Medicines Australia

Joint Standing Committee on Trade and Investment Growth
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RE: Inquiry into supporting Australia's exports and attracting investment

Medicines Australia welcomes the opportunity to provide a submission to the *Joint Standing Committee on Trade and Investment Growth – Inquiry into supporting Australia's exports and attracting investment.*

Medicines Australia believes that that any policies that underpin trade and investment should be consistent with the following key principles:

- Ensuring all Australians have access to high quality, safe, efficacious and cost-effective medicines
- Ensuring Australia remains competitive internationally to incentivise the presence of industry
- Recognising the value of our industry in advancing the overall health and wellbeing of Australians.

Medicines Australia is the peak industry body representing the innovative research-based medicines industry in Australia. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. They are proud of the contribution they make to the health and well-being of everyday Australians, as well as to the local economy. Our industry provides high value jobs for Australians, generates up to $4 billion in exports and invests over $1 billion in research and development every year[1]. This high level of investment has many important benefits, including enhancing the health and welfare of Australians and reducing healthcare costs. In fact, it has been estimated that for every $1 invested in Australian pharmaceutical research and development, the average return on health benefits is $2.17[2].

The innovative medicines industry has developed some ground-breaking discoveries. These emerging innovative medicines and therapies (such as CAR-T and precision medicine) are helping to fight previously untreatable diseases and are providing patients with better survival rates and improved quality of life. However, medicines investment is high-risk with approximately only 12% of medicines that enter clinical trials reaching approval for use by patients[3]. Therefore, our industry is highly reliant on a stable policy environment that strongly supports innovation, research and development, and commercial translation to the same levels as competitor nations. Without these policies, there will be limited incentive for ongoing investment into Australia.

Medicines Australia believes there is a valuable opportunity to boost the profile of Australia's innovative medicines industry internationally, encouraging foreign investment and trade, thus driving economic growth and prosperity, by supporting the following measures:

- Acknowledgement of the unique role of innovative pharmaceutical technologies in enhancing 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.

Please see Appendix 1 below for a more detailed discussion on the above issues.
Medicines Australia welcomes the opportunity to discuss and collaborate with the Australian Government and other stakeholders on this important issue. Please feel free to contact [redacted] on [redacted] if you would like to further discuss our submission.

Yours sincerely

[redacted]

Elizabeth de Somer
CEO
Medicines Australia

Medicines Australia

APPENDIX 1

Free trade agreements, investment and pharmaceutical exports

The pharmaceutical industry in Australia has an exciting opportunity to grow its exports and attract greater investment into the innovative medicines sector, 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. Indeed, 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.[4]

In order to ensure this ongoing contribution to Australians and the economy, Government needs to maintain not just a well-funded PBS, but also continue to support a policy environment that:

- Is stable, transparent and supports incentives to attract investment in priority areas such as medical research, e.g. R&D tax incentives for clinical trials, reduction of inappropriate trade barriers related to rules of origin
- Is globally harmonised with respect to regulatory standards, e.g. the OECD Mutual Acceptance of Data (MAD) system
- Includes a strong effective and stable IP system
- Includes the establishment/reinvigoration of medicines working groups that tackle issues relating to future medicines and therapies that do not neatly fit into established tariff codes nor existing regulatory and reimbursement frameworks, e.g. CAR-T therapies.
- Recognises the social and economic benefits of a patient focused agenda.

Medicines Australia continues to strongly support free trade agreements (FTAs). With respect to Australia, a number of these agreements are with countries that have high growth economies in the Asia region, which are major export destinations for medicines and vaccines. The establishment of a number of FTAs has provided the following benefits to Australians and the economy:

- Greater economic activity and job creation, delivering opportunities for big and small Australian businesses to benefit from greater trade and investment
- Establishment of new markets, giving Australian consumers and businesses improved access to a wider range of competitively priced goods and services, new technologies, and innovative practices
- Reduction in trade barriers
- Increased exports due to an environment that is conducive to investment in medical research
- Faster access to innovative pharmaceuticals for Australians thereby reducing morbidity and mortality and improving quality of life
- Increased competitiveness for the Australian innovative medicines industry.

