26 July 2018

Manager

Small Business Entities & Industry Concessions Unit

The Treasury

Langton Crescent

PARKES ACT 2600

By email: RnDamendments@treasury.gov.au

Dear Sir/Madam,

Medicines Australia's Response to the Consultation on the draft Treasury Laws Amendment (R&D) Bill 2018

Medicines Australia (MA) welcomes the opportunity to comment on the Research and Development Tax Incentive Legislative Amendments. We support efforts by the Australian Government to encourage science and innovation in Australia. However, these efforts should target the entirety of the research and development eco-system. MA is concerned that the proposed changes to the R&D Tax Incentive do not recognise the critical role that the pharmaceutical industry plays in developing and bringing to market lifesaving innovations.

Medicines Australia member companies invent, manufacture and supply innovative medicines and vaccines for the Australian community. Their medicines, discovered through global as well as local research and development, contribute to the prevention of disease in Australia and help keep Australians healthy and productive. Our member companies are at the forefront of innovation and science in Australia. They directly employ around 12,000 Australians with many thousands more employed indirectly.

Our industry is the largest high-technology exporter from Australia ($3.810 billion in 2010-11) and the highest manufacturing industry investor in R&D (over $1 billion every year since 2010). It is also one of the largest employers of medical science graduates in Australia. The economic contribution of pharmaceutical companies is amplified through substantial linkages with other parts of Australia's medical research sector.

Australia competes on the global stage to promote R&D activity in Australia. It is therefore critical to maintain a stable, supportive and consistent policy environment to encourage life sciences businesses to make strategic decisions around R&D activity and bring additional investment into Australia.

The current R&D Tax Incentive:

1. Provides significant support to businesses in our sector to undertake, develop and extend their R&D activities that would not be otherwise possible or that would be significantly delayed;
2. Plays a significant role in maintaining Australia's competitiveness as a preferred location for R&D activities, including pre-clinical testing and clinical trials;

3. Brings spill over benefits into the Australian health system by providing Australians with access to early stage medicines, diagnostics and medical devices during clinical trials and as final products;
4. Supports public sector research with contract R&D resulting from companies engaged in new research programmes;
5. Contributes to building a home-grown innovation ecosystem in R&D-intensive industries, ensuring Australia can deliver world-class research into treatments, cures, diagnostics, medical devices and vaccines; and
6. Provides opportunities to streamline administration and compliance with the incentive which makes it easier for companies to focus their resources on undertaking research and development activities.

Australia has a strong international reputation for high-quality researchers and institutions. However, it is also described as a high cost economy by international standards. Competitive advantages should be expanded upon, through strong, supportive and stable policies that encourage research to our shores, and importantly, enable Australia to bring these discoveries to the world. The R&D intensity thresholds, as proposed, along with other policies such as IP provisions that do not meet global best practice, do not leverage Australia's existing strengths and could result in avoidable and detrimental unintended consequences.

R&D is an important part of Australia's economy. We are good at it. However, R&D has little benefit to Australians if they do not get access to the innovations. As such, the Australian Government should support R&D through all stages of the R&D pipeline. This submission will demonstrate that the introduction of intensity thresholds as outlined in the proposed legislated changes to the R&D Tax Incentive do not equitably do this and undermine the incredible value that larger companies provide not only to the Australian economy, but also, and most importantly, to providing access to life-changing and life-saving innovations to Australians.

As always, we would welcome the opportunity to discuss and collaborate with the Australian Government further on this issue. Please feel free to contact me on (02) 6122 8525 or email edesomer@medaus.com.au.

Yours sincerely,

Elizabeth de Somer

CEO

Appendix

Calculation of R&D Intensity – total expenditure

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

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 R&D incentive rules of a premium R&D tax offset 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 allocation of appropriate resources to manage program compliance more challenging.

Clarity around how "total expenditure" is defined in the calculation of R&D intensity would be helpful, as this is a new and undefined concept. We also note that in determining eligibility for either the refundable or non-refundable tax incentive, the criteria is based on turnover, whereas for the calculation of R&D intensity threshold, it is proposed that "total expenditure" is used. Therefore, inconsistencies are apparent.

