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1 November 2018

Senate Standing Committee on Economics
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Sir / Madam,

Enclosed is a submission prepared by GlaxoSmithKline Australia (**GSK**) on the consultation paper released by Treasury into the proposed amendments to the Research and Development Tax Incentive.

This submission discusses the Australian Pharmaceutical industry operating environment and a summary of GSK's position on the proposed amendments to be introduced to law by the *Treasury Laws Amendment (Making Sure Multinationals Pay Their Fair Share of Tax in Australia and Other Measures) Bill 2018* (Cth). This submission only discusses the proposed changes to the R&D tax incentive covered by Schedules 1 to 3 of the Bill.

GSK welcomes the opportunity to comment on Australia's research and development tax incentive program. Both independently, and through our peak industry associations Medicines Australia and the BioMelbourne Network, we are committed to working with Government to ensure a viable innovative pharmaceutical industry in Australia.

If you have any questions about our submission, or if we can be of any further assistance, please contact [redacted].

Yours faithfully,

[redacted]

Anne Belcher
Vice President and General Manager
GlaxoSmithKline Australia

[redacted]

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GlaxoSmithKline Australia

Response to Research and Development Tax Incentive Amendment Public Consultation

About GlaxoSmithKline (GSK)

GSK is a science-led global healthcare company with a substantial global footprint, operating in more than 100 countries around the world. We research and develop a broad range of innovative products in three primary areas: Pharmaceuticals, Vaccines and Consumer Healthcare. Our goal is to be one of the world's most innovative, best performing and trusted healthcare companies. GSK has been consistently recognised as a leader in access to medicines and has been ranked first in the Global Access to Medicines index for five consecutive years.

Globally, GSK produce medicines to treat a broad range of acute and chronic diseases. Our global pharmaceuticals portfolio currently focuses on the development of new medicines in respiratory, HIV/infectious diseases, oncology and immuno-inflammation. We are involved in the world's only company 100% dedicated to HIV, ViiV Healthcare, in collaboration with Pfizer and Shionogi. We are particularly proud of our investment in advancements in respiratory medicines. Since the invention of our first asthma treatment in the 1960s, we have invested more in respiratory research than any other company worldwide. In Australia, we continue to bring innovative medicines to market to treat asthma and chronic obstructive pulmonary disease (**COPD**). Our new medicine to treat COPD was listed on the Pharmaceutical Benefits Scheme by Minister Hunt in June this year.

Our vaccines portfolio is one of the most comprehensive in the world and we produce paediatric and adult vaccines for a range of infectious diseases. In Australia, our vaccines help prevent illnesses such as hepatitis, rotavirus, diphtheria, tetanus, whooping cough, measles, mumps, rubella, bacterial meningitis and influenza.

In Australia, over 1400 employees work to deliver access to innovative medicines, vaccines and healthcare products to Australian patients and consumers. Our employees are engaged in skilled roles from graduate through to managerial level and in diverse areas including research and manufacturing. In 2017, we invested approximately $39 million in research and development activities in Australia and manufactured over $370 million in exports at our two manufacturing facilities in Ermington, New South Wales, and Boronia, Victoria.

Our two manufacturing facilities in Australia make products for more than 60 different countries. Our manufacturing plant in Boronia, on the outskirts of Melbourne, is GSK's largest pharmaceutical manufacturing plant in the Southern Hemisphere and is home to 10 innovative blow-fill-seal (**BFS**) filling lines and two Relenza (pandemic flu treatment) lines. This facility manufactures high technology pharmaceutical products, most of which are manufactured for export.

Our other manufacturing site based in Ermington, New South Wales, makes consumer products such as Panadol (paracetamol). This site is currently undergoing a phased closure, expected to be completed by 2020.

GSK has a high level of involvement in clinical trials in Australia. We collaborate with approximately 200 institutions Australia-wide, working on genetic and biochemical research projects and participate in about 50 active clinical studies at any one time. Our collaboration on clinical trials enables medical and scientific experts within hospitals and research institutions in Australia to be involved in research involving cutting edge medical and scientific technology.

GSK is proud to be currently supporting the *'B Part of It'* study in South Australia through funding and the supply of free vaccine. This study is the largest randomised clinical trial to ever occur in Australia and is the largest study to

investigate the impact of vaccination on carriage of bacteria causing invasive meningococcal disease in the world. The clinical trial is sponsored by the University of Adelaide in partnership with SA Health. Professor Helen Marshall is the investigator primarily responsible for the study. 238 schools from across South Australia (over 95% pf SA schools) have registered to take part in the study, enabling more than 60,000 South Australian students in years 10, 11 and 12 the opportunity to take part and receive the meningococcal B vaccine for free.

