number of years. Historically, medicines had been Australia's leading manufactured exports, but recently have fallen and are now ranked second<sup>12</sup>. In fact, Australian pharmaceutical exports plummeted by nearly a third from \$4.3 billion to \$2.9 billion between 2012 and 2014. As a result of this decline in exports, eight pharmaceutical manufacturing plants have either closed or been significantly downsized since 2007<sup>13</sup>. Although FTAs have provided a demand side incentive to increase manufacturing through increased access to new markets, without further domestic supply side policy support for the manufacturing industry, these opportunities cannot be harnessed.

Another challenge in the industry has been that since 2007, as many as 2,500 jobs have been lost across the Australian pharmaceutical industry. Ongoing contraction of the sector will undoubtedly apply even more pressure on jobs due to the difficult fiscal settings: downward pressure on prices for pharmaceuticals and limited investment incentives for research & development, intellectual property or direct foreign investment. In this context, the innovative medicines industry is sensitive to any further policy changes that would alter the current business environment.

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<sup>6</sup> Department of Health and Ageing and Medicines Australia 2013. Trends in and drivers of Pharmaceutical Benefits Scheme expenditure. Report for the Access to Medicines Working Group.

<sup>7</sup> Australian Government 2015 National Health Amendment (Pharmaceutical Benefits) Bill 2015

<sup>8</sup> Sweeney 2013. The Impact of Further PBS Reforms.

<sup>9</sup> Australian Government 2014. Industry Innovation and Competitiveness Agenda.

<sup>10</sup> Australian Government 2012. Australia in the Asian Century.

<sup>11</sup> Medicines Australia 2015 Facts Book 4.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid.

## **FTAs and the Australian Innovative Medicines Industry**

The establishment of a number of 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.

Of the largest markets for medicines and vaccines, 3 out of the 4 have FTAs with Australia. South Korea is Australia's largest market for medicines and vaccines, with nearly \$575 million exported in financial year 2013-2014<sup>14</sup>. Other major export destinations include China (\$338 million), Taiwan (\$283 million) and New Zealand (\$247 million), with Taiwan the only top four export market not having a FTA with Australia.

Despite having access to these growth markets through FTAs, Australia faces stiff competition from other countries for the manufacture of innovative medicines. Countries such as Singapore and Taiwan offer significant incentives to attract investment.

Currently, Australia's share of global outward trade in pharmaceutical goods and services is less than 1%<sup>15</sup>. This is despite pharmaceutical manufacturers in Australia having a competitive advantage with our highly-skilled work force and access to high quality science and facilities. Even though Australia has a reputation for manufacturing safe, high-quality medicines and vaccines, imports are significantly higher than exports. Growing manufacturing capacity would help Australia to maintain a healthy balance of trade in pharmaceutical goods and services in the future.

## **Benefits of FTAs**

A number of benefits have arisen from FTAs for the pharmaceutical industry in Australia. Reduced trade barriers, such as tariffs, have assisted a range of Australian manufacturing exports, of which pharmaceuticals are a large component. Other benefits have included increased transparency and reviews of the Pharmaceutical Benefits Advisory Committee (PBAC), opportunities to enhance data exclusivity, whilst enabling continued protection and streamlining of intellectual property rights, and establishing the Medicines Working Group (now called the Access to Medicines Working Group). These benefits have been noted in a previous submission by Medicines Australia to a Joint Committee Inquiry into the USA-Australia Free Trade Agreement<sup>16</sup>. A key issue noted in the submission was that further investment in Research and Development (R&D) is required to ensure that Australia's reputation as a world leader in the development of intellectual property continues.

Increased transparency and reviews of the PBAC has assisted the industry, consumers and medical specialists to be more confident that the best decisions are being made for Australian patients and consumers. This process has enabled the medical profession and industry to be better informed and understand why a medicine has or has not achieved PBS listing. The system for independent review of a PBAC decision has provided a safeguard for Australians, whilst procedural fairness is maintained in gaining timely access to critical new medicines for patients.

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<sup>14</sup> Department of Foreign Affairs & Trade, Canberra 2014, Composition of Trade Australia.

<sup>15</sup> World Trade Organisation, Geneva, 2013, 'International Trade Statistics, Merchandise Trade'.

<sup>16</sup> Medicines Australia 2004. Submission to the Inquiry into the free trade agreement between Australia and the United States of America.

