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Manager
Small Business Entities & Industry Concessions Unit
The Treasury
Langton Crescent
PARKS ACT 2600

By email: RnDamendments@treasury.gov.au

Dear Sir/Madam,

Submission on the R&D Tax Incentive Consultation Paper

We welcome the opportunity to make a submission to Treasury in relation to the Consultation Paper released on Friday 29 June 2018 concerning the proposed changes to the Research & Development (**R&D**) Tax Incentive regime.

In addition to the questions raised in the Consultation Paper, we have also used this opportunity to make general submissions on the proposed changes to the R&D Tax Incentive regime.

Please do not hesitate to contact us if you require any further clarification regarding our position.

Yours Sincerely,

Brian Gladsden
Country President

Gregorio Oliveira
Country Chief Financial Officer

Submission on the R&D Tax Incentive Consultation Paper

General Comments

Novartis is a global healthcare company based in Basel, Switzerland, with a history going back more than 150 years. We provide healthcare solutions that address the evolving needs of patients and societies worldwide. Novartis products are sold in about 155 countries and they reached nearly 1 billion people globally in 2017. About 126,000 people of 145 nationalities work at Novartis around the world.

Our Australian operations started in 1957. Since then, Novartis has grown to approximately 800 people, with our head office located in Sydney and sales teams represented in all principal cities across Australia. Novartis is pleased to invest in Australia's economic and social health and wellbeing. Our people are employed across a range of fields including medical, regulatory, finance, marketing and filed based representatives.

With regard to clinical development activities, we collaborate with many of the finest academic and scientific researches and institutions in Australia to conduct clinical trials. Novartis undertakes trials across a wide range of therapeutic areas, including blood cancer, central nervous system, skin disorders and ophthalmic conditions and invests approximately AUD 30 million per year in clinical trials in Australia. In terms of the numbers, we support more than 140 clinical trials across more than 500 sites, involving an excess of 400 physicians and over 1,000 patients in Australia. According to an independent analysis of clinicaltrials.gov registrations in 2014, Novartis was the industry's largest investor in clinical trials across Australia.

Clinical trials play an important part in the Australian economy and society. Clinical trials expose Australian clinical staff to world-leading healthcare practices allowing them to develop new skills and expertise, contribute to a research culture and infrastructure in healthcare and support thousands of Australian jobs within the research and healthcare system such as doctors, nurses, researches and administrators. Clinical trials also allow Australian patients to gain early access to new treatments and therefore an improved standard of care and higher efficiency without the healthcare cost during the trial conduct. The activity also generates a range of flow-on benefits and economic multiplier effects. As such as one of the pharmaceutical industry's significant contributors to clinical trials in Australia, Novartis helps ensure the ongoing viability, sustainability and dynamism of Australia's research, development and scientific operating environment.

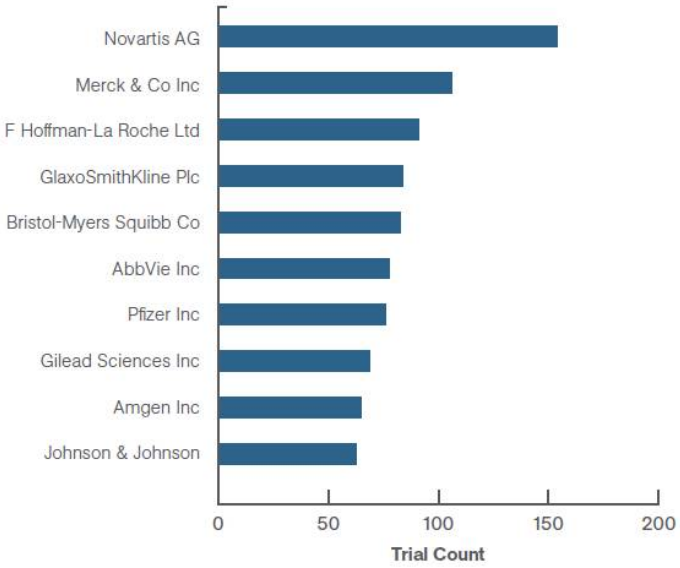
Many markets around the world compete for clinical trials activity (especially industry sponsored). Novartis is a strong supporter of the R&D Tax Incentive as an important driver of the continued attractiveness of Australia as a destination to conduct global clinical trials by pharmaceutical groups. In particular, from an investment perspective, Australia is a high cost economy by international standards, accordingly measures which reduce the cost of conducting trials in Australia (such as the R&D Tax Incentive) are key for Australia to compete for a share of global investment in clinical trials. Indeed, comparable costs, high research and quality standards (especially early phase capability), timely trial approval and reliable patient recruitment make Australia an attractive destination to conduct clinical trials.

