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Senate Standing Committees on Economics
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***Treasury Laws Amendment (Research and Development Tax Incentive) Bill* 2019**

Medicines Australia welcomes the opportunity to provide a submission to the Senate Economic Legislation Committee's inquiry into the *Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019* (the Bill).

This submission complements the collective submission made by Medicines Australia, Research Australia, AusBiotech, MTAA, the BioMelbourne Network, AAMRI and LSQ.

As with the collective submission, Medicines Australia **opposes the Bill and calls on the Senate Committee to recommend the Senate reject the Bill**. We note that nothing substantial has changed since the Senate committee considered and recommended its rejection in 2018/19.

Medicines Australia is the peak industry body representing Australia's innovative research-based medicines industry. Our members are innovative companies that research, develop, manufacture and supply new medicines, therapies and vaccines to the Australian market. They are proud of their contribution to the health and well-being of everyday Australians, as well as to the local economy.

The innovative medicines industry has developed some ground-breaking discoveries. These emerging innovative medicines and therapies (such as CAR-T and precision medicine) are helping to fight previously untreatable diseases and are providing patients with better survival rates and improved quality of life. However, medicines investment is high-risk with approximately only 12% of medicines that enter clinical trials reaching approval for use by patients[3] at an estimated investment of $2.55bn.[1] Therefore, our industry is highly reliant on a stable policy environment that strongly supports innovation, research and development, and commercial translation to the same levels as competitor nations. Without these policies, there will be limited incentive for ongoing investment into Australia.

It is Medicines Australia's view that the Bill weakens the Research and Development Tax Incentive (R&DTI) and will risk Australia losing its international competitiveness at a time where competition with

[1] DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics 2016;47:20-33. (media release: https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66adc758d46b001a996d6/1522952924498/pr-coststudy.pdf)

regional and emerging players for R&D investment dollars is increasing, particularly from South Korea, China and South America countries. In turn, this can make the commercial viability of developing and marketing medicines in Australia even riskier. This is significant as Australia's innovation ranking has fallen from 20th in 2018 to 22nd in 2019 on the World Intellectual Property Organization's (WIPO) Global Innovation Index.[2] This is also at a time when the clinical trials R&D sector in Australia is poised to continue to grow, especially in rural and remote regions.

Clinical Trials must be encouraged

The R&DTI plays an important role in attracting clinical trials to Australia. The growth in clinical trials in Australia in recent years (under the current R&DTI) have exemplified additionality and been targeted to maximise spill over benefits.

Clinical trials can provide many benefits with respect to the economic and physical health of Australians. In fact, the intensity of clinical trials activity acts as a reliable proxy for an economy's attractiveness for foreign direct investment in the biopharmaceutical sector.[3] In 2018, pharmaceutical companies in Australia invested $1.5 billion[4] into R&D, mostly through conducting clinical trials. This investment has the potential to grow, should Australia's policy approaches align with global best practice. High levels of clinical trial activity bring multiple benefits to Australians including:

- Early patient access to cutting edge therapies, providing patients with improvements in their health and quality of life
- Improvements in the knowledge of participating healthcare professionals
- Creation of high skill jobs and a robust workforce
- Provision of opportunities for Australian scientists and medical researchers to be at the forefront of medical research
- Opportunities for more clinical trials (known as tele-trials) in rural and remote regions which strengthen local health infrastructure capabilities
- Generation of taxable income and a source of government revenue.

This Bill discourages R&D activities coming to Australia. Australian patients will miss out on new potentially life-saving medicines of last resort, while the economy will miss out on foreign direct investment, developing expert knowledge and high skilled jobs.

Medicines Australia is concerned that the proposed changes to the R&DTI do not recognise the critical role that the pharmaceutical industry plays in the economy and developing and bringing to market lifesaving innovations. In 2017-18 and 2018-19, Australia's discovery-led pharmaceutical sector

[2] See WIPO website: https://www.wipo.int
[3] US Chamber of Commerce Global Innovation Policy Center. 2019 – Providing certainty and predictability: How pharmaceutical linkage mechanisms help innovators, follow-on manufacturers, and patients.
[4] https://www.mtpconnect.org.au/images/2019%20MTPConnect%20Sector%20Competitiveness%20Plan.pdf

contributed $2.9 billion[5] and approximately $3.1 billion[6] respectively to the national GDP. In February 2020, AstraZeneca committed $200m to the company's manufacturing facility in North Ryde, Sydney. The investment follows $100m announced in 2017 and will go towards increasing the facility's production capabilities, creating 250 jobs and increasing exports from $1bn to $4.4bn over the next four years. Another Medicines Australia member, GlaxoSmithKline (GSK), manufactured approximately $346 million in exports. This Bill disadvantages such companies and disincentivises the expansion and start-up of manufacturing when the company also undertakes research and development activities. This would include companies that have made their innovative discovery through R&D in Australia.

