Submission to the Australian Department of Foreign Affairs and Trade on a future UK-Australian Free Trade Agreement

March 2020

GSK is committed to developing and producing innovative new medicines and vaccines, and we stand ready to play our part in making these as accessible as possible to countries at all levels of income and development. We are a leading pharmaceuticals and consumer healthcare company, with three global businesses that research, develop and manufacture innovative pharmaceutical medicines and consumer healthcare products. Our mission is to improve the quality of human life by enabling people to do more, feel better and live longer.

Headquartered in the United Kingdom (UK), GSK operates in over 100 markets worldwide. **We have a proud history of operating in Australia since the early 1900s and have a nearly 1500 strong workforce in Australia.** In 2018, GSK manufactured approximately AUD346 million in exports from our two Australian manufacturing facilities (located in New South Wales and Victoria), and invested approximately AUD28 million in research and development. In addition, in 2018, GSK imported approximately AUD615 million worth of pharmaceutical and consumer healthcare products from the European Union (EU) to Australia, of which a significant proportion was directly imported from the UK.

Both Australia and the UK are global leaders in health innovation and have world leading capabilities in areas important to our business. Both countries are home to leading public healthcare systems, respected Health Technology Assessment (HTA) processes for medicines and vaccines, and our governments demonstrate an interest in nurturing the pharmaceutical sector for growth and investment. We are proud to have a strong presence in both countries and to play a key role in driving innovation to address public health challenges.

GSK is supportive of a strong trading relationship between Australia and the UK. One area of opportunity in the bilateral trade relationship is in pharmaceuticals. Both Australia and the UK depend on a knowledge-based economy for future economic growth, and free trade plays an important role in harnessing the potential of knowledge-intensive, technology-intensive sectors like the pharmaceutical industry for both nations. For GSK, reducing trade barriers helps us harness global science to innovate more and enables greater access to medicines for those who need them. We recognise that every country has a unique health system and priorities.

Our submission to the Australian Department of Foreign Affairs and Trade's (DFAT) public consultation process on a future Australia-UK FTA addresses the issues which GSK would like to be addressed in a possible trade agreement. It is provided without prejudice to future discussions and submissions and builds upon our submission and evidence given to the Australian Parliament's Joint Standing Committee on Foreign Affairs, Defence and Trade in 2017, and previous discussions with DFAT. **GSK looks forward to ongoing and frank engagement with the Australian Government in order to inform the future direction and development of Australia's economic relations with the UK, including in the context of a future FTA.**

GSK PRIORITIES FOR A FUTURE AUSTRALIA-UK FTA

Tariff liberalisation

Considering the current dynamics in the global trading system and the application of unilateral tariff measures, it is critical that the Australian and UK Government eliminate – to the maximum extent possible - any risk of tariffs being applied to all products produced by the life science industry (outside of those covered by the WTO Pharmaceutical Tariff Elimination Agreement), including those classified as prescription medicine or consumer health products. This includes the following product categories:

- finished form pharmaceuticals;
- API's, intermediates and starting material; and

- research products that are used in the early stages of the R&D chain (phases I and II of the drug development process, and exceptions that currently apply to phase III).

As part GSK's commitment to health, our portfolio includes consumer healthcare products such as oral care and nicotine products which directly support prevention and wellness. Therefore, we request comprehensive reduction in all tariff chapters, eventually leading to zero duties on all tariffs on consumer healthcare products with all FTA partners (to the maximum extent possible). Due to the health benefits of oral healthcare products, we would encourage a tariff exemption for products classified under 3306 of the Harmonised System of tariff nomenclature, as the tariffs for finalised products can add 10-25 per cent in additional duties.

Rules of Origin and Customs Procedures

Rules of Origin should be simplified and based on common, defined chemical and pharmaceutical processing activities that make commercial sense and are easy for customs administrations to verify. In particular:

- where possible, rules of origin should reflect industrial conditions and technological innovation of the life science industry that uses a sophisticated and complex R&D networks and supply chains that build on global expertise and centres of excellence;
- proof of origin requirement should not result in large cost and administrative burdens and for continued consistency, requirements should align with practices in existing FTAs; and
- as industries continue to innovate, these rules should undergo periodic reviews to ensure they remain fit for purpose.

