Consultation on the draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018 and Explanatory Materials

ROCHE SUBMISSION JULY 2018

Roche Products Pty Limited
Pharmaceuticals Division, Sydney

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in-vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them antibiotics, antimalarials and cancer medicines. Roche has been recognised as the leading healthcare company in the Dow Jones Sustainability Indices since 2009.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed more than 94,000 people worldwide. Roche invests around 10 billion US Dollars each year in research and development worldwide, including over AUD 44 million in pharmaceuticals in Australia in 2017. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

Roche's pharmaceutical division in Australia employs over 350 people who are dedicated to the clinical development, registration, sales, marketing and distribution of innovative pharmaceutical medicines. Australian patients have access to around 40 Roche medicines, and the company is the leading provider of cancer medicines in Australia by sales.

For more information, please visit www.roche-australia.com.

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Executive Summary

As an innovative biopharmaceutical company, Roche is a significant investor in research and development (R&D) activities in Australia. Australian participation in clinical trials that will lead to the next wave of new medicines is contingent on appropriate incentives, such as the R&D tax incentive, to keep investment flowing. Further restriction of the R&D tax incentive will add downward pressure on Australia's competitiveness to retain and attract investment in clinical trials. An alternative to these restrictions is to examine how other policy changes, such as harmonising regulatory systems and reducing start-up costs, could promote Australia as a preferred destination for clinical trial investment.

There are three key concerns with the proposed legislation:

1. A focus on simplistic administrative processes that do not consider the quality of the R&D activity and may lead to unintended consequences;
2. The proposed intensity thresholds (based on total expenditure in the calculation of intensity) reduce the marginal incentive for further investment; and
3. The clinical trial carve-out is only available for companies with turnover of less than $20 million and creates an uneven playing field.

Roche would welcome further review and amendment of the proposed legislation to provide a greater incentive for investment in priority research and development areas such as biomedical technology.

Maintaining the Research and Development Tax Incentive (R&DTI)

Research and Development (R&D) activities are important for the continuation of innovation. In Australia, Roche is a large investor in R&D activities, especially clinical trials for new medicines. Clinical trials benefit Australia through providing patients with early access to medicines; enhancing translation of evidence into local practice; forging links between local and international researchers; driving investment; and raising the capability of our health system. Despite these benefits, our international competitiveness in attracting trials continues to decline.

The pharmaceutical industry's contribution to research in Australia is important for investment and jobs. Industry investment in active clinical trials was over $1 billion in 2015[1]. The Australian clinical trials sector supported at least 6,900 highly skilled jobs in 2015[1], the large majority requiring tertiary education levels. The industry growth centre, MTPConnect, has identified the potential for Australian trials to surpass $2 billion of annual expenditure in the next 10 years, creating more than 6,000 new high-skilled jobs[1]. Roche is a major contributor to this ecosystem, investing over $44 million in clinical research in Australia in 2017[2] and employing over 100 local study staff who currently support approximately 117 local trials involving over 2,099 patients[3]. Roche's local trial staff also support regional trial activities.

Early access to new medicines through clinical trials has been estimated to save Australian taxpayers around $100 million annually in hospital and Pharmaceutical Benefits Scheme (PBS) costs[4], as well as providing patients with significant benefits from timely treatment. Other benefits include: enhanced translation of evidence into local practice; enhanced local clinical trial expertise; enhanced global profile and linkages for Australian researchers; and retention of researchers in the Australian public health system. Without an appropriate incentive to invest in clinical trials, the early access to new treatments which is currently possible for many patients will not occur which will ultimately lead to increased costs through the PBS.

Australia has recently experienced modest growth in pharmaceutical sponsored clinical trials of 2% between 2012 and 2015[1]. Roche continues to invest in Australian clinical research, yet in line with the broader industry, it is experiencing significant competition within the Asia Pacific region. Recent regulatory and clinical trial improvements in China have opened pathways for participation in global registration trial programs, potentially reducing opportunities for Australian patients to participate. As of 2017, China contributes the largest number of patients to the Roche Asia Pacific regional clinical trial program for medicines[5]. Moreover, compared to countries with similar sector profiles such as Canada or the UK, Australia attracts 14% fewer phase III or later development clinical trials across all companies[1].