In addition, Medicines Australia has previously, and continues to, strongly advocate for the inclusion of a pharmaceutical chapter in FTAs[6]. The inclusion of a set of mutually agreed principles that recognise the significant role that innovative pharmaceutical products play in delivering high quality health care is essential in providing the foundation for a successful FTA.

Intellectual property

Medicines Australia has long emphasised the need to maintain a strong, stable and predictable IP environment. 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 incentivising investment, leading to increased productivity and competitiveness. In this way, IP is a cornerstone of increased access to life-changing and life-saving medicines for Australian patients. Indeed, economies that act to strengthen and improve their biopharmaceutical IP environments experience significantly higher rates of desired outputs that spur social and economic growth[7]. In light of this, Medicines Australia calls on the Australian Government to recognise the important role of IP and ensure Australia's regime is globally competitive.

Regulatory data protection

A key IP policy mechanism for the pharmaceutical industry is regulatory data protection (RDP). As well as encouraging R&D investment and follow-on innovation, RDP recognises the extensive time, effort and cost of drug discovery, development and particularly clinical trials, required to ensure that medicines are of a high quality, safe and effective, by protecting against unauthorised third-party use of data submitted by the innovator for regulatory approval. Medicines Australia strongly encourages the Australian Government to align Australia's RDP period, which is currently five years, with at least that of the EU. The EU provides innovators with ten years of RDP, which can be increased to 11 years for new indications with significant clinical benefit for patients. In addition, Medicines Australia seeks to align Australia's RDP periods and incentives for orphan drugs, paediatric indications and areas where there is high unmet need (such as the development of new antimicrobial therapies) to that of the EU.

Patent Notification

As mentioned above, the innovative pharmaceutical industry relies on a strong, stable and predictable IP regime to invest in R&D and to bring new and essential medicines to the Australian market. The Australian Government has persisted with a policy of seeking to recover damages from innovators in cases where challenges to patents on PBS-listed medicines have ultimately been upheld following an initial granting of a preliminary injunction. This policy creates significant uncertainty for pharmaceutical patent owners in Australia and undermines the rights of patent holders by introducing a strong disincentive to defend their IP. This uncertainty is exacerbated by the difficulty in resolving patent challenges prior to market entry, due to lack of adequate patent holder notification. Contrary to its obligations under the Australia United States Free Trade Agreement (AUSFTA), Australia has not implemented a system by which the patent holder receives advance notice of potentially patent-infringing products applying for marketing approval to enter the market before patent expiry.

An effective notification system would enable patent holders to defend their intellectual property in a timely manner and without causing potentially unnecessary delays to generic or biosimilar market entry. Medicines Australia proposes that sponsor and medicine details be published at the time of the acceptance of the application for evaluation by the Therapeutics Goods Administration (TGA) (at pre-submission). This could be via amendment to the Therapeutic Goods Act to require direct notification to the patent owner of impending generic entry, introduction of a policy requirement for notification or publication of receipt of application for registration by the TGA.

This particular approach supports the TGA goal of transparency, the industry's aim to minimise litigious activity over patents, and assists the Australian Government to satisfactorily fulfil its obligations under the Australia United States Free Trade Agreement (AUSFTA) Article 17.10.4, on patent notification.

In addition, Medicines Australia proposes that the Government revert to its previous policy of not pursuing damages against innovator companies following the loss of patent proceedings and dismiss all existing claims for damages.

Transparency in reimbursement and regulation of pharmaceutical products

Medicines Australia strongly supports the implementation of a consultative approach towards the establishment of clear mechanisms through which procedures, criteria and new regulations are decided. An approach to the development and implementation of procedures and regulations that is appropriately consultative and transparent, will lead to greater business and operating certainty, thereby strengthening the confidence of the innovative medicines industry to operate in Australia.

