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Senator Bridget McKenzie
Joint Standing Committee on Foreign Affairs, Defence and Trade
PO Box 6021
Parliament House
Canberra ACT 2600

Dear Senator,

Thank you for the opportunity to provide a submission to the Joint Standing Committee's *Inquiry into Australia's trade and investment relationship with the United Kingdom*.

GSK is a research-based pharmaceutical and healthcare company operating in more than 100 countries around the world. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

Here in Australia, we have a proud history dating back to the early 1900s. Today, our 1240 Australian employees work to deliver access to innovative medicines, vaccines and healthcare products. In 2015, we invested over \$40 million in Australian research and development, and we manufactured over \$461 million in exports at our two manufacturing facilities (representing over 18 per cent of Australia's pharmaceutical exports in 2015).

As a global company headquartered in the UK and with a strong heritage in Australia, we are supportive and committed to contributing to a strong trade relationship between the UK and Australia. Free trade is a critical driver of economic growth and opportunities, and we believe a thriving trade relationship between the UK and Australia which is based on mutually recognised high trading standards can benefit both countries and provide a model for free trade to other partners.

One area of opportunity for the trade relationship between our two countries is pharmaceuticals. Both the UK and Australia will depend on the knowledge-based economy for future growth. Free trade plays an important role in harnessing the potential of knowledge-intensive, technology-intensive sectors like the pharmaceutical industry for both nations.

As successive Australian Governments have recognised, most recently in the Turnbull Government's National Innovation and Science Agenda, the pharmaceutical industry is a key sector of competitive advantage for the country. We share this enthusiasm for our industry in Australia—GSK's investment of over AUD\$100 million in our Boronia manufacturing facility since 2012, to support an innovative Blow Fill Seal manufacturing technology, is just one marker of the opportunities we see in Australia for growth. As a primary supplier of the National Immunisation programme (NIP), a significant contributor to Pharmaceutical Benefits Scheme (PBS) options for respiratory health, and as one of the country's largest pharmaceutical manufacturers and innovators, GSK is well-placed to partner with Government to realise the potential of a thriving pharmaceutical sector.

As the Joint Committee and the respective Governments of the UK and Australia consider trade and investment opportunities, we recommend consideration of the following areas for collaboration:

Principles and unique drivers of the pharmaceutical sector

Compared to other high technology industries (for example automotive or medical devices), it takes a very long time to bring just one pharmaceutical product to market—often up to 15 years and at a significant financial investment. Longer product development cycles expose our industry to more commercial risks from changes in the policy and business environment when a product is still in development. This unique context for pharmaceuticals requires special attention and focus in any discussion on trade and investment. In seeking to optimise the trade relationship between Australia and the UK in the future, we recommend discussion of shared principles relevant to the pharmaceutical sector, such as recognition of: the important place of innovative medicines in a high quality health care system; the health and economic benefits of a thriving pharmaceutical industry; the unique attributes and commercial barriers for innovative medicines requires specific government and regulatory considerations; assessments of pharmaceutical products by or to governments should operate under transparent, objective procedures which afford due process to affected stakeholders.

As one example: the UK and Australia are both home to leading public healthcare systems, respected health technology assessment (HTA) processes for medicines and vaccines, and also an interest in nurturing the pharmaceutical industry for growth and investment. These commonalities position the UK and Australia to collaborate on best practice principles for HTA (for example: patient involvement, transparency, etc) that could set a global example and ensure our sector faces fewer barriers in bringing new medicines to patients.

Regulatory Harmonisation

Reducing non-tariff barriers through the harmonisation of international regulatory requirements should be a core focus for countries eager to encourage trade and investment for the pharmaceutical industry, and other highly regulated sectors.

The pharmaceutical industry is regulated in order to ensure standards for quality, safety and efficacy of the medicines and healthcare products we develop, manufacture and deliver to patients across the world are met. Whilst maintaining autonomous decision-making, there is great potential to reduce red tape and speed access to markets through alignment of processes and international work-sharing (a model which is currently undertaken by the Therapeutic Goods Administration and international counterparts like the European Medicines Agency). Continuity of this good international partnership and other aspects of regulatory harmonisation should be a focus area as Australia looks to strengthen trade relationships with the EU and with the UK, particularly during this time of transition post Brexit.

A focus in this area is well-aligned with the emphasis successive Australian Governments and the Australian Parliament have placed on ensuring our regulatory system is efficient and world-leading, for example most recently through the introduction of the Therapeutic Goods Amendment (2016 Measures No.1) Bill 2016 (relating to the Medicines and Medical Devices Review).

Robust IP standards

Globally, in 2016 GSK invested £3.6 billion in R&D. Given this significant investment, protection of IP is vitally important and an essential component for our continued investment in the markets in which we operate, including Australia.

