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SUBMISSION ON THE SECOND EXPOSURE DRAFT TAX LAWS AMENDMENT (RESEARCH AND DEVELOPMENT) BILL 2010

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