Novartis however does not support the proposed implementation of a benefit which is tied to R&D intensity having regard to overall expenditure. Such an approach results in an adverse impact on some of the largest contributors to clinical trials in Australia, including Novartis, and reduces Australia's ability to compete for global clinical trials. Further, such a proposal appears to inadvertently punish entities conducting more than one activity (such as distribution) and hence those which arguably have a larger contribution to the Australian economy or which are consolidated for Australian taxation purposes (and hence have higher levels of 'expenditure').

The growth in Clinical Trials in Australia in recent years (under the current R&D Tax Incentive) has exemplified additionality and been targeted to maximize spill over benefits. Importantly industry sponsors have driven most of the growth.

The top industry sponsors for Australian clinical trials are large global pharmaceutical groups.

Figure 5: Top Industry Sponsors for Australian Clinical Trials[33]



Scope (provided by GlobalData)
between January 1 2012 and December 31 2016.

The *Review of the R&D Tax Incentive* released in April 2016 identified "that the programme falls short of meeting its stated objectives of additionality and spill overs" (page 2) and the changes proposed are designed to encourage additionality and increase spill overs.

Australia has 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 regime. The June 2017 MTPConnect/L.E.K. Report (Clinical Trials in Australia: The Economic Profile and Competitive Advantage of the Sector) identified that clinical drug trial activity in Australia has grown by 2.7% during 2010–2015 and importantly, that industry sponsors have driven most of the growth in clinical trials in Australia, specifically from 2012 to 2015 (page 24 and Table 4 - below).

Table 4 Clinical trial activity growth, by intervention type and phase

	Drug						Device	Drug & Device[32]	Other	Total
	Phase I	Phase II	Phase III	Phase IV	Other	Drug Total				
Growth (p.a. 2010-15)	6.6%	3.2%	2.7%	(1.2%)	(2.3%)	2.7%	12.6%	13.4%	5.0%	4.7%

Source: ANZCTR; L.E.K. analysis

From a sponsor and trial type perspective, the majority of growth in number of trials was driven by industry sponsors, specifically from 2012 to 2015.[33]

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

The majority of clinical trials growth in this period has been in Phase I (6.6% growth) and Phase II (3.3% growth). Phase I and Phase II clinical drug trials tends to occur in the larger academic centres which are either publicly-funded research organisations (**PFROs**) or the principal investigators may have dual appointments with PFROs.

As such, the growth seen in the clinical trials sector in Phase I/II clinical drug trials is in fact well targeted at maximising spill over of knowledge via increasing collaboration between companies (i.e. Small & Medium Enterprises (**SMEs**) and large companies) and PFROs collaborating on these early phase clinical trials.

The proposed carve-out for clinical trials expenditure from the refundable R&D Tax Incentive cap of $4 million recognises the criticality of maintaining the growth of early phase clinical trials in Australia

It is noted that a carve-out for clinical trials expenditure from the refundable R&D Tax Incentive cap of $4 million (for entities with turnover below $20 million) has been proposed. Novartis would contend this is to ensure there is no disincentive for continued growth in placing early phase clinical trials in Australia by SMEs.

This is welcomed by Novartis as a sensible exclusion to ensure that the spill overs and additionality of this unique R&D investment is not lost under the proposed R&D Tax Incentive regime to smaller companies. However, the growth in early phase clinical trials clinical is also due to large companies attracting early phase clinical trials to Australia.

For Novartis in particular, the number of Phase I/Ib trials has increased from 10 to 49 between 2012 and 2017. This is because Novartis in Australia has specifically targeted increasing early phase clinical trials work from its key global early phase research units to bring to Australia.

