Senate Standing Committee on Economics
Committee Office
Department of the Senate
Parliament House Canberra ACT 2600
www.aph.gov.au/senate

9 July 2020

Dear Senate Committee Members,

Thank you for the opportunity to appear before you on 29 June 2020 as part of your inquiry into the *Treasury Laws Amendment (Research and Development Tax Incentive) Bill 2019* (the Bill).

This letter responds to the questions on notice that Medicines Australia undertook to answer following the hearing. Having reviewed the Hansard alongside information available to us, we consider it appropriate to further discuss issues related to the additionality and spillover effects within medicines research and manufacturing, which includes aspects of commercialisation of products, as they relate to the Research and Development Tax Incentive (RDTI) scheme and broadly across the life sciences sector.

Additionality and spillover within medicines research and manufacturing

We note that an argument used by the Government to justify reforming the RDTI relates to the claim that the scheme does not deliver positive spillovers or additionalities to the Australian economy. It is clear to all life sciences stakeholders that this claim is not underpinned by a sector specific analysis of research and development intensive sectors such as ours.

The life sciences sector, including Medicines Australia members as well as those represented by our 'Health Innovation Collective', is based on innovative research and development. Innovation is part of our members' core business, which leads to subsequent commercialisation opportunities and advanced manufacturing.

Successful innovation is founded on a sustainable and growing ecosystem of partnerships for research and development.

Research and development is key; partnerships are essential. The current RDTI, weakened though it is already from previous versions, still manages to play its part in encouraging this ecosystem.

The spillover effects and additionalities of the research and development initiatives incentivised by the RDTI include the

- organisations it encourages to start-up, grow and mature
- number of highly skilled people that it employs, including
  - developing and retaining Australian talent
  - encouraging Australian talent to return home after gaining international experience
  - the skilled migrants that it attracts to Australia, and in turn the economic benefits which they bring

- increased numbers of clinical trials that are conducted
- foreign direct investment that it brings
- exports that it creates
- unquantifiable health outcomes to Australian patients that it delivers, particularly through clinical trials of new medicines and treatments.

It is part of the reason why the life sciences sector now encompasses 1,852 organisations and more than 240,000 jobs. It is why, in 2018, Medicines Australia members contributed approximately $10 billion to the Australian economy; employing over 23,000 Australians and annually investing over $1 billion into research and development to help 33,000 Australians get early access to emerging therapies. It is why there has been a 22% increase in clinical trials between 2015-2019, with 1,820 ongoing clinical trials being registered across Australia in 2019. As we have mentioned, in 2017-18, our industry exported $1.6 billion worth of medicinal products (rising to nearly $4 billion if medicaments are included).

If the RDTI is significantly weakened, as it is under this Bill, then Australia will become less competitive internationally for research and development investment and the abovementioned figures are likely to shrink over time; just like the BERD has been steadily decreasing as noted by this Committee and other stakeholders involved in this inquiry.

It is also why a recent report published by AusBiotech (*R&D Tax Incentive Additionality and spillovers for the life sciences industry*[1]) found that

- 63 per cent of respondents advised that the RDTI materially influenced the decision to undertake research and development
- 61 per cent of respondents advised that the proposed changes to the RDTI would not only affect their expenditure on research and development, but would also threaten the sustainability of their businesses
- 57 per cent advised that changes to the RDTI would impact on the amount of research and development their companies undertake in the future
- A 29 per cent (mean) reduction in research and development was anticipated due to RDTI changes
- clinical trials are critically important to survey respondents, and to businesses who provide third-party services for clinical trials. However, the broader ecosystem shows that the volume of clinical trials is dependent upon the health of companies relying on broader RDTI contributions
- as well as the additional research and development that occurs due to the RDTI, significant spillovers are also generated in relation to employment, training and skills development, together with growth of the sector and advances in health and innovation.

And as has been noted by Medicines Australia and others over the years, there are significant spillovers in medical research, and clinical trials in particular, including

- early patient access to cutting edge therapies, providing patients with improvements in their health and quality of life, including ongoing access to these after the clinical trial phase

[1] https://www.ausbiotech.org/documents/item/606

- there is no cost to the public health system for the clinical trials
- improvements in the knowledge of participating healthcare professionals
- creation of high-skill jobs and a robust workforce, based on an internationally recognised talent pool of home-grown and international experts
- becoming an attractive destination for skilled migration thereby contributing to Australia's economic growth, specialist expertise and cultural diversity
- 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
- strengthened local and rural health infrastructure capabilities
- generation of taxable income and being a source of government revenue.

Now more than ever, the government should be strengthening, not weakening the RDTI. Encouraging a stronger ecosystem of partnerships that innovate, develop, and manufacture high-quality/high-tech biopharmaceuticals, treatments and vaccines should form a central component to a health-led COVID-19 economic recovery. This may open the door to the niche bio-pharmaceutical manufacturing and other health related innovations, including medical devices and software, that support high value/highly skilled jobs.

Australia needs a stable, uncomplicated and internationally competitive RDTI that will support a healthy, growing research and development sector. With this, our SMEs and large companies will continue to commercialise and deploy new products and methodologies that positively impact the health of Australians, will increase skilled, STEM-based jobs, attract new investment and grow the sector, thereby contributing to our global leadership and competitiveness.

Conclusion

Medicines Australia is very concerned that the Bill will reduce opportunities for the ongoing success of the life sciences sector. This is increasingly important in the context of the COVID-19 pandemic which is negatively impacting jobs, investor interest and corporate growth.

Medicines Australia is fundamentally opposed to significant elements of the Bill and calls for it to be voted down or withdrawn in its current form:

- **Medicines Australia does not support the intensity-based premiums contained in the proposed R&D Tax Offset for large R&D entities with aggregated turnover of $20 million or more.** *There is no evidence that this would incentivise additional R&D. Perversely, almost all submissions relating to the Bill outline how this proposed system would negatively impact almost all companies.*
- **Medicines Australia does not support the proposed R&D Tax Offset for R&D entities with aggregated turnover of less than $20 million.** *The proposal also substantially lowers the tax offset from 43.5% to a rate equal to their corporate rate plus a 13.5% premium. This is not the time to be reducing support for SMEs, which help drive innovation and help put Australia ahead of its international competitors.*
- **Medicines Australia does not support capping the amount of a refund a R&D entity can receive at $4 million per year.** *Medicines Australia welcomes the exemption for clinical trials.*

However, the proposal excludes the important pre-trial stage of developing new therapeutics, diagnostics and medical devices.

We welcome the opportunity to engage with the Government to ensure a strengthened RDTI that delivers

- a program that recognises that research and development in the life sciences provides public welfare outcomes in addition to high-skilled employment, innovation and economic growth
- a strong, stable and predictable RDTI scheme that facilitates the discovery of innovative pharmaceuticals, biotherapies, vaccines and manufacturing processes, such as through
    - clear and specific exemptions that encourage research and development in the life sciences (i.e. clinical trial and manufacturing)
    - a return to a 45% refundable tax offset (an increase of 1.5%)
    - collaboration premiums for research and development activities, for example, between companies and publicly-funded research institutes through non-refundable tax offsets (e.g. 20%).
- a streamlined and stable system with no retrospectivity that clearly defines which activities are eligible under the scheme; one that cuts red tape, improves administrative processes and promotes the integrity of research and development.

I thank you again for the opportunity to discuss these issues with you at the hearing and in this follow up response.

Yours sincerely,

[redacted]

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Medicines Australia