Roche is concerned that further restriction of the R&DTI will add downward pressure on Australia's competitiveness to retain and attract investment in clinical trials. In reality, larger companies such as Roche look at costs in a global context and may see Australia as less competitive with such changes to the incentive.

Response to consultation questions

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

There are a number of potential challenges that will arise from the proposed R&D intensity measure. These can be summarised as:

- Unintended consequences from focusing on simple administrative process rather than targeting the overarching policy objective of the incentive;
- Further clarity is required in defining the elements of the intensity calculation; and
- Ensuring integrity, consistency and equity in application of the proposed measure.

Unintended consequences from focusing on simple administrative process

The proposed changes are broad brush in nature. Roche understands that a focus on total expenditure may appear administratively simple as the basis for calculating the intensity threshold, but this may lead to unintended consequences. The same measure is proposed to be used, regardless of the industry or type of R&D activity. This does not capture or reflect that industries such as innovative pharmaceutical companies perform R&D that is both higher-risk and more likely to generate significant new knowledge and capability than in other industries. Roche's investment in clinical trials meets the R&DTI objectives of additionality and spillover benefits for Australians. There is no consideration in the proposed calculations of the quality of the investment in riskier, or higher value R&D activities such as clinical trials.

It is unclear from the explanatory materials as to how this measure can be applied consistently across industries. Companies that have a higher level of R&D investment, but also have a high total expenditure level will be penalised compared to the current arrangements. The operating expense base for companies will be determined by their sector and business model and will not be related to a company's level of R&D. The proportion of total expenditure put towards R&D in no way reflects the level of additionality or quality of the R&D, particularly for multinational companies where R&D decisions are made globally. For example, if two companies in different sectors have the same amount of R&D expenditure each year, and one of these companies has a larger operating expense base, that company will receive less offset under the proposed intensity thresholds. By using total expenditure in the calculation of R&D intensity, this will reduce the attractiveness of increasing investment in clinical trials in Australia compared to other regions that do not impose an arbitrary threshold and who may now be seen to be more competitive.

Further clarity in definitions

The two elements of the calculation (R&D expenditure and total expenditure) should be defined further. The current definition is broad and open to interpretation – reflecting the

desire for simple administration. It is unclear from the explanatory materials and draft Bill how these two elements will be defined and recorded by the Australian Taxation Office (ATO).

The current definition of total expenditure in the calculation should be reconsidered, as this is not truly reflective of the level of intensity of investment in research and development activities. Different business models will drive different total expenditure profiles. Expenditure on business as usual activities can be unrelated to the research and development. By including expenditure on business as usual activities, the value of R&D is diminished under the proposed intensity thresholds. A perverse incentive may be apparent, with companies being rewarded for reducing total expenditure profiles rather than increasing R&D expenditure. While rewarding R&D intensity might be simple and appealing in theory, it is difficult to implement without unfairly discriminating between sectors that have different cost structures.

Ensuring integrity, consistency and equity in the application of the measure

Roche does not foresee any ongoing compliance challenges arising from the calculation changes (pending further clarification of the elements). For the current R&DTI, all elements are calculated and audited as part of annual accounts which are reviewed by an external tax firm. As there is currently no guidance from the ATO on its preferred method of calculating the incentive, each year agreement needs to be sought on an appropriate method of capturing the complex elements in the research and development of pharmaceuticals. Given the increasing level of administrative complexity that this legislation will impose, there will be a further impost and requirement to engage and source external expertise to ensure compliance with the new calculations.

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

It is difficult to determine if there are potential integrity risks without further guidance on how the elements of the intensity threshold will be calculated and what expenses will be captured or excluded. Roche has a number of procedures and processes for collecting both the annual eligible R&D expenditure and total expenditure. Currently, documentation is kept for all decisions made and methods used for calculating the R&DTI to ensure processes are clear, transparent and consistent with financial standards including a focus on continuous improvement. This is supported by internal audit and external consultancy advice. Moving to the intensity threshold approach will require additional technical expertise to be externally sourced and will increase the costs associated with claiming the incentive.

Under the proposed intensity thresholds, Roche's R&D expenditure would be in the 2-5% category. This would lead to a substantial decline in the eligible tax offset that Roche would be able to claim compared to the current incentive. As Roche has been investing in highly

valued and risky R&D activities, it is unclear why, as a larger company that invests in clinical trials, there should be a reduction in the amount of offset received for the same activity.

