The Manager
Business R&D
Department of Industry, Innovation and Science
GPO Box 9839
CANBERRA ACT 2601

28 October, 2016

Via email: R&DTaxIncentiveReview@industry.gov.au

Dear Sir/Madam,

Re: Consultation on R&D Tax Incentive Review Report

Medicines Australia welcomes the opportunity to comment on the R&D Tax Incentive Review report findings and recommendations. We are very pleased that the Australian Government is encouraging science and innovation in Australia through, for example, Australia's first ever National Innovation and Science Agenda. We also welcomed the identification by Australia's Chief Scientist, entrusted with the oversight of a whole-of-government 10-15 year plan for growing and promoting innovation and science investment in Australia, of our sector as one of the five most promising growth sectors in Australia.

The members of Medicines Australia invent, manufacture and supply innovative medicines and vaccines to 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 members are at the forefront of innovation and science in Australia. They directly employ around 15,400 Australians with many thousands more employed indirectly.

Although our industry is a global one, we are proud that, despite significant international competition, our members invest around $450 million annually in clinical trials in Australia and also contribute around $1 billion to the Australian economy each year. Innovative research partnerships between hospitals, research institutions and medicines companies support thousands of jobs for Australian scientists and researchers and we believe that with the right incentives, Australia can become an even stronger international innovation and investment destination.

As biotechnology and medical technology are global industries, Australia must compete to retain the R&D activity of local companies, as well as to attract international R&D activity into Australia. It is critical to maintain a stable, supportive and consistent policy environment in Australia to encourage life sciences businesses to make strategic decisions around R&D activity and bring additional investment into Australia.

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The current R&D Tax Incentive:

- 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;
- plays a significant role in maintaining Australia's competitiveness as a preferred location for R&D activities, including pre-clinical testing and clinical trials;
- brings spill over benefits into the Australian health system by providing Australians with access to early stage therapeutics, diagnostics and medical devices during clinical trials and as final products;
- provides public sector research with contract R&D resulting from companies engaged in new research programmes;
- contributes to building a home-grown innovation ecosystem in R&D-intensive industries, ensuring Australia can deliver world-class research into treatments, cures, diagnostics devices and vaccines; and
- allows opportunities to streamline the administration and compliance of the incentive to make it easier for companies to focus on undertaking research and development activities.

We note that the review found that the programme fell short of meeting its stated objectives, and could be better targeted in improve the integrity of the programme. As the peak body for the innovative, research based pharmaceutical manufacturers in Australia, we support the reviews finding that spillovers are likely to be greatest in the science sectors, in which our members operate. The reviews recommendations impact on our members is as follows:

Recommendation 1*: Retain the current definition of eligible activities and expenses under the law, but develop new guidance, including plain English summaries, case studies and public rulings, to give greater clarity to the scope of eligible activities and expenses.*

Further guidance and plain English summaries would help clarify and increase transparency in how the programme is being interpreted by the Australian Taxation Office and Department of Industry, Innovation and Science. This will help to ensure that companies claiming the incentive are aligned with these interpretations. As noted in the review, Medicines Australia agrees that it is too soon to change the definition of the programme, and should maintain a period of stability. If there is an opportunity to assist in the assessment and development of guidelines we would be pleased to offer our help.

Recommendation 2*: Introduce a collaboration premium of up to 20 percent for the non-refundable tax offset to provide additional support for the collaboration element of R&D expenditures undertaken with publicly funded research organisations. The premium would also apply to the cost of employing new STEM PhD or equivalent graduates in their first three years of employment. If an R&D intensity threshold is* *introduced, companies falling below the threshold should still be able to access both elements of the collaboration premium.*

Medicines Australia welcomes the recommendation of a collaboration premium that recognises the importance of partnerships between industry and the academic sector. Medicines Australia's members already undertake a number of partnerships with both publicly funded and private research organisations. A collaboration premium would be a positive incentive for innovative pharmaceutical companies that are claiming the incentive to strengthen their relationships with the research sector. Medicines Australia recommends that the collaboration premium should be expanded to include private research organisations, as the benefits that flow from research partnerships with industry extend beyond the public organisations.