Creating a Competitive R&D Environment

In order to increase trade and investment in R&D intensive industries like pharmaceuticals, it is critical that the fewest possible barriers for investment in R&D exist, particularly in relation to clinical trials. At present, the local clinical trial environment in Australia faces significant obstacles, such as cost-inefficient duplicative ethics and research governance processes and lack of patient awareness.

To rectify this, GSK recommends the streamlining of research and ethics governance approval by moving towards a national mutual standard of approval in order to eliminate process misalignment and duplication across states, territories and institutions which result in significant costs and time delays for sponsors wanting to proceed with a clinical trial. There remains significant opportunity to promote patient engagement and recruitment in clinical trials with health professionals who can engage with their patients regarding clinical trials which may be available for them. GSK also strongly encourages the Australian Government to establish a national system which monitors, measures and provides feedback for all clinical trial activity within Australia. This would enable comparisons of costs and performance by sponsors.

Beyond clinical trial reform, GSK strongly encourages stability on policy measures which attract investment in Australian R&D, such as the R&D Tax Incentive, and encourage on-shore manufacturing. GSK encourages the Australian Government and private sector to identify opportunities to partner with UK-based companies on pharmaceutical manufacturing to facilitate export growth.

Regulatory Coherence

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

GSK notes that until the outcome of any UK-EU negotiations on a future regulatory cooperation model, it is difficult to propose the exact nature of the regulatory relationship between Australia and the UK on medicines and medical devices. However, we welcomed the March 2019 announcement of a continuity Mutual Recognition

Agreement on conformity assessment and good manufacturing practice (pharmaceuticals), which will take effect after the UK leaves to the EU, when the EU-Australia agreement will no longer apply to the UK.

GSK encourages further consideration of potential areas in which red tape can be reduced and access to markets can be accelerated 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 effective international partnerships and other aspects of regulatory harmonisation should be a focus area as Australia looks to strengthen its trade relationship with the UK, particularly during this time of transition post Brexit. If the UK Medicines and Healthcare products Regulatory Agency operates as a standalone regulator (i.e. outside the EU Medicines Regulatory Network), we encourage the Australian Government to seek to establish and maintain an enhanced relationship with this entity. As a baseline, this should include minimum confidentiality agreements, which would allow the sharing information on regulatory procedures, product safety etc and facilitate targeted assessments in the UK. Like MRAs, these agreements can be adopted outside an FTA.

Given the commonalities of our respective public healthcare systems, Australia and the UK are well-positioned to collaborate on best practice principles for HTA (including patient involvement and transparency) that could a global example and ensure our pharmaceutical sectors faces fewer barriers in bringing new medicines to patients.

Intellectual Property

A robust intellectual property system is a prerequisite to the availability of new medicines. Although there are areas in which it can be strengthened, the UK has one of the strongest overall IP frameworks globally. It provides innovative companies researching and developing new medicines the certainty they need to invest in the long, complex, risky and costly process of developing new medicines and launching them in a market. The Australian IP system needs to be strengthened in line with the UK system and other gold standard systems via:

- the expansion of patent term extension periods to include all medical use inventions consistent with the UK system to reflect and compensate for effective patent term lost because of the need to satisfy regulatory requirements before a product may enter the market;
- like the United States, the introduction of a notification regime to inform innovators at the time an application to register a generic medicine or vaccine is made to allow innovators and generic manufacturers time to potentially resolve patent disputes before the generic/biosimilar launch; and
- alignment of Australia's regulatory data protection (RDP) periods in line with the highest international standards and, at a minimum, in line with the standards in the UK, so that investments by innovator companies in generating clinical data can be recouped and re-invested in future innovation
    - at present, Regulatory Data Protection in the UK (and EU) provides for 8 years exclusivity following the first marketing authorisation of the original reference product, during which generic manufacturers are prohibited from relying on the test and trial data generated and submitted for the original reference product. When that 8 year "data exclusivity" period expires, generics can apply for marketing authorisation in reliance on the innovator's data but may not be placed on the market for another 2 years, known as the "market protection" period. Further, under the circumstance that a new indication is authorised for the original reference product within the first 8 years which is deemed to bring significant clinical benefit, one additional year's market protection can be granted. **In any future trade negotiation, GSK would look to secure alignment of RDP at least of the same level with that currently granted by the UK.**