We are also proud of our work with Australian biotechnology companies to bring innovative medicines to the world. Our partnership with Biota on *Relenza*, a medical innovation used to treat and prevent influenza (particularly pandemic influenza), is an excellent example of these Australian-based collaborations.

Today GSK distinguishes itself not only through its innovative and commercial success but also through a collective ethical approach to all areas of business. As one of the largest pharmaceutical companies in the world, we understand our great responsibility to people in the communities we serve.

In 2012, we launched GSK's first Reconciliation Action Plan, which marks GSK's recognition of Aboriginal and Torres Strait Islander peoples and will help shape our efforts to close the life expectancy gap between Indigenous and non-Indigenous Australians. We are currently in the process of launching our second Reconciliation Action Plan to build upon the success of the first Plan. GSK also proudly supports members of the LGTBIQ community in Australia and around the world. GSK publicly supported the campaign for marriage equality in Australia.

The Australian pharmaceutical operating environment

The pharmaceutical industry is one of Australia's most innovative industries. Approximately 50 global research-based pharmaceutical companies and more than 400 locally-owned biotechnology firms operate in Australia.[1] The industry employs thousands of highly-skilled Australians, generates billions in exports, invests millions of dollars in research and development and, most importantly, delivers innovative medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.[2]

Globally, the pharmaceuticals industry is highly R&D intensive and some sources suggest it is the largest source of private sector R&D in the global economy. According to the Pharmaceutical Industry Strategy Group, nearly one out of every five dollars spent by the world's largest 1400 companies on R&D was on pharmaceuticals-related R&D.[3] Figures released by the Australian Bureau of Statistics in September 2017 show that the Australian medicines industry has invested over $1 billion in local R&D for eight successive years.[4]

The economic contribution of pharmaceutical companies is amplified through partnerships with other parts of Australia's medical research sector. For example, 60 per cent of all industry-funded clinical trials in Australia are conducted in partnership with public hospitals and a further 15 per cent are conducted through private research institutes.[5] The clinical trial sector in Australia contributed approximately $1.1 billion in 2015 to the Australian

[1] Medicines Australia, *Facts Book*, Fourth Edition, 2015, page 4.
[2] Medicines Australia, *Facts Book*, Fourth Edition, 2015, page 4.
[3] Pharmaceutical Industry Strategy Group *Final Report*, 2008
[4] ABS statistics available at http://www.abs.gov.au/ausstats/abs@.nsf/mf/8104.0
[5] Pharmaceuticals Industry Council, *2011 Survey of Privately Funded Clinical Research Activity in Australia*, 2012

economy via direct expenditure or investment[6] and according to a 2011 survey privately funded clinical trials are worth $636 million in Australia each year.[7]

In Australia, patients access medicines primarily through the Pharmaceutical Benefits Scheme (**PBS**), a taxation-based, risk pooled social welfare policy delivered by the Federal Government. Government acts as a monopsony purchaser of pharmaceutical products, utilising regulatory and cost effectiveness assessment systems to determine whether to list medicines on the PBS.

Pharmaceutical policy in Australia is a highly contested space, fuelled by debates over listing and pricing of medicines and concerns over the long-term sustainability of the PBS. Reform of the PBS from 2006-2018 has focused on generating greater efficiencies and cost savings through competition in generics and by increasing revenue into the system through consumer co-payments.

In 2017, the Federal Government signed a five-year Strategic Agreement with the innovative industry's peak body, Medicines Australia (**MA**). The Strategic Agreement was designed to provide Government with savings of $1.8 billion whilst giving industry pricing predictability and a stable business operating environment. This is being achieved through mandatory price disclosure and price reductions for generic medicines on the PBS. These savings are in addition to the $1.9 billion of additional savings delivered to the Federal Government by the innovative medicines industry under the then four -year Memorandum of Understanding reached between MA and the Federal Government in 2014, through statutory price cuts enacted as part of the Agreement.

The importance of a stable and predictable policy environment

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. On average, the cost of bringing a new medicine or vaccine to market is approximately US$2.6 billion (including the cost of failed research and development projects) and it can take between 10 to 15 years to complete the process.[8] This process covers primary scientific research through to clinical trials to ensure regulatory requirements are met.

