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Mr Andrew Dawson, Inquiry Secretary
Joint Standing Committee on Foreign Affairs, Defence and Trade
PO Box 6021
Parliament House ACT 2600

Dear Mr Dawson

AstraZeneca appreciates the opportunity to make a submission to the JSCFADT Inquiry into Australia's Trade and Investment Relationship with the United Kingdom. It thanks the Committee for its invitation.

AstraZeneca Footprint

AstraZeneca is one of the largest manufacturers and exporters of Innovative pharmaceuticals, in Australia. It commenced its operations here in 1957. Its head Office and Manufacturing Plant are located in Macquarie Park, NSW.

Over the past 60 years, AstraZeneca has built up a substantial presence, where over a million Australian patients use an AstraZeneca medicine every day.

AstraZeneca employs just under 1,000 direct employees split roughly 50/50 between its manufacturing facility and its commercial and medical operation.

The investment in Clinical Trials, extends to every state and territory in Australia. It exceeds 52 separate trials and involves in excess of 1,500 patients. Investment in R&D over the last 10 years exceeds AUD\$250m

The investment by AstraZeneca into its operations in Australia since 2011, has exceeded AUD\$130m. **There is potential for significant additional investment into Australia by AstraZeneca. It will be influenced in no small measure by a constructive and positive relationship with the Federal Government that is successful in attracting additional capital investment by companies like AstraZeneca in a highly competitive global environment, where capital is increasingly mobile.**

Looking further ahead, it will also be influenced by the outcomes of Brexit, Free Trade Agreement negotiations between the UK and Australia and the extent to which Business and Government can demonstrate that they are able to work constructively together to deliver mutually beneficial outcomes.

Manufacturing and Exports

AstraZeneca's manufacturing presence in Australia extends back 60 years.

Today it exports to 20 markets globally. It manufactures 86 product lines; in excess of 50% of which are for the Australian Market; with export growth anticipated to exceed domestic sales as early as 2018.

The Manufacturing site now operates 24x7, incorporating 8 to 12-hour shift patterns, demonstrating the Company's ability to deliver large scale capital projects.

Productivity just in the past 6 years, has exceeded 130 percent, which is phenomenal!

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AstraZeneca's manufacturing in Australia, against the backdrop of a growing number of closures of manufacturing facilities in many industries, including the pharmaceutical sector, is a demonstration of world's best practice.

The AstraZeneca plant is supported by engineering excellence from Melbourne. It is committed to the provision of an agile and flexible supply network; manufacturing performance at the highest level and R&D collaboration.

UK and International Operations

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines; primarily for the treatment of diseases in three main therapy areas – Oncology, Cardiovascular & Metabolic Disease and Respiratory. AstraZeneca works in over 100 countries with around 59,700 people employed globally. At the end of 2016, 19,600 were employed in Europe and 22,500 in Emerging Markets. 12,200 people at 31 sites in 18 countries are working on the manufacture and supply of AstraZeneca products.

The UK remains a key location for AstraZeneca, with a strong presence in science and manufacturing. AstraZeneca employs 6,500 in the UK and has considerable investments in Cambridge and Macclesfield. Overall in 2015, AstraZeneca invested £ 2Bn in R&D in the UK; and exported just under £5Bn in products from the UK. AstraZeneca is presently building its new Global R&D Centre and Corporate Headquarters in Cambridge, UK.

AstraZeneca has also recently invested in major manufacturing facilities in Sweden, Russia, China and USA. Its largest manufacturing operations are in China, UK and the United States. It hosts 3 substantial Global Research Hubs in the UK, Sweden and USA. 8,400 people are employed in R&D. In 2016 AstraZeneca invested \$US 5.9 billion in the discovery and development of life-changing medicines.

Brexit and the merits and risks of a possible bilateral free trade agreement with the UK

In her speech to Parliament on the formal trigger of Article 50 on 29 March 2017, the UK Prime Minister stressed the Government's intent for the UK to maintain a positive and constructive partnership between Britain and the EU, with the least possible disruption to trade and other important issues for business. She also stressed that the UK would look to a future where it becomes more global in its outlook, working more closely with old and new trading partners and that the Government will be seeking new trade agreements with countries throughout the world. This is of significant importance to AstraZeneca Australia, where present and future trade and investment relationships with Britain need to be underpinned by certainty and clarity.

AstraZeneca is committed to working with both UK and Australian Governments, should it be their mutual intention to negotiate a bilateral FTA after the UK formally leaves the EU. We would want to ensure a smooth and speedy transition to a successfully negotiated trade agreement that will foster new opportunities, unlock additional value and create mutual benefit for both nations and their economies.

In this context, consideration should be given to the inclusion of a dedicated pharmaceutical chapter in any proposed UK/Australia FTA; which reflects some of the policy priorities (fiscal, science and innovation, regulatory and trade) and including non-tariff barriers such as regulatory standards, product approvals, clinical trials and manufacturing inspections that are essential for the smooth operation of a global research based biopharmaceutical company.

A dedicated pharmaceutical chapter would need to take into account challenges and opportunities across a number of subject areas:

- Supply chains today are globally integrated and operate under just-in-time systems and should be unhindered in an FTA. Any interruption to the supply chain (commercial supply [intermediate & finished medicinal products], clinical trial and compassionate use) after Brexit and during FTA negotiation process will be a concern for business management and could also have a material bearing on the supply of medicines for patients.



- Regulatory Harmonisation – the assessment and approval of new medicines is a complex and costly process and is designed to deliver patient safety. The UK and Australia, have an opportunity to look at ways to recognise assessments and decisions taken by its respective regulators, including the inspection of manufacturing facilities.
- Introducing clear and simple conditions to qualify for preferential import duty rates, such as those in the FTA between Australia and China, will help in reducing costs and deliver benefit to patients. The mutual recognition of Trusted Trader/AEO programs implemented in each country will facilitate the movement of goods across borders at export and import. This will benefit businesses in both countries.
- Intellectual Property standards and clarity of Government policy relating to Public involvement in Private patent disputes.
- Research and development is another area where UK and Australia could strengthen their cooperation and collaboration in Life Sciences and other areas. The UK intends to develop and execute a new Life Sciences Industrial Strategy with the objective of making the UK a more attractive place for life sciences research, development, advanced manufacturing and uptake of innovative medicines – all underpinned by using the NHS. Australia has a real opportunity to look at this model and consider how it can be aligned to work in the UK and build new and better collaborations with UK academics, research institutions, business and the NHS.
- Attractive fiscal environment (tax & VAT, transfer pricing, customs duty waivers, R&D tax, fiscal incentives for innovation and manufacture and capital controls)

AstraZeneca is publicly supportive of a free trade agreement between Britain and Australia. An FTA has the capacity to further grow business opportunities and create significant advantages for employment and most importantly patients.

The Committee is formally invited to visit the AstraZeneca Manufacturing Site in Macquarie Park; which we believe represents a valuable opportunity to see first-hand the excellence of AstraZeneca's manufacturing operation, the potential for future growth and the importance of trading relationships and the early negotiation of a Free Trade Agreement with the UK.

AstraZeneca would welcome the opportunity to provide more detail and answer any follow up questions, should the Committee intend to hold public hearings, in support of its Inquiry.

Thank you again for the opportunity to submit to this Inquiry.

Paul Spittle
Company President for Australia and New Zealand