## Continuing Challenges

Despite these benefits, there are a number of continuing challenges. Despite commitments in the Australia-US FTA, Australia still lacks a patent notification process. Further, while a independent review process for rejections of new medicines submissions by the Pharmaceutical Benefits Advisory Committee (PBAC) has been implemented, the availability of this mechanism is largely insignificant (and seldom utilised) as it does not provide for a full merits review for PBAC recommendations.

Currently in Australia, pharmaceutical patents owners do not receive notice of a third party's intention to register a product that may infringe a valid and enforceable patent on the Australian Register of Therapeutic Goods (ARTG). This is despite Australia being required to do so under the terms of its Free Trade Agreement with the United States.<sup>17</sup>

The first notice a patent owner gets of the intended launch of a generic product is usually when the product is registered on the ARTG. This means that instead of proceedings for infringement commencing at the time an application for registration is lodged, with the potential for the claim to be resolved concurrently with the registration process, infringement proceedings follow the registration process, requiring temporary injunctions and potentially delaying valid market entry by competitors.

Despite the FTA providing a mechanism for an independent review of PBAC recommendations, industry experience has been that when used, these reviews have referred back to the original recommendation of the PBAC without clear justification or further recourse. There is scope for further development of the review process to be merits based, with transparent justification for decisions communicated to all stakeholders.

## Investment in Research & Development

The pharmaceutical industry is a critical component of Australia's innovative industries<sup>18</sup>. Our industry already undertakes more than a combined \$1 billion of Research and Development annually in Australia<sup>19</sup>. This high level of investment has myriad important benefits for the country, including enhancing the physical health and welfare of Australians and helping to reduce health costs. It has been estimated that a dollar invested in Australian health research and development (R&D) will return an average health benefit of \$2.17<sup>20</sup>.

Additional investments in R&D or high-tech manufacturing also generate new intellectual property, enhanced local infrastructure and production capacity, and new jobs in advanced manufacturing and other highly-skilled fields in Australia. There is significant scope for further expansion of our industry's medical R&D activity in the short to medium term. This expansion will by no means be automatic – it will only happen if Australia distinguishes itself as a desirable and genuinely competitive location in which to perform such research, especially as more FTAs are signed and competition for R&D investment increases.

The cost of development of a new prescription medicine that gains marketing approval is over \$US 2.5 billion<sup>21</sup>. This includes the costs of the pre-human and clinical phases of development. Consequently pharmaceutical companies require stability and certainty once medicines are on the market to enable further investment in new innovative products. In addition to this, it takes on average 12-15 years from preclinical trials to when the medicine is widely available to patients. With these long lead times, access to markets and certainty in

<sup>17</sup> Department of Foreign Affairs and Trade, Canberra, Article 17.10.4 of the Australia-US Free Trade Agreement.

<sup>18</sup> Department of Industry, Canberra, 2014, Australian Industry Report

<sup>19</sup> Australian Bureau of Statistics 2012, 'Business Expenditure Report on R&D'

<sup>20</sup> Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II

<sup>21</sup> Tufts Center for Study of Drug Development 2015. Cost of Developing a New Drug.

the business operating environment are important to ensure continued R&D investment. Although FTAs have assisted in providing access to new markets and assistance in reducing the costs of exporting, there is further opportunity for the government to provide a supportive policy environment to encourage further investment in R&D in Australia for new innovative medicines.

## **Conclusion**

Medicines Australia supports further measures that will open new markets and reduce barriers to trade for the innovative medicines industry. Although there have been benefits for the medicines industry from FTAs, without further incentives for investment to conduct R&D and to manufacture medicines in Australia, the potential will not be completely captured. The Australian innovative medicines industry is a dynamic, vital part of the Australian economy and society. It provides access to affordable medicines for Australians and creates investment and jobs.

Despite the current challenges facing the industry, there are opportunities for Australia to grow its share of the pharmaceutical trade, with global demand for medicines expected to double in a decade. This will mean more local jobs, increased economic growth and provide Australians with better, faster access to treatments. To achieve this we must ensure that our trade and investment system is designed to encourage, not hinder, future investment.

Thank you for your consideration of our submission.

We would be pleased to clarify or amplify these statements, including at any hearings that may follow.

Yours sincerely

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