Due to the arbitrary nature of the thresholds, it is unlikely that companies could increase their R&D investment by a magnitude that will lead to a higher threshold. For Roche to move to a higher intensity threshold the current amount it invests in clinical trials would need to double. The marginal incentive to increase investment is significantly less attractive for Roche to invest further in Australia under the proposed intensity thresholds compared to the current scheme. In an increasingly competitive international clinical trial landscape, these changes will make the business case for substantially increased Australian investment in trials more difficult.

A further integrity risk is that the current system is burdensome with a need to negotiate an individual method and process which creates uncertainty on whether to submit a future return. Moving to the new threshold system without further guidance and detailed information on how the R&DTI will be administered will increase the level of red tape burden.

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

Whilst Roche has robust and rigorous processes, there is a potential for a lack of transparency and appropriate proportioning to relevant areas if a broader economic group model is used. There would need to be a revision of processes to ensure alignment with a more aggregated approach, and without further clarity there is an increased risk of potential unintended consequences. With a range of business models and approaches in use, this level of aggregation would not provide an appropriate incentive to encourage further investment. Further consultation with industry may assist with understanding the scope of issues that would arise by using a broader economic group approach.

The diverse range of company structures makes it difficult to establish a system that suits all. With each company so different, with a different focus and set up, it will be difficult to come up with a 'one size fits all' model that captures aggregated expenditure. There would also need to be clear guidelines on how to calculate this aggregate expenditure, to ensure that it is not interpreted differently. Until there is complete detail on this option, including how it would be administered, it is difficult to determine the impact it would have for Roche.

4. **Clinical trials carve out for smaller companies creates an uneven playing field**

The proposed clinical trials exemption to be only available for companies eligible for the refundable component creates an uneven playing field. This approach does not recognise the value that larger companies, such as Roche, bring in building and supporting the infrastructure required for ongoing clinical trials in Australia. In an environment that is

becoming increasingly competitive, both domestically and internationally, only allowing smaller companies access to the clinical trial exemption creates a disincentive for larger companies to invest. For multinational companies, clinical trial investment decisions may be made at the global or regional level, and with a signal being sent that smaller companies will have a financial competitive edge to invest in clinical trials, this may reduce Australia's competitiveness to attract further clinical trial investment. One alternative option to address this is to consider providing the clinical trial carve out for both the refundable and non-refundable components of the incentive.

Another alternative is to examine how other policy changes could promote Australia as a preferred destination for clinical trial investment. Some of these changes could involve harmonising regulatory systems and reducing start-up costs. The current regulatory system is complex with variances across states and territories. A holistic solution focused approach to address this challenge could be through a single, more streamlined approach to research governance approval that is nationally recognized. This would assist with start-up times and reduce overall costs and, in conjunction with the right tax incentives, promote further clinical trial investment.

Conclusion

The proposed changes to the R&DTI would create a number of unintended consequences. Whilst the policy intention of the changes is targeted towards further investment, the current ambiguity in definitions and the proposed intensity tiers would reduce the level of R&DTI that Roche currently receives for investing in clinical trials. Whilst the policy intent is to incentivise further investment in R&D, the proposed threshold rates may not achieve this, as a result of a lower marginal incentive for investment. Further revision of the intensity threshold rates and refining how total expenditure is defined may assist with providing a greater incentive for further investment.

The carve out of clinical trial investment for smaller companies creates an uneven playing field, and raises questions over equity of process. For larger multinational companies where clinical trial investment decisions are made at the headquarters or regional level, it may become more difficult to justify future investment where smaller companies will now be seen to have a competitive edge. Roche's continued investment in clinical trials in Australia is important to ensure that the next wave of innovative medicines is made available to Australian patients. There are a number of other changes in the clinical trial system that would further support greater investment and make undertaking trials simpler and cheaper.

Roche would welcome further review and amendment of the proposed legislation that provides a greater incentive for further investment in priority research and development areas such as biomedical technology, and which avoids the potential unintended consequences of the proposed changes.

References

[1] MTPConnect. 2017. "Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the sector". Melbourne
[2] Roche data on file
[3] Roche data on file
[4] Commonwealth Department of Industry. 2011. "Clinically Competitive: Boosting the Business of Clinical Trials in Australia". Clinical Trials Action Group Report. Australian Government, Canberra
[5] Roche data on file