Innovation and Access

As global centres of life sciences innovation, we strongly encourage Australia and the UK beginning to explore the policies, processes, and incentives needed to incentivize, regulate and approve new pharmaceutical medicines and vaccines; and deliver future health innovations that may utilize new technologies, techniques, and/or data

development. While we recognize this will be a new area for discussion, we hope that new FTAs would not only look to address current trading needs but also encourage cooperation to explore the future ecosystem of innovation, including artificial intelligence and 3D printing of drugs, for example.

Investment

It is critical that any trade agreement ensures a level playing for foreign and domestic companies. In trade agreements, this can be addressed by:

- effective enforcement of laws criminalising bribery of foreign officials that are aligned with the robust standard demonstrated by both Australian and UK law;
- supporting company investment plans by introducing government mandated Beneficial Ownership Registers (on which potential investors can rely for accurate and up-to-date ownership information). These can help to tackle corruption and attract investment; and
- removing discriminatory policies that introduce an unlevel playing field and bias markets and procurement toward domestic producers rather than from trading partners.

Labour

Global mobility is of fundamental importance for international companies. Mobility needs range from attending short-term meetings through to longer-term training requirements and project work. This movement can be both within a company and through posting to external firms. In our sector, mobility supports collaboration in science by increasing access to skills, ideas and international networks. It is a key driver of innovation.

Ongoing revisions to the 457-visa program, including labour market testing provisions, presents a significant barrier to bringing overseas talent and expertise into our Australian business. GSK strongly objects to the requirement to disclosing employee salaries in recruitment advertisements in order to discharge the LMT requirements. This is damaging to both companies and employees and would inevitably lead to a race to the bottom in a market where slow wage growth is an issue. GSK encourages the Australian Government to consider ways in which mobility of skilled workers could be addressed in a mutually beneficial way in a bilateral FTA with the UK.

Social Issues

GSK believes that improving social policies and standards are critical for not only improving the competitive environment, but also the welfare of those who use our medicines and vaccines. Therefore, we would seek for FTAs to lead by example in strengthening global pandemic preparedness efforts by agreeing to the rapid sharing of pathogens during a potential or actual public health emergency. Recent disease outbreaks such as Zika and Ebola highlighted more than ever the need for a collaborative response to global health challenges. Governments, regulators, industry and the broader scientific community need to work together to ensure public health challenges are swiftly and systematically addressed.

Improved Conditions in Third Country Trading Partners

Future trade agreement negotiations between Australia and the UK also provide an opportunity for both governments to work together in order to encourage improved conditions with other trading partners to set global standards in areas including regulatory coherence, IP, and removing discriminatory policies that introduce an unlevel playing field and bias markets and procurement toward domestic producers rather than from trading partners. We look forward to both countries working together to encourage other countries to adopt and respect non-discriminatory health system, procurement, regulatory, IP and investment policies that encourage and reward innovation.

CONCLUSION

GSK looks forward to working closely with the Australian Government as it develops its trade and investment with the UK (as an independent trading partner), and to ensure that patients globally have access to medical innovations.

The reduction and elimination of trade barriers is ultimately for the benefit of patients, who should have greater access to life-saving and life-enhancing new medicines. The opportunities in and barriers to trade and investment between Australia and the United Kingdom can be addressed in several ways, including through comprehensive and ambitious trade discussions. However, free trade agreements are not the only mechanism by which to unlock market access opportunities, and new mechanisms and prioritisations are required to interact with and capitalise on the two-way benefits that exist between the Australia and the United Kingdom. GSK encourages consistent and frank engagement between the Australian Government and private sector to discuss where more immediate benefits to business might be able to be achieved.