These lengthy product development cycles expose our industry to more commercial risk from changes in the policy and business environment when a product is still in development.

Within this competitive landscape, GSK is one of the few pharmaceutical companies operating in Australia with a diverse economic footprint. In a period of rapid consolidation and disinvestment since the 1990s, GSK has not only stayed in Australia, but has also invested heavily in the Australian arm of the business to ensure we are globally competitive within the GSK global supply chain and have focused our manufacturing capability into high-value, niche production.

The expansion of our manufacturing facilities in Boronia is a good example of this commitment. In February 2012 we announced a $60 million investment to expand our Boronia factory. This investment increased the site's current BFS capacity and supported the creation of a pilot scale industrialisation facility for the development of new powder

[6] MTP Connect, *Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector*, 2017
[7] Pharmaceuticals Industry Council, *2011 Survey of Privately Funded Clinical Research Activity in Australia*, 2012
[8] Medicines Australia, *Facts Book*, Fourth Edition, 2015, page 7.

and sterile liquid pharmaceutical and vaccines products. This includes a new manufacturing innovation that uses BFS technology to package an oral vaccine, the first vaccine of its kind utilising this technology.

While these investment decisions may be driven locally, they require the commitment and support at the highest level from our global parent company. Securing this investment requires confidence in the stability and profitability of the Australian market.

From an investment perspective, Australia is described as a high-cost economy by international standards. The recent rise in energy prices in Australia has exacerbated this position. This coincides with the expansion of manufacturing capacity in emerging economies, which now compete with Australia for a share of global investment.

There is intense competition in the global pharmaceutical supply chains, with a premium on speed, cost and quality. Measures that help to reduce our cost base in Australia will give us a competitive advantage against other GSK sites, particularly in Asia, and help us compete successfully for our share of global investment.

While the rise of Asia offers unprecedented opportunities, our success in Asian markets is not guaranteed. As the cost of doing business in Australia continues to rise, Government and industry sectors need to find ways to expand our competitive advantage and identify ways to ensure Australian industries remain competitive.

For GSK, Australia's high-cost environment, coupled with ongoing reforms to Government pharmaceutical purchasing practices, means the competitive advantage for investing in Australia lies in the business environment. The strength of Australia's research networks, intellectual property protection, the assurance of regulatory and manufacturing quality and competitive taxation are crucial incentives for ongoing global investment.

A viable and self-sustaining innovative pharmaceuticals industry in Australia is a key factor in ensuring that Australians continue to have consistent access to new medicines, as new discoveries are our best defence against some of the challenges facing society, such as an ageing population and the increased burden of chronic disease.

It is critical to ensure that adequate public support and long-term policy settings are in place to enable Australia to bring these discoveries to the world – right from the beginning of the R&D pipeline, through clinical trials, commercialisation and delivery.

Incentivising research and development activity through a stable R&D tax incentive system helps stimulate investment, both in the pharmaceutical sector and in other industries. In this way, government can assist business to meet the challenges of operating in and investing in a high-cost Australian market.

The Proposed Changes to the R&D Tax Incentive

GSK is concerned with the number of changes that have occurred to the research and development tax incentive over recent years. Instability in the policy environment acts as a barrier to business investment.

GSK is a strong supporter of the R&D tax incentive as an important driver of investment in Australian research. GSK's primary concerns regarding the proposed changes to the scheme are as follows:

- The proposal to include intensity thresholds to qualify for the non-refundable credit will act as a disincentive for innovative medicines companies to undertake advanced manufacturing in Australia.
- The proposed changes place innovative medicines companies that manufacture in Australia, such as GSK, at an inequitable, competitive disadvantage to their peers.
- There is no policy to increase collaboration between researchers and industry as recommended by the 2016 Ferris, Finkel and Fraser Review.

Each of these concerns are addressed below.

Disincentive to Manufacture in Australia

Under the policy reforms announced in the 2018 Federal Budget, an intensity threshold will be introduced to determine the sum of the non-refundable credit that may be claimed by a company, such as GSK, relating to its qualifying R&D spend. The denominator in the intensity calculation includes all expenditure (including, for example, capital and manufacturing expenditure). GSK's concern is that calculating a company's relevant intensity threshold as a proportion of annual expenditure will disproportionately impact pharmaceutical manufacturers.

