MEDICINES Australia

Better Health through Research and Innovation

Submission to the Joint Committee Inquiry into Trade and Investment with the United Kingdom

April 2017

Introduction

Medicines Australia welcomes the opportunity to provide input to the Joint Committee's inquiry into the trade and Investment relationship with the United Kingdom (UK). We encourage and support more open trade with key economic partners such as the UK. Medicines Australia's members, and the pharmaceutical industry more broadly, have strong business ties to the UK, including imports from and exports to the UK as well as other key partnerships. With the UK set to leave the European Union (EU), there is an opportunity to address existing barriers to increasing the level of trade for the pharmaceutical sector in a future trade agreement between Australia and the UK. Similar to other Free Trade Agreements (FTAs) the development of an agreement with the UK would expand opportunities for Australian based pharmaceutical companies to grow their export prospects and increase domestic contributions to the Australian economy.

Medicines Australia represents the research based pharmaceutical industry in Australia. Our member companies invent, discover, research, manufacture and supply innovative medicines and vaccines to the Australian community. These medicines keep Australians out of hospital, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our membership consists of more than 50 companies, all of whom are committed to advancing the health outcomes of all Australians. By employing approximately 15,000 and as a key part of Australia's largest advanced manufacturing export, our members make an important contribution to the Australian economy.

The trade and investment relationship between Australia and the UK is important for the innovative pharmaceutical industry for a number of reasons. A significant proportion of Medicines Australia's members have either headquarters located in the UK, or have investments in manufacturing and associated supply chain components. With the UK's pending exit from the EU, there is currently substantial international scrutiny of the likely regulatory environment and incentives for large multinationals to remain, many of which are innovative pharmaceutical companies. Given that the UK is in the top ten of Australia's largest trading partners, any changes that result from Brexit will have a flow on for companies in Australia that have ties to the UK[1].

Summary

Reducing trade barriers and forming mutually beneficial FTAs will increase Australia's competitiveness as a global trading partner, strengthen Australia's economy and ensure Australians have access to innovative health care solutions. This will strengthen our regional position and further grow the Australian economy to meet the demands of a growing and aging population in a resource constrained environment. The pharmaceutical sector is primed to meet the challenges of the century and to harness our extraordinary talents to grow the Australian economy.

The key to successful trade agreements for the pharmaceutical sector are:

- A foundation of strong and mutually agreed principles acknowledging the unique role of innovative pharmaceutical technologies to Australians' health and economic prosperity;

[1] Department of Foreign Affairs and Trade, 2016. United Kingdom Country brief http://dfat.gov.au/geo/united-kingdom/pages/united-kingdom-country-brief.aspx

- Recognition of our niche strengths in research capability and advanced and specialist manufacturing;
- Harmonisation of regulatory standards across key trading partners, including strengthening review mechanisms;
- Commitment to a strong and competitive Intellectual Property system to foster and reward innovation, including strengthening the current patent notification system;
- Embedded policy incentives to attract direct and indirect investment in research & development;
- Streamlined and efficient processes to create a destination of choice for research and development;
- Avoidance of policies that harm the ability to attract and retain innovation and invention; and
- Cooperative mechanisms to continuously monitor, strengthen and improve bilateral and multilateral trade relations.

Establishment of Principles

A mutually agreed set of principles lays the foundation for successful trade agreements. This is attested by previous experience; for example, in the development of the Australian-US Free Trade Agreement (AUSFTA). The acknowledgement of these principles culminated in the inclusion of a specific chapter on pharmaceuticals in the AUSFTA. Thus for the health sector, the founding principles ensured that the best possible outcome for Australians' access to health services, was successfully upheld. Hence, it will be important that changes and enhancements to the current trade and investment relationship with the UK should similarly be approached from a principles basis.

Medicines Australia, therefore, suggests the inclusion and recognition of principles similar to those below in future free trade agreements[2]:

(a) the important role played by innovative pharmaceutical products in delivering high quality health care;
(b) the importance of research and development in the pharmaceutical industry and of appropriate government support, including through strong intellectual property protection and other policies;
(c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures, without impeding a Party's ability to apply appropriate standards of quality, safety, and efficacy; and
(d) the need to recognise the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

An option to monitor the trade relationship between Australia and the UK could be achieved through the formation of a medicines working group in a future trade agreement. This will enable the innovative pharmaceutical sector to engage more effectively in the supporting movements towards reducing regulatory burden that limits timely access to new medicines in both countries.

[2] For further detail on these principles, please see Annex 2c of the Australia and United States Free Trade Agreement.