For instance, with respect to trade agreements, in the Pharmaceuticals Annex to the AUSFTA, the United States and Australia agreed on provisions for increased transparency and accountability, and enhanced consultation on the operation of the PBS. Annex 2-C of the AUSFTA establishes four basic obligations pertaining to the operation of the PBS, including agreed principles on the role of innovation, transparency, an independent review process, and establishment of a bilateral Medicines Working Group. Medicines Australia supports the reestablishment of this Medicines Working Group (it has not met since 2007), and we believe it is important in enabling the innovative pharmaceutical sector to engage effectively in monitoring and supporting trade relationships between Australia and other jurisdictions.

Workforce mobility and the labour market

Medicines Australia supports the exchange of talent between Australia and our international counterparts via the reduction of barriers to the unimpeded flow of skilled migration. The medicines industry employs around 24,602 Australians, many of which are in highly skilled jobs, with above average incomes[8]. Australia's future prosperity will rely on science, technology, engineering and mathematics (STEM) – disciplines that are at the core of innovation. STEM qualified employees help to drive productivity and are fundamental for businesses which rely on STEM graduates to remain competitive and their expertise will continue to facilitate and sustain economic growth.

Therefore, Medicines Australia calls for policies that support appropriate talent exchange (including the ability to fast track visa approvals for mid-term inter-company transfers) within the pharmaceutical sector. This will ensure equal opportunity for bringing expertise to Australia which will enhance and grow local talent, whilst also providing opportunities for Australians to work internationally and bring expertise home.

Regulatory harmonisation and collaboration

Medicines Australia strongly believes that regulatory cooperation and closer harmonisation of regulatory systems would be beneficial in promoting economic ties between countries and it would also facilitate the streamlining of regulatory approval processes, leading to faster access to medicines for Australians.

Medicines Australia supports the following initiatives with respect to regulatory harmonisation:

- With regards to regulatory processes, any pharmaceutical chapter in future trade agreements should seek alignment with the recently implemented Medicines and Medical Devices Review reforms

- Regulatory cooperation should, where practicable, include the full and genuine mutual recognition of each jurisdiction's Good Manufacturing Practice (GMP) inspections and certifications as a means of reducing barriers to trade.

- *Organisation for Economic Cooperation and Development (OECD) Mutual Acceptance of Data (MAD) system* – which allows for chemicals that have been tested in one country – in accordance with OECD Test Guidelines or similar methods (e.g. ICH guidelines) and the OECD Principles of Good Laboratory Practice (GLP) – to be accepted for assessment in all 36 OECD member countries as well as in six non-member full adherents to MAD, thus avoiding duplicative testing. This system significantly reduces the costs of testing to companies. In fact, the majority of the EUR 309 million in net savings to industry and government every year as a result of the OECD's Environment, Health and Safety (EHS) Programme, was due to the OECD MAD system. The MAD system can also save time on the process to achieve marketing authorisation in different countries as the need for duplicative testing and/or inspections is negated[9].

- *Project Orbis* – Recently, the US Food and Drug Administration (FDA) announced Project Orbis, an initiative of the FDA Oncology Center of Excellence. Project Orbis provides a framework for concurrent submission and review of oncology drugs among its international partners. Under this project, the FDA, the TGA and Health Canada collaboratively reviewed applications for two oncology drugs, allowing for simultaneous decisions in all three countries. Collaboration among international regulators may allow patients to receive earlier access to products in other countries where there may be significant delays in regulatory submissions[10].

Clinical Trials

Medicines Australia acknowledges the Australian Government's commitment to establishing a working group led by Medicines Australia to progress clinical trial governance harmonisation, and we strongly support the collaboration of all relevant parties to work together to implement the subsequent recommendations.