Recommendation 3*: Introduce a cap in the order of $2 million on the annual cash refund payable under the R&D Tax Incentive with remaining offsets to be treated as a non-refundable tax offset carried forward for use against future taxable income.*

Medicines Australia would like to better understand the rationale and evidence for introducing a cap for the refundable component of the incentive. We believe that further investigation of publicly available analysis and evidence should be undertaken to determine the impact and potential unintended consequences of introducing a cap on different sectors. For example, as noted by Biotech Daily[1] on 29 September, the majority of companies receiving more than the proposed $2 million cap (since 2011, 39 companies had refunds payable of greater than $2 million) were biotechnology based companies.

Therefore there is a concern that this cap will have a negative influence on burgeoning biotechnology companies, which rely on the refundable component to support further growth in the early research stages of start-ups. We believe that the setting of a $2 million cap should be reconsidered taking into account evidence and analysis of eligible activities that would be impacted.

Recommendation 4*: Introduce an intensity threshold in the order of 1 to 2 percent for recipients of the non-refundable component of the R&D Tax Incentive such that only R&D expenditure in excess of the threshold attracts a benefit.*

It would be helpful to understand how a figure of 1-2 percent was reached, and the evidence that this threshold level would increase the efficient allocation of the incentive. Medicines Australia is concerned that the proposed intensity measure may, in fact, send a contrary signal to innovative pharmaceutical companies making investments in R&D in Australia.

[1] Biotech Daily www.biotechdaily.com.au

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The common goal is to stimulate and attract investment in eligible activities, particularly for the biotechnology and pharmaceutical sector. It will be critical that, should an intensity threshold be introduced, it does not perversely reduce the amount of R&D eligible activities that will be able to be claimed, or reduce the incentive to invest in such activities. Medicines Australia would propose for inherently higher R&D intense industries, such as the biotechnology and pharmaceutical sector, that a lower intensity threshold should be considered.

Recommendation 5: *If an R&D intensity threshold is introduced, increase the expenditure threshold to $200 million so that large R&D intensive companies retain an incentive to increase R&D in Australia.*

Medicines Australia welcomes the proposed increase in the cap to $200 million, but notes that the requirement to implement the intensity threshold may limit the benefit from this increase. Although this recommendation may provide further incentive for investments in R&D in Australia by larger organisations, this will be highly contingent on the intensity threshold level that is implemented. It is unclear from the report whether there will be potential unintended consequences and how the combined effect of recommendations four and five will impact on different sectors. We would welcome the opportunity to work with the Government to better understand how this recommendation could be implemented to ensure that the integrity and efficiency of the programme is maintained to foster innovation and grow the economy.

Recommendation 6*: That the Government investigate options for improving the administration of the R&D Tax Incentive (e.g. adopting a single application process; developing a single programme database; reviewing the two-agency delivery model; and streamlining compliance review and funding processes) and additional resourcing that may be required to implement such enhancements. To improve transparency, the Government should publish the names of companies claiming the R&D Tax Incentive and the amounts of expenditure claimed.*

Medicines Australia supports measures that reduce red tape, improve transparency and increase efficiency where appropriate. The specific details of any proposed transparency and public reporting of the recipients of the incentive will need to be clearly defined and considered by Medicines Australia and other industry sectors, noting the consequences of this reporting. We would like to further understand the rationale, and benefits for publishing companies' names and R&D expenditure information as they are currently unclear. A comprehensive education and awareness program to ensure that any changes to the incentive are well understand is also required.

The innovative pharmaceutical sector will be impacted differently depending on how the measures, or package, were to be implemented. Therefore further information (including data and modelling) for different sectors should be shared or released by the Department to help assist in determining the potential impact and consequences of these recommendations.

As identified by the Government through the National Innovation and Science Agenda, there is a need for further incentives to invest in the life sciences sector in Australia. The recently passed reductions in the incentive rate for refundable and non-refundable offsets to 43.5 per cent and 38.5 per cent respectively, and the subsequent release of the review report, has introduced uncertainty.

Whilst Medicines Australia is concerned with the potential unintended consequences that implementing Recommendations 4 and 5 may have on the biotechnology and pharmaceutical sector, we welcome the increased focus on collaboration between research organisations and industry, and the role that large organisations play in investing in R&D in Australia.

We would welcome the opportunity to work with the Department of Industry on alternative options that will support and better target the innovative pharmaceutical sector to optimise the enormous potential our sector has in the post resources environment.

Please feel free to contact me on (02) 6122 8501 or Elizabeth de Somer, Director of Policy and Research on (02) 6122 8525.

Kind regards

Milton Catelin

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Chief Executive

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