As discussed above, unlike many other pharmaceutical distributors in Australia, GSK has a diverse economic footprint and undertakes both R&D and manufacturing activities in Australia. There is a high cost base involved with advanced manufacturing. As a result, GSK has higher levels of annual expenditure in Australia than other comparably sized companies that also conduct R&D in Australia, without a manufacturing presence. Unfortunately, this means that despite being a larger contributor to the overall economy, through employment and export revenue connected with our manufacturing facilities, under the proposed changes GSK will receive a lower entitlement to an R&D tax incentive than a comparatively sized company that does not manufacture, despite undertaking the same level of R&D expenditure.

Set out below is a hypothetical example to demonstrate how the proposed changes may operate as a disincentive to continue to manufacture in Australia.

Example 1

Company A and Company B both operate in the pharmaceutical sector. Both companies have an annual turnover of $900 million from the sale and distribution of their medicines within Australia. Company B also manufactures locally and generates an additional $400 million in revenue connected with export sales from manufacturing. Both companies having annual qualifying R&D spend of $23 million.

Impact of the proposed R&D changes:

	Company A:	Company B:
Distribution sales	$900,000,000	$900,000,000
Export sales	$nil	$400,000,000
Total expenditure (incl R&D)	$850,000,000	$1,213,650,000
Manufacturing expenditure:	$nil	$363,650,000
Qualifying R&D spend	$23,000,000	$23,000,000

Net Profit	$50,000,000	$86,350,000
Including Manufacturing Expenditure:		
Intensity level	2.706%	1.895%
R&D Intensity Rate	6.5% rate	4.0% rate
R&D Tax Incentive Benefit	$1,495,000	$920,000
Excluding Manufacturing Expenditure:		
Intensity level	2.706%	2.706%
R&D Intensity Rate	6.5% rate	6.5% rate
R&D Tax Incentive Benefit	$1,495,0000	$1,495,000

Company B is worse off than Company A under the proposed changes by $575,000. This is despite both companies undertaking the exact same amount of qualifying R&D expenditure and despite the larger contribution of Company B to Australia's economy through increased employment activity and export sales.

This example demonstrates that the proposed changes to the R&D tax incentive via the introduction of the intensity measure has an unintended consequence for the Australian economy. The proposed intensity measure favours companies that do not conduct multiple business activities in Australia, such as manufacturing, marketing or distribution and may operate as a disincentive for companies to continue to undertake advanced manufacturing activities in Australia.

Alternative Pathways

GSK submits that the proposed intensity measure be reviewed to ensure that it does not operate as a disincentive to manufacturing locally. This could be achieved, for example, by the removal of manufacturing based expenditure from the definition of "annual expenditure" in the intensity calculation. We recognise that this would make the calculation more complex and could potentially lead to companies manipulating their expenditure base to improve their entitlement to the R&D tax incentive. However, the strengthening of the anti-avoidance rules in Part IVA of the Income Tax Assessment Act would help to alleviate this concern.

As an alternative, an intensity measure could still be realised by using available R&D historical data and claims data to arrive at a simple level of expenditure table which would enable claims at the proposed rates depending upon the level of expenditure. The expenditure table could be designed to differentiate between small, medium and large entities, based on turnover. Using the historical data and information available to AusIndustry to set the levels in the expenditure table would enable the accurate forecasting of the total cost to Government of the R&D tax incentive and permit the Government to achieve the desired overall savings.

No commitment to support public-private collaborations

The 2016 report into the R&D Tax Incentive Scheme, undertaken by Chair of Innovation Australia Bill Ferris, Australia's Chief Scientist Alan Finkel and Secretary to the Treasury John Fraser, recommended introducing a collaboration premium of up to 20% to encourage industry collaboration with publicly funded research

organisations. It also recommended that the R&D Tax incentive be applied to the cost of employing new STEM PhD graduates in their first three years of employment.

Australia is home to some of the best researchers, healthcare professionals and medical pioneers in the world. We boast world-class research infrastructure and a strong pharmaceutical manufacturing capability. When linked together through collaboration, these strengths make Australia an attractive environment for investment from the biotechnology and pharmaceutical sectors.

GSK has been privileged to partner with several universities to conduct research activities. Most recently with the University of Adelaide relating to the 'B Part of It' study discussed above. This partnership has been nominated for an award at the 2018 South Australian Industry Research Excellence Awards.

GSK has also partnered with Monash University's Institute of Pharmaceutical Sciences. Together with Monash University we have investigated and developed new processes, products and devices to be industrialised, including the development of new processes for the manufacture of vaccines at our Boronia manufacturing facility.