Harmonisation across IP systems and ensuring Australia's IP system meets international standards is a critical role for Government. Maintaining strengths in our system, and where necessary continuing work to bring our IP system in line with other leading OECD countries, will improve Australia's attractiveness as a destination for foreign investment by GSK and other global companies.

Strong IP systems drive innovation and are an essential foundation for knowledge- and innovation-based economies like those in the UK and Australia. Through this bilateral trade relationship, and through Australia's trade relationship with the EU, nations can set a high standard which sets an example for a level playing field amongst developed nations. In reviewing appropriate settings,

consideration should be given to the unique nature of pharmaceutical development which requires several years and significant financial investment in R&D prior to commercialisation and launch into the market place. In the IP context, therefore, consideration should be given to appropriate patent term restoration; data exclusivity provisions; and patent notification systems.

Manufacturing, investment and policy consistency

In 2015, GSK's global manufacturing network of 87 sites delivered 2 billion packs of medicines, 5.4 billions packs of consumer healthcare products and over 800 million doses of vaccine. Our ability to continue to grow our output of high quality products and reach more patients, particularly in emerging markets like many in the Asia Pacific region, is dependent on our manufacturing capabilities and investment. Whilst protectionism relating to on-shore manufacturing can be a detriment to free trade and should be discouraged in Australia's trade relationships, countries which lower barriers and provide an encouraging environment for manufacturing investment are enabling companies like GSK to grow.

We recommend that Australia continue to identify opportunities to partner with UK-based companies on pharmaceutical manufacturing, for example through strategic co-investment which can enable our export growth. We also recommend continued support for MTPConnect, which partners with our industry and is well-positioned to provide advice on government policies and programs which can act to either encourage growth and investment for our industry, or to reduce barriers or red tape. One model or approach to industry policy is insufficient. Having a unique, dedicated, independent and ongoing voice for key growth sectors like the pharmaceutical sector (as provided by MTPConnect) is essential so that successive Governments are supported with the right, tailored advice to harness trade, investment and growth opportunities.

GSK also welcomes broad international consensus in support of the OECD's recommendations to prevent Base Erosion and Profit Shifting (BEPS). We recommend that G20 countries like the UK and Australia now promote implementation as a coherent and consistent package across the world, removing opportunities for abuse while promoting a certain and stable international tax framework. Uncertainty during the implementation phase could have a negative impact on investment, growth and employment globally.

Competitive R&D Environment

To increase levels of trade in R&D-intensive industries like pharmaceuticals, it is critical that the fewest possible barriers for investment in R&D and, in particular, clinical trials. The development and commercialisation model for innovative medicines requires extensive, global clinical research programs to demonstrate our medicines our safe and efficacious. Where countries with strong R&D capabilities, such as the UK and Australia, work together to minimise barriers, our sector benefits and importantly, so do patients and the research community.

Australia is home to some of the best leaders in research, healthcare professional and medical pioneers globally as a result of our world-class research infrastructure and a high quality healthcare system. However, the local clinical trial environment still faces significant impediments such as inefficient and cost-ineffective duplicative ethics and research governance processes and lack of patient awareness.

Australia can encourage greater investment in clinical trials by implementing the recommendations of experts groups like the Clinical Trial Action Group¹ in 2011 and the Strategic Review of Health and Medical Research (McKeon Review)². In particular, GSK recommends the streamlining of research ethics and governance approval by moving towards a national mutual standard of approval in order to eliminate process misalignment and duplication across states and institutions which result in

¹ Clinical Trials Action Group, Clinically Competitive: Boosting the Business of Clinical Trials in Australia, March 2011.

Accessed online 5 April 2017

<http://www.industry.gov.au/industry/PharmaceuticalsandHealthTechnologies/ClinicalTrialsActionGroup/Documents/ClinicalTrialsActionGroupReport.pdf>

² McKeon, Simon. Strategic Review of Health and Medical Research—Better Health through Research, April 2013.

Accessed online 5 April 2017: <http://www.mckeonreview.org.au/>

significant costs and time delays for sponsors wanting to proceed with a clinical trial. We highlight the opportunity to promote patient engagement and recruitment in clinical trials with health professionals who can engage with their patients regarding clinical trials options which may be available for them. GSK also recommends the investment in a national system that monitors, measures and provides feedback for all clinical trial activity within Australia which will allow sponsors and investigator to compare performance and costings.

Whilst progress is sought in clinical trial reforms, more broadly, we encourage stability on policy measures which attract investment in Australian R&D such as the R&D Tax Incentive. Alongside the strength and quality of Australia's research ecosystem, the R&D Tax Incentive plays a significant role in maintaining Australia's competitiveness in attracting investment.

Once again, thank you for the opportunity to contribute to this inquiry to raise areas which we believe should be a focus for Australia as it looks to strengthen its trade relationship with the UK. Please do not hesitate to contact me should you wish to discuss our submission in more detail.

Yours faithfully,

David Herd
Director, Healthcare Environment
GSK Australia