Clinical trials can provide many benefits with respect to the economic and physical health of Australians. In fact, the intensity of clinical trials activity acts as a reliable proxy for an economy's attractiveness for foreign direct investment (FDI) in the biopharmaceutical sector[7]. High levels of clinical trial activity bring multiple benefits to Australians including:

- Early patient access to cutting edge therapies, providing patients with improvements in their health and quality of life
- Improvements in the knowledge of participating healthcare professionals
- Creation of high skill jobs and a robust workforce
- Provision of opportunities for Australian scientists and medical researchers to be at the forefront of medical research
- Generation of taxable income and a source of government revenue

Australia has many advantages as a place to conduct clinical trials. This is in large part because Australia is home to some of the world's best researchers and health professionals and boasts a world-class research infrastructure, a stable socio-political environment, and high clinical and research standards that ensure confidence in the scientific conclusions reached by clinical trials conducted in Australia.

Unfortunately, there are some impediments to Australia's attractiveness as a market for clinical trials including:

- Complex arrangements to establish a trial including variable arrangements for clinical governance and ethics approval, leading to unnecessary delays in the initiation of multicentred clinical trial sites.
- Lower recruitment rates and slow timelines potentially leading to trial closure
- High trial costs
- Inconsistent processes between states and territories
- Lack of a coordinated long-term strategy

Unless Australia is prepared to continue to reform the trials environment to remain an attractive location for global clinical trials and develop a long-term strategy, Australia runs the risk of significant competition from lower cost geographies such as the Asia Pacific and Latin America. As international competition intensifies, Australia will have to address these challenges.

Medicines Australia therefore calls for the following solutions to ensure Australia remains an attractive destination for clinical trials:

- The Australian Government, through the Council of Australian Governments (COAG), to work with industry and the State and Territory Governments, **t**o find agreement for regulatory harmonisation and mutual recognition that optimises clinical trial initiation and shortens commencement times.

- Government and clinical trials stakeholders to work together to enhance patient access to clinical trials through improved coordination, promotion of the value of clinical trials, harmonisation of patient records, and enhanced tele-health initiatives to improve patient recruitment in remote and regional areas
- Retainment of the Clinical Trial Notification (CTN) scheme. The CTN scheme does not require sponsors to submit a Clinical Trial Application (CTA) to be assessed by the TGA.

References

1. Medicines Australia Facts Book, 4th Edition: https://medicinesaustralia.com.au/wpcontent/uploads/sites/52/2010/11/MAFactsBook4_update2015.pdf
2. Access Economics 2008. Exceptional Returns: The Value of Investing in Health R&D in Australia II: https://asmr.org.au/wp-content/uploads/library/ExceptII08.pdf
3. PhRMA, Medicines: Cost on Context. Available at: http://www.phrma.org/cost
4. PwC Consulting (2017), "The economic contribution of the innovative pharmaceutical industry to Australia" accessed via https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/07/Economic-Contribution-Innovative-Pharma-industry-Australia.pdf
5. IQVIA Institute for Human Data Science (2019). 'The Global Use of Medicine in 2019 and Outlook to 2023'. Available at https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023
6. Medicines Australia submission to the Department of Foreign Affairs and Trade (DFAT) – Australia-European Union Free Trade Agreement (AEUFTA). 2018. Available at: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/10/Medicines-Australia-submission-on-the-Australia-European-Union-Free-Trade-Agreement.pdf
7. US Chamber of Commerce Global Innovation Policy Center. 2019 – Providing certainty and predictability: How pharmaceutical linkage mechanisms help innovators, follow-on manufacturers, and patients.
8. Key Fact; AusBiotech; Australia's Life Sciences Sector Snapshot 2017. Available at: https://www.ausbiotech.org/documents/item/389
9. Organisation for Economic Cooperation and Development (OECD). Saving Costs in Chemicals Management – How the OECD Ensures Benefits to Society. 2019. Available from: http://www.oecd.org/publications/saving-costs-in-chemicals-management-9789264311718-en.htm
10. US Food and Drug Administration (FDA). *FDA takes first action under new international collaboration with Australia and Canada designed to provide a framework for concurrent review of cancer therapies, approving treatment for patients with endometrial carcinoma.* 2019. Available from: https://www.fda.gov/news-events/press-announcements/fda-takes-first-action-under-new-international-collaboration-australia-and-canada-designed-provide