Manufacturing and exports

Pharmaceuticals and vaccines are a significant advanced manufacturing export for Australia. Currently medicines and pharmaceutical products are the largest manufactured export, worth as much as $3 billion annually. Australia has seen a diminishing manufacturing footprint over recent years. Opening up new, and strengthening current, trading relationships will provide an incentive for greater investment and securing jobs for Australians.

With global demand for medicines expected to double in a decade, there are opportunities for Australia to grow its share of the international pharmaceutical trade through increasing advanced manufacturing and enhancing research and development activity. Making the most of this opportunity will help drive economic growth, secure more high-skills jobs, and provide Australians with improved access to new medicines. A trade agreement with the UK would be a prime opportunity to further support investment and potential expansions of our advanced manufacturing base in Australia.

Much of the potential growth will come from partnerships and investment in Australia's medical technology, pharmaceutical and biotechnology research industry. This industry has the skills and capacity to construct specialist, innovative manufacturing plants which will deliver jobs for STEM graduates. In addition to the potential for export and advanced manufacturing growth, innovative pharmaceutical companies also support other Australian businesses through investing in research and development, engineering and other associated functions.

Regulatory Harmonisation

The UK, like Australia, is a knowledge driven economy, with various supporting programs to drive investment into intellectual property and manufacturing environments. There is a need to ensure that whilst closer harmonisation of regulatory systems would be beneficial in promoting closer economic ties, it should not be to the detriment of displacing investment between the two countries. Any future trade agreements should look to streamline regulatory approval processes for access to new medicines, including alignment with the current reforms being undertaken by the Therapeutic Goods Administration as part of the Medicines and Medical Devices Review.

With Australia also currently looking to establish a free trade agreement with the European Union, the exit of the UK could create possible divergence in regulatory systems. The Australian Government should also consider how to ensure ongoing alignment in regulatory processes across the three jurisdictions, given the close ties between the UK and the EU. This is particularly important for the pharmaceutical industry in Australia, with the current global supply chains of many of Medicines Australia's members. If regulatory systems were to change, or trade barriers imposed, then this could have a potential impact on the timely access to new medicines for Australian patients. One key area where this could have a resounding impact is on the investment in clinical trials.

The formation of a new free trade agreement, also provides the Australian Government with an ideal opportunity to streamline and harmonise clinical trials regulation to more closely align with our key trading partners. Clinical Trial reforms in Australia are much needed and universally supported. However, persistent differences in research governance systems including ethics approvals, and inconsistencies within and between States and Territories in Australia, continue to hamper our potential to attract new clinical trials from key trading partners such as the UK.

Intellectual Property (IP)

The UK and Australia, as knowledge driven economies, have an opportunity to show leadership in ensuring both countries have a strong IP system. The development of a trade agreement with the UK should ensure that there are no further reductions to Australia's IP system. This may be achieved by maintaining a commitment to and where appropriate strengthening, well accepted incentives to innovate, such as the period of exclusivity through patents, as well as suitable periods for data protection with regulators. Such systems recognise the important balance between risk and reward, particularly in highly novel areas. Additionally, appropriate patent notification schemes should be enforced. Trade agreements that do not adequately support the important role of a strong IP system, undermine investment and economic growth.

Patent rights are one of a number of factors which influence companies' investment decision making. Australia makes up only around 1% of the global pharmaceutical market, and therefore does not carry enormous weight from a global perspective. Therefore, it is in fact even more important that Australia has globally competitive strengths in such areas as IP, medical research and high regulatory standards to continue to attract pharmaceutical investment and incentivise greater future investment in Australian's overall health outcomes.

Regulatory data protection (RDP), or data exclusivity, is distinct from patents and is equally necessary for all innovative medicines, and particularly important for biologic therapies. Where the period of market exclusivity from a patent cannot be assured, which is more likely for biologics, innovators will rely more heavily on data protection to enable them to recoup up-front investment. Without these parallel systems in place, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new medicines and specifically new biologics to market.

Strengthening RDP protections in Australia to align with global best practice would further enhance Australia's ability to compete for foreign investments in the knowledge- and innovation-intensive biomedical sector that can drive future economic growth. The formation of a new trade agreement with the UK would be an ideal opportunity to further strengthen, and support the IP environment in Australia to foster further innovation.

R&D tax incentive

Although our industry is a global one and despite significant international competition, Medicines Australia's members invest in research and development (R&D) intensive activities, such as clinical trials, of approximately $450 million annually in Australia. Whilst the research based pharmaceutical industry is, by nature, research intensive, decisions on where and when to place R&D activities are made globally and will be influenced by a number of factors against which Australia needs to introduce and maintain a competitive edge.

Innovative research partnerships between hospitals, research institutions and medicines companies currently support thousands of jobs for Australian scientists and researchers. However, with the right incentives, Australia can become an even stronger international innovation and investment destination. Future trade agreements between the UK and Australia could leverage this investment and ensure that incentives to support investment in R&D are strengthened and retained.