The proposal for the R&D offset rates to be determined based on R&D as a proportion of total business expenditure for an income year assumes that R&D is a key business driver. Business spending decisions are, however, based on a complex mix of commercial, economic, strategic and industry specific influences. The proposed method of calculating R&D intensity may therefore result in substantially different rates of benefit between income years, even for sustained or increased levels of R&D expenditure, with no commensurate difference in the level of compliance required.

Additional challenges arising from the changes have been highlighted by a number of MA member companies. For example; the proposed legislation will significantly increase the complexity and compliance burden on R&D claimants. This complexity will likely spill over to the Industry as either added (advisor/consultant) costs or increased resource requirements from local finance staff.

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

There is 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.

The calculation of R&D intensity inherently advantages/disadvantages certain industries and organisational structures. 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 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.

Potential options to maximise the incentive include:

- Increasing the amount of R&D done in Australia to reach a higher threshold – this however, is flawed as the nature of a threshold is that once hitting a higher threshold, only the amount spent above that threshold is claimable at the higher rate; Or
- Reduce spending on manufacturing, thus increasing the proportion of R&D spend relative to the total spend. One way to reduce the spend on manufacturing in Australia, is to spend that money offshore. MA is certain that it is not the intent of the Australian Government to incentivise moving significant manufacturing facilities offshore with significant cost to the local economy and job losses. However, the proposed changes, whilst only one of several factors considered when making decisions on location of research, has the potential to do just that.

3. Could total expenditure be aggregated across a broader economic group?

Healthcare companies can spend significant amounts on R&D in Australia, whilst also incurring significant operating expenses across other parts of their business. Aggregating expenditure and including activities unrelated to R&D would further dis-incentivise investment in valuable research activities. Therefore, expenditure must apply to the claimant entity only, and assessment based solely on activities related to the R&D undertaken.

4. 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?

MA does not dispute the TGA's definition of clinical trials under the existing pharmaceutical drug development paradigm. However, if the definition is to change for the purpose of the R&DTI, further consultation with a wide range of stakeholders would be needed to ensure the definition is current, fit for purpose and recognises the importance of all parts of the R&D ecosystem; including medical devices and other non-pharmaceutical therapeutic interventions and emerging technologies that may be inadvertently disadvantaged by the current definition.

5. Does the proposed finding process represent an appropriate means of identifying clinical trials expenditure for the purposes of the $4m refund cap?

The R&D Tax Incentive has played an important role in attracting clinical trials to Australian businesses. Our clinical trials make a valuable contribution to the economy. The growth in clinical trials in Australia in recent years (under the current R&D Tax Incentive) have exemplified additionality and been targeted to maximise spill over benefits.

Australian subsidiaries of global companies have been successful in competing for global clinical trials to be placed in Australia through ensuring the local environment provides a competitive environment for clinical trials – including through the R&D Tax Incentive program. MTPConnect has identified that clinical drug trial activity in Australia has grown by 2.7% from 2010–2015, and importantly that industry sponsors have driven most of the growth in clinical trials in Australia, specifically from 2012 to 2015. [1]

It is clear, the current arrangements of the R&D Tax Incentive for clinical trials have in fact been associated with additionality in the clinical trials sector.

We support the carve out for clinical trials expenditure from the refundable R&D Incentive cap of $4 mill (for entities with turnover below $20million) as it recognises the criticality of maintaining the growth of early phase clinical trials in Australia. We could contend that this is to ensure there is no disincentive for continued growth in placing early phase clinical trials in Australia by SMEs. This is welcomed as a sensible exclusion to ensure that the spill overs and additionality of this unique R&D investment is not lost due to the proposed new R&D Tax Incentive Scheme.

However, the growth in early phase clinical trials is also due to large companies attracting such trials to Australia, and the proposal does not recognise the value that larger companies provide in supporting ongoing clinical trials. Therefore, MA strongly believes that the proposal as it stands is inequitable and 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 global clinical trials under the current R&D Tax Incentive has displayed both good additionality (through clear growth as noted above) and was well targeted spill overs that maximise fostering collaboration.

MA also notes that the collaboration premium proposed in the Ferris, Finkel and Fraser Review is not in the current proposal. Such a policy, if implemented appropriately, so as to also include private research organisations, could incentivise further collaboration between industry and academia to continue to grow the pharmaceutical sciences sector in Australia. Therefore, its exclusion should be reconsidered.

[1] MTPConnect. 2017; *'Clinical Trials in Australia: the economic profile and competitive position of the sector'*