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26 July 2018

Manager
Small Business Entities and Industry Concessions Unit
The Treasury
Langton Crescent
PARKES ACT 2600

Email: RnDamendments@treasury.gov.au

Dear Sir/Madam,

RE: Consultation on R&D Tax Incentive Legislative Amendments

Thank you for inviting the Medical Technology Association of Australia (MTAA) to provide input into the consultation on the Draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018.

MTAA is the peak association representing around 70 medical technology companies to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

Based on the Australian Bureau of Statistics definition of business size, around 80% of MTAA members are small – medium size enterprises (SMEs) and 20% are large businesses with some of our members being subsidiaries of international companies whereas others are Australian owned.

The diversity of our membership together with the diversity of medical devices manufactured and/or supplied by our members means that the impact of the changes to the R&D Tax Incentive (RDTI) will be varied.

Given MTAA understands the policy settings for the RDTI changes cannot be further adjusted (including the 'numbers' used in the calculations), the focus of this submission is to ensure that the implementation of the changes is appropriate and does not result in unintended consequences.

In this context, the key areas of MTAA feedback relate to the definition of clinical trials for the purposes of administering the exemption provisions relating to the $4 million cap tax refund and the calculation of the tax offset for companies with a turnover of $20 million or more.

These are discussed in more detail below.

1) Definition of Clinical Trials

MTAA welcomes the Government's decision that tax refunds on clinical trial expenditure will not be capped under the RDTI changes. This is an important concession granted by Government in recognition of the role clinical trials play in providing patients with access to life-saving or life-changing treatments, improving health outcomes and healthcare delivery and contributing to the economy.

It is therefore important that the clinical trial definition supports the intent behind the $4 million cap exemption for clinical trials.

There are two key issues MTAA would like to raise in this regard.

a) The clinical trial definition excludes biologicals, medical devices and in-vitro diagnostics

The proposed definition of clinical trials only covers medicines.

At a very minimum, the clinical trial definition needs to cover the range of therapeutic goods that are regulated by the Therapeutic Goods Administration (TGA). Therapeutic goods cannot be supplied on the Australian market unless the TGA has granted marketing approval following a technical / clinical assessment.

The therapeutic goods regulated by the TGA are:

- medicines (including prescription medicines, over-the-counter medicines and complementary medicines)
- medical devices (including in vitro diagnostic medical devices (IVDs))
- biologicals (including human cell and tissue-based therapeutic goods, or live animal cells, tissues and organs)

In terms of medical devices, Section 41BD of the *Therapeutic Goods Act 1989* defines a medical device as follows:

A medical device is:

b) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
iii. investigation, replacement or modification of the anatomy or of a physiological process;
iv. control of conception;

***and** that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or*

c) an accessory to such an instrument, apparatus, appliance, material or other article.

Reference to the TGA definition of medical device could be helpful to ensure medical devices are covered by the $4 million cap exemption.

Additionally, if the terms 'safety and efficacy' are used in the definition of clinical trial, it would it useful to add 'performance' as well to ensure medical devices are covered. This is because, for medical devices, the TGA conducts assessments to determine that the safety of a medical device is acceptable and the device performs as intended. This is also consistent with the definition used in ISO 14155:2011 which addresses good clinical practice for the design, conduct, recording and reporting of clinical trials carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes.

d) Limitations of requiring trials to be in humans

Limiting the current definition to the trials being conducted in humans may inappropriately limit the scope of the exemption provisions. Firstly, for many medical devices, expenditure on human clinical trials is not as significant as in the preclinical studies and therefore the value of applying the cap exemption provisions for medical devices is limited. Medical device companies invest significantly in conducting the preclinical stage of device development. This is the stage in which the design of the product is set, including functionality and safety aspects and validation of the selected materials and processes. Preclinical testing can also include final testing of the device design prior to regulatory submissions. As these studies are associated with the near-final or final device design, regulators expect to see more preclinical data.

The significant cost of preclinical studies is a unique consideration for medical devices and it may be possible that in some instances, these costs exceed those of conducting the clinical trials in humans. As such, MTAA considers that the exemption provisions should be implemented in a way that would allow medical device companies to receive an uncapped tax refund for conducting preclinical studies.

IVDs are not generally tested in humans – rather, they are tested on human samples. Consequently, restricting the definition of clinical trials to those conducted in humans may inappropriately exclude these products from the exemption provisions.

MTAA would request that IVD Australia be included in the consultation if this has not occurred given the impact on that sector.

2) Calculation of the tax offset for companies with a turnover of $20 million or more

The key concerns in this regard relate to the uncertainty and complexity of the new arrangements.

Our members are concerned about the increased financial uncertainty (and therefore risk) incurred in making R&D investment decisions under the changes to the calculation of the tax offset for companies with a turnover of $20 million or over.

This is because R&D investment decisions are made prospectively based on predicted cash inflow and outlfow (which includes the predicted value of the RDTI tax offset) and the greater the number of variables introduced in predicting a company's financial position, the greater the level of financial uncertainty and risk.

The way the tax offset will now be calculated will be based solely on variables as the only non-variable in the calculation under the previous arrangements (the 43% tax offset rate) has been removed. This will significantly increase the uncertainty and risk of companies in making decisions to invest in R&D.

A related concern is that under the changes, companies will have to estimate predicted total expenditure as part of their calculation of R&D intensity rather than turnover and predicting expenditure is much more difficult than predicting turnover.

Finally, the tiered approach to calculating the offset based on incremental R&D intensity is complicated and compounds the added uncertainty in calculating the tax offset.

As a consequence of the changes the following may occur:

- companies may overinvest in R&D which could place them in financial difficulty; or
- companies may underinvest in R&D which would have a detrimental effect on patients, healthcare and the economy; or
- companies will invest in R&D offshore with detrimental effects on the economy.

It is important that the legislation provides for mechanisms to recognize that R&D investment decisions are made prospectively whereas the tax offset calculation is applied retrospectively and this is when the impact of a company getting their predictions wrong will be felt. Greater certainty needs to be introduced into the arrangements to reduce a company's financial exposure when the tax offset is calculated.

While MTAA understands that the policy underpinning the RDTI legislative amendments cannot be reversed, it believes it is possible to design the implementation (and enabling legislation) to ensure that the changes adequately cater for medical devices with respect to the cap exemption provisions and that the uncertainty associated with the tax offset changes is brought back to acceptable levels.

I am available to discuss any of the above should you wish to do so.

Your sincerely

Ian Burgess
Chief Executive Officer