As biotechnology and medical technology are global industries, Australia must compete to retain the R&D activity of local companies, as well as to attract international R&D activity into Australia. It is important to maintain a stable, supportive and consistent policy environment in

Australia to encourage life sciences businesses to make strategic decisions around R&D activity and bring additional investment into Australia. A key incentive is the R&D Tax Incentive. This incentive is a key foundation for the innovation that is the life blood of pharmaceutical and medical technology sector in Australia

The current R&D Tax Incentive:

- provides significant support to businesses in our sector to undertake, develop and extend their R&D activities that would not be otherwise possible or that would be significantly delayed;
- plays a significant role in maintaining Australia's competitiveness as a preferred location for R&D activities, including pre-clinical testing and clinical trials;
- brings spill over benefits into the Australian health system by providing Australians with access to early stage therapeutics, diagnostics and medical devices during clinical trials and as final products;
- provides public sector research with contract R&D resulting from companies engaged in new research programmes;
- contributes to building a home-grown innovation ecosystem in R&D-intensive industries, ensuring Australia can deliver world-class research into treatments, cures, diagnostics devices and vaccines; and
- allows opportunities to streamline the administration and compliance of the incentive to make it easier for companies to focus on undertaking research and development activities.

A key part of R&D in Australia is investment in clinical trials. Clinical trials are well accepted as critically important to Australians to provide early access to new and breakthrough medicines under clinical development; these new medicines will assist Australians to treat, manage and potentially cure their conditions. A thriving clinical research infrastructure in Australia also creates employment opportunities in our research institutions, universities and hospitals. Without the investment and collaboration of innovative pharmaceutical companies, many clinical trials would not be viable. Entrenched support for the clinical trial environment in Australia should be considered a core component in developing free trade agreements, especially as pharmaceutical companies compete internally with other regions for investment in trials.

Incentives such as the R&D tax incentive should be retained and acknowledged in free trade agreements, to ensure that investment in R&D activities in Australia is not unintentionally hampered. It also provides as an incentive for foreign direct investment in Australian clinical trials and advanced manufacturing of pharmaceuticals that can then be exported to the Asia Pacific region.

Damages Claims

When considering this trade agreement the Australian Government should reconsider and rescind the current policy of the Government seeking to be a party to damages claims for innovative pharmaceutical products where a patent challenge is upheld by the courts. Australia's preliminary injunction policy effectively circumvents the due process afforded to inventors through the patent and court systems by penalising inventors who have sought to defend their legitimate patent rights in court, which ultimately proved to be unsuccessful. The precedent set by this policy jeopardises well-accepted principles of due process and severely

discourages innovators from exercising their rights to defend their IP. Moreover, this policy contravenes Australia's obligations under TRIPS.

The Australian Patent Office (APO) requires substantive patent examination; the patentee must show it is entitled to a patent. Because of this burden placed on the patentee, one essential component of a granted patent is the *presumption of validity* – thus providing inventors with a reasonable expectation that they will be able to exclude others from making, using, or selling the relevant technology. This presumption provides the legal and practical certainty required by inventors to carry out costly, high risk up-front, R&D activities, and to enjoin others from infringing relevant IP rights. The ability to quickly and efficiently enforce IP is especially crucial for pharmaceutical innovators. For this reason, courts often employ provisional enforcement measures, *e.g.* preliminary injunctions, to ensure that patentees do not encounter irreparable harm during the course of a judicial proceeding.

Similarly, biopharmaceutical innovators are severely disadvantaged if they do not seek preliminary injunctive relief in Australia. If a generic product launches, PBS price reduction mechanisms are triggered, thus significantly lowering the reimbursed PBS price. However, if a court later determines that the generic company infringed the originator's patent, restoring PBS prices to levels prior to generic market entry is at the discretion of the Department of Health. In other words, there is no legal mechanism or policy that automatically readjusts the PBS price index after a generic product is introduced and subsequently removed from the market.

Conclusion

Australia's trade and investment relationship with the UK is likely to change with the UK's exit from the EU. For the innovative pharmaceutical sector in Australia, the strong ties with the UK provide a base from which future trade agreements could leverage increased economic collaboration. The strengths of previously negotiated FTAs with Australia's key trading partners can be used to guide the approach to the development of a bilateral agreement with the UK. There is a need for any future FTA to have a pharmaceutical chapter to address the unique needs, and opportunities that the pharmaceutical and medical technology sector provides. Similarly, there are lessons that can be learned from previous trade discussions. Medicines Australia would welcome the opportunity to discuss our suggestions in more detail, and appreciate the opportunity to provide input to this inquiry.