Through this collaboration, we provided over 100 Monash students with the opportunity to utilise state-of-the-art facilities and develop their real-world skills, while at the same time we benefit from a competitive edge with access to world class researchers and facilities to enable innovative industrialisation capability. In November 2013 the Monash-GSK collaboration was awarded two Business-Higher Education Round Table (B-HERT) awards, one for Best Research and Development Collaboration and one for Outstanding Excellence in Collaboration. GSK was also one of the founding members of the *Medicines Manufacturing Innovation Centre* based in the Institute of Pharmaceutical Sciences, Monash University. The Centre provides technical and scientific advice and research to Industry in helping them develop new formulations for their innovative medicines.

Collaborations like ours could be even more valuable if extended to include other companies and institutions. However, the administration hurdles necessary to get larger collaborations off and running (management; seed funding; contracts; etc) can act as deterrents. Government programs and policy can help to address these deterrents and set a framework for a range of collaborations to benefit different sectors. Introducing a collaboration premium as proposed in the Ferris, Finkel and Fraser Review could incentivise more players from both industry and academia to collaborate and continue to growth the pharmaceutical sciences sector in Australia.

We believe that Government support for pharmaceutical manufacturing collaboration and innovation could bolster our individual successes and add value across the sector to allow organisations to maintain a competitive advantage internationally while boosting our sector's attractiveness internationally.

Response to Questions raised in the Consultation Paper

In addition to our comments above, we offer the following submission in relation to the specific questions raised in the consultation paper.

Do you foresee any implementation and ongoing compliance challenges arising from the proposed calculation of R&D intensity?

GSK supports any Government measures that will incentivise further additional R&D investment in Australia. However, for the reasons discussed above, GSK does not support the proposed calculation of the R&D intensity thresholds. It is important that any proposed measures introduced to incentivise increased R&D activity in the economy do not create barriers to investment in other areas of the economy (for example in manufacturing) or create inequities between companies operating in the same sector.

Does the proposed method of calculation of R&D intensity pose any integrity risks?

The concepts used in the intensity measure compare a tax based determination of the numerator with an accounting based concept for the denominator. This potentially poses an integrity risk such that accounting concepts are less precise than those used for taxation purposes. The accounting concept for total expenditure provides an opportunity to report expenditure items in a way which maximises the R&D tax incentive claim under the intensity calculation.

Could total expenditure be aggregated across a broader economic group? Would this create any implementation and ongoing compliance challenges?

GSK's statutory accounts are consolidated for taxation purposes. Based on the exposure draft released for public consultation, it appears that "annual expenditure" will be assessed across the economic group where an entity operates on a divisional basis and potentially a consolidated basis. This will include expenditure across all business units regardless of whether those individual business units are involved in undertaking R&D activities. This encourages the separation of business units into separate legal entities which complicates business operations and structures and creates inefficiencies.

For the reasons discussed above, GSK is not supportive of consolidating expenditure across a broader economic group as it disproportionately impacts companies that operate more than one core business activity in Australia.

Does the definition of clinical trials for the purpose of the R&DTI appropriately cover activities that may be conducted now and into the future?

By its nature, innovation is constantly evolving and it is impossible to predict the advancements of tomorrow. The definition of clinical trials, therefore, needs sufficient flexibility to encompass future technologies. For example, the definition currently attempts to define "interventions" as a "medicine, treatment or diagnostic procedure". This list is out of date, as it doesn't include vaccines or medical devices (which are neither a medicine, treatment or diagnostic procedure).

If examples are included in bracketed text, in our submission this list should be non-exhaustive so as not to inadvertently exclude a future technology requiring future legislative change.

Our proposed additions to the definition are outlined below:

A clinical trial is a planned study of the safety or efficacy in humans of an intervention (including, but not limited to, a medicine, treatment, vaccine, medical device or diagnostic procedure) with the aim of achieving at least one of the following:
– the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;
– the identification of adverse reactions or adverse effects;
– the study of absorption, distribution, metabolism or excretion.

Summary

GSK encourages the Federal Government to reconsider some of the proposed changes to the R&D tax incentive scheme. For the reasons detailed above, some of these changes may lead to the loss of jobs and export revenue generated by local manufacturing and the reduction in the investment in scientific research across the Australian medical and research communities. GSK would encourage further engagement with the medical and life sciences sector to understand alternatives to the current policies to ensure that the policy environment encourages, rather than dis-incentivises, continued investment and growth of the industry and its economic contribution to Australia.