One example of such early phase trials attracted to Australia includes CAR-T cell therapy clinical trials that have been awarded to early phase clinical trial centres in Australia, including three centres attached to PFROs. Involvement in these trials has provided the opportunity for these PFROs to gain experience with a range of technical aspects of the delivery of cell therapies and engage with global experts in CAR-T cell processing.

Proposed changes to the R&D Tax Incentive will decrease Australia's competitiveness for (early phase) clinical trials conducted in Australia by large companies

The proposal to tie the rates of the non-refundable R&D Tax Incentive to the incremental intensity of R&D expenditure will decrease the non-refundable R&D Tax Incentive accruing for large companies (turnover more than $20 million) bringing global clinical trials to Australia.

As a large company, Novartis distributes life-saving medicines for access to the Australian population in addition to conducting clinical trials. The expenditure associated with distribution is significant (in particular the purchase of medicines) and reported on a consolidated basis in the income tax return as a multiple entry tax consolidated group. The proposed calculation of the R&D intensity based on 'total expenditure' reported in the income tax return therefore decreases the incentive for clinical trial activity to be conducted in Australia as it dilutes the investment made by companies which perform additional functions in Australia or which are consolidated for Australian taxation purposes.

As such, the attractiveness of Australia to 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 to produce spill overs

(from early phase clinical trials). The growth in early phase clinical trials is derived from companies both small and large.

Novartis would therefore propose that the intensity measure be reviewed to ensure that it is not a disincentive to continued investment in clinical trials by companies undertaking distribution by the removal of cost of goods sold (**COGS**) from the 'total expenditure'. Novartis however recognises that this may result in further complexities to the calculation and in turn unfairly differentiate between companies which incur COGS and those that do not. An alternative is perhaps a simple table that sets out different R&D Tax Incentive rates for varying levels of expenditure incurred, rewarding higher levels of expenditure. This table can also be used to provide varying levels of benefit for companies of different sizes should this be deemed necessary.

Response to questions raised by the consultation paper

In addition to our comments above, we offer the following submission in relation to the specific questions raised in the consultation paper.

Calculation of R&D Intensity – total expenditure

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

Prima facie, the calculation is able to be performed with relative ease by extracting the total expenditure from a tax return. However, Novartis does not support the proposed implementation of a benefit which is tied to R&D intensity having regard to overall expenditure for the reasons stated above.

We would also like to highlight the following issues with the proposed methodology for this intensity calculation:

- Accounting standards and principles are significantly less precise than taxation laws. Further, accounting standards do not require transactions to be measured on an arm's length basis.

- There are often mismatches between accounting and tax rules, such as concepts of 'incurred' for taxation purposes and versus that of 'matching' for accounting purposes. A further example of this is for an entity which is require to make Transfer Pricing adjustments pursuant to a review or audit by the Australian Taxation Office for historical years. Such adjustments may only be required to be reflect in the current year accounts whereas in each of the years in question for taxation purposes.

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

There is an integrity risk which arises from adopting this approach as the 'total expenditure' disclosed on the income tax return are based on amounts determined and reported according to accounting standards and concepts. As mentioned above, accounting standards and principles are significantly less precise than taxation laws. Accordingly, there may be an incentive to report expenditure amounts in a way to bring about a higher R&D intensity when the nature of the activities have not changed (e.g. by offsetting expenditure amounts with revenue). In addition there may be an incentive not to consolidate for tax purposes to maintain a lower level of 'expenditure.'

Clinical Trials exemption under the $4 million refund cap

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?

> "*A clinical trial is a planned study of the safety or efficacy in humans of an intervention (including a medicine, treatment or diagnostic procedure) with the aim of achieving at least one of the following:*
>
> - *the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
> - *the identification of adverse reactions or adverse effects;*
> - *the study of absorption, distribution, metabolism or excretion*."

Although the current proposed definition taken from the Therapeutic Goods Administration (TGA) appears to be sufficiently broad to cover medicine trials, the definition should be expanded to include medical devices.

Further it is predicted that in the future there will be greater use of big data, health system data and real world evidence that could contribute to the clinical trials process. It may therefore be that in the future this definition should be broadened to include other methods of gathering data that may contribute towards obtaining the data listed in the bullets above, or to give better clinical context to that data.