The current R&D Tax Incentive:

- provides significant support to businesses to undertake, develop and extend their R&D activities that would not be otherwise possible or that would be significantly delayed
- plays a major role in maintaining Australia's competitiveness as a preferred location for R&D activities, including pre-clinical testing and clinical trials
- contributes to the health system by providing Australians with access to early stage therapeutics, diagnostics and medical devices during clinical trials and as final products
- provides new public sector R&D through partnerships with life sciences companies
- fosters a home-grown innovation ecosystem in R&D-intensive industries so that Australia delivers world-class treatments, cures, diagnostics devices and vaccines.

Proposed changes to the R&D Tax Incentive

The Bill weakens R&D incentives, creates commercial uncertainty in regard to business expenditure and disincentivises businesses with R&D and manufacturing ambitions.

Under the current R&D Incentive laws, the potential R&D tax offset can be reliably estimated for a given budget of R&D expenditure. This certainty allows appropriate resources to be allocated for R&D governance and program compliance. Under the proposed Bill, where a premium R&D tax offset is based on R&D intensity, the potential R&D tax offset may not be determined until near, or after the end of the income year. Such uncertainty will make decisions for the allocation of appropriate resources to manage program compliance more challenging.

There is also a potential for the rate of R&D benefit to vary significantly between income years, effectively rewarding spikes of R&D spending as a proportion of total expenditure within an income year. Organisations dedicated to building centres of excellence for ongoing research and commitments of R&D spending are at a comparative disadvantage, particularly if the expenditure is of a nature that is not eligible for the R&D Tax Incentive.

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[5] Australian Bureau of Statistics data for Industry Value Added (IVA) measures
[6] IBIS World Pharmaceutical Product Manufacturing in Australia 2019 (an independent market analysis organisation) (https://www.ibisworld.com.au/)

Medicines Australia has previously expressed its concern that introducing an intensity threshold could result in unintended consequences by reducing the incentive to invest in R&D in Australia. This could particularly be the case for large manufacturers, who, whilst investing significantly on R&D in Australia, could find themselves worse off under the intensity threshold scale. For example: a foreign multi-national manufacturer that does R&D in Australia but conducts its manufacturing overseas could have a higher calculated R&D intensity, and therefore be incentivised. Whereas a company that invests in Australian manufacturing and performs the same level of R&D as (or greater than) the company that manufactures wholly off-shore, may not qualify for the incentive.

Medicines Australia also strongly believes that the proposed exemption from the $4 Million cap on clinical trial investment should not be limited to organisations with turnover of less than $20 million. The proposal to tie the rates of the non-refundable R&D tax offset to the incremental intensity of R&D expenditure creates an unlevel playing field and will likely reduce the non-refundable R&D Tax credit accruing for large companies bringing global clinical trials to Australia. As such, Australia's attractiveness as a destination to conduct global clinical trials will be reduced at a time when the growth in clinical trials under the current R&D Tax Incentive has displayed both good additionality and has well targeted spill overs that maximise fostering collaboration.

In summary, the Bill will not enhance the R&D space in this country nor encourage greater innovation. As such Medicines Australia reiterates its **strong opposition the Bill and calls on the Senate Committee to recommend the Senate reject the Bill**. The appendix below provides a tabled summary of Medicines Australia's concerns.

We look forward to having the opportunity to discuss these issues further during any hearings that may be conducted for this inquiry. For more information please contact Peter Komocki (Manager, Industry and Regulatory Policy) on [redacted]

Yours sincerely,

[redacted]

Elizabeth de Somer
CEO
Medicines Australia

APPENDIX

Current law	***New law***	***Medicines Australia position***
The expenditure threshold		
The R&D expenditure threshold is legislated to cease on 1 July 2024.	The R&D expenditure threshold is raised and made a permanent feature of the law.	Given the constant tinkering with and efforts to weaken the RDTI, industry views this with some skepticism.
The R&D Tax Offset for large R&D entities		
R&D entities with aggregated turnover of $20 million or more are entitled to a non-refundable R&D tax offset at a rate of 38.5 per cent.	R&D entities with aggregated turnover of $20 million or more are entitled to an R&D tax offset equal to their corporate tax rate plus a premium based on the level of their incremental R&D intensity for their R&D expenditure.	Do not support intensity-based premiums. There is no evidence that this would incentivise additional R&D. Perversely, under current R&D figures, this would negatively impact almost all companies.
The R&D Tax Offset for small R&D entities		
R&D entities with aggregated turnover of less than $20 million are generally entitled to an R&D tax offset rate of 43.5 per cent.	R&D entities with aggregated turnover of less than $20 million are generally entitled to an R&D tax offset rate equal to their corporate tax rate plus a 13.5 per cent premium.	As above, do not support intensity-based premiums. This proposal substantially lowers the tax off-set and only provides the possibility of additional off-sets if the R&D is proportionately high enough.
R&D entities with aggregated turnover of less than $20 million are entitled to a tax refund for any R&D tax offset they receive in excess of their income tax liabilities.	The amount of a refund that an R&D entity can receive is capped at $4 million per annum. Offset amounts that relate to expenditure on clinical trials do not count towards the cap and remain refundable.	Do not support caps. The definition of clinical trials and exemption for clinical trials, overlooks the pre-trial stage and other forms of life sciences R&D.