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16 August 2021

Paul Fischer Corporate and International Tax Division The Treasury Langton Crescent PARKES ACT 2600

Dear Mr Fischer.

Re: Australian Government, Treasury Patent Box Consultation

Thank you for the opportunity to provide GSK Australia's views on the proposed design of the Patent Box.

GSK supports the implementation of a Patent Box building on the established R&D (research and development) Tax incentive. However, given the limitations in the current proposed design, we do not believe that the current design is able to achieve the Government's stated aims.

It is GSK Australia's view that the proposed Patent Box design will not be sufficient incentive for larger pharmaceutical companies such as GSK to redirect R&D activity and other IP commercialisation activities to Australia, it is insufficient by global comparison and will not achieve the Government's aims in it its implementation unless it is supported by broader health system reform.

In order to maximise the benefits of innovation in Australia's medical and biotechnology sectors to the economy and community, Government must act to better support new medicines to be developed, trialled and delivered to Australian patients. It is only through supporting new medicines and medical devices across their life cycle, Government will encourage companies to retain patents, base their medical and biotechnology R&D operations, and commercialise innovation in Australia.

GSK applauds the Government for its recognition of the medical and biotechnology sectors importance to the Australian economy. As evident in the recent 2021 Intergenerational Report, the sectors are, and will continue to be, responsible for a significant proportion of Australia's economic and social outcomes¹.

To maximise benefits of the proposed Patent Box to the economy and community and achieve Governments aims in its implementation, key points of note are:

¹ Commonwealth of Australia 2021, 2021 Intergeneration Report, https://treasury.gov.au/sites/default/files/2021-06/p2021_182464.pdf.

 The proposed 'substantial activity requirement' linking taxation concessions with the proportion of research and development conducted in Australia will be prohibitive for larger Australian and International companies.

Research and development by pharmaceutical companies is global in nature. Clinical trials, which make up a significant amount of R&D expenditure with new drug development, are conducted across several international jurisdictions

Major regulators, including the TGA, will understandably insist that the expansive clinical trial data which goes into an initial drug application include a comprehensive number of patients from a variety of cultural backgrounds.

Similarly, medical research expertise is spread globally across specialist research facilities in several countries.

Although Australia presents several advantages to conducting clinical trials due to the well-developed and globally recognised medical system, the size of its population as well as other commercial factors, mean the amount of R&D expenditure in this Australia is much less compared with other larger jurisdictions.

 The Australian Patent Box lacks scope to compete in the global medical and biotechnology sector.

The Government's proposed concessional tax rate of 17% is well below global equivalents to compete. Similar tax regimes to the proposed Patent Box exist in more than 20 jurisdictions. In the UK, the location of GSK headquarters and a majority of the company's IP assets, the concessional tax rate under a Patent Box is 10% ². In Singapore income from IP assets is taxed at either 5% or 10%, while in the US the concessional tax rate is 13.13% ³⁴.

Furthermore, Australia struggles to compete with other nations on a number of additional commercial factors which make local IP commercialisation challenging. This includes high manufacturing, logistics and labour costs relative to overseas markets⁵.

Broader issues in the health system will limit the Patent Box's opportunity for success.

Australia is not currently well positioned to access new drugs and novel medical technologies in a timely manner and respond to emerging global trends – thus limiting incentives for local innovation in the medical and biotechnology sectors. Global companies will be reluctant to invest significant resources in markets where products face significant barriers to reimbursement and uptake.

This was noted in GSK Australia's submission to the House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into approval processes for new drugs and novel medical technologies in Australia. The following issues must be addressed building on the Patent Box and R&D incentives to support innovation:

- Ensuring that approval processes adapt to the speed of medical innovation and development of personalised medicine, this requires payors to accept data of individual patient outcomes, as opposed to those targeted at a population level.
- Adapting the evaluation criteria to appropriately capture the social and economic contributions of medicines and vaccines, including methods for productivity,

² Pearce N, Chadbourne J, Bristow E, 2021, Unwrapping the (Patent) Box: much ado about nothing?, Pearce IP, https://www.pearceip.law/2021/05/14/unwrapping-the-patent-box-much-ado-about-nothing/.

³ Singapore Economic Development Board, 2020, IP Development Incentive (IDI), https://www.edb.gov.sg/content/dam/edb-en/how-we-help/incentive-and-schemes/IDI%20circular%20(Jan2020).pdf

⁴ OECD 2020, Intellectual Property Regimes, https://qdd.oecd.org/data/IP_Regimes.

⁵ Medicines Australia, 2019, Growing Australia's Innovative Medicines Industry Through Investment, https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/7.-Growing-Australias-innovative-medicines-industry-through-investment.pdf.

participation and community (including carer impacts), including the use of real-world data.

Recognising that the current approval processes for reimbursement of therapies were designed for the assessment of medicines and not for preventative therapies, such as vaccines. The current system undervalues the benefits delivered by vaccination, which may accrue many years later. The methodology applied under the health technology assessment system to value vaccines must be reformed to recognise the breadth of public health and economic benefits derived from vaccination and to ensure equitable access for all Australians.

Again, thank you for the opportunity provide GSK Australia's views on the proposed design of the Patent Box. For more information or if I can assist further contact myself at peta.d.james@gsk.com or 0422 907 935.

Kind regards,

Peta James Head Government Affairs and Policy GSK Australia

About GSK

GSK is a science-led global healthcare company with a special purpose to improve the quality of human life by helping people do more, feel better and live longer. In **Australia**, we offer a broad portfolio of innovative and established **vaccines** and **medicines** in respiratory disease, HIV and oncology. In 2020 we invested over \$9 billion in research and development globally, focusing on science related to the immune system, human genetics and advanced technologies.

Across the country, we employ approximately 1500 Australians in many areas of expertise from graduates to senior managers. We have committed to accelerate our progress on inclusion and diversity and to be a leading company in how we support employee health, wellbeing and personal development.

For more information visit <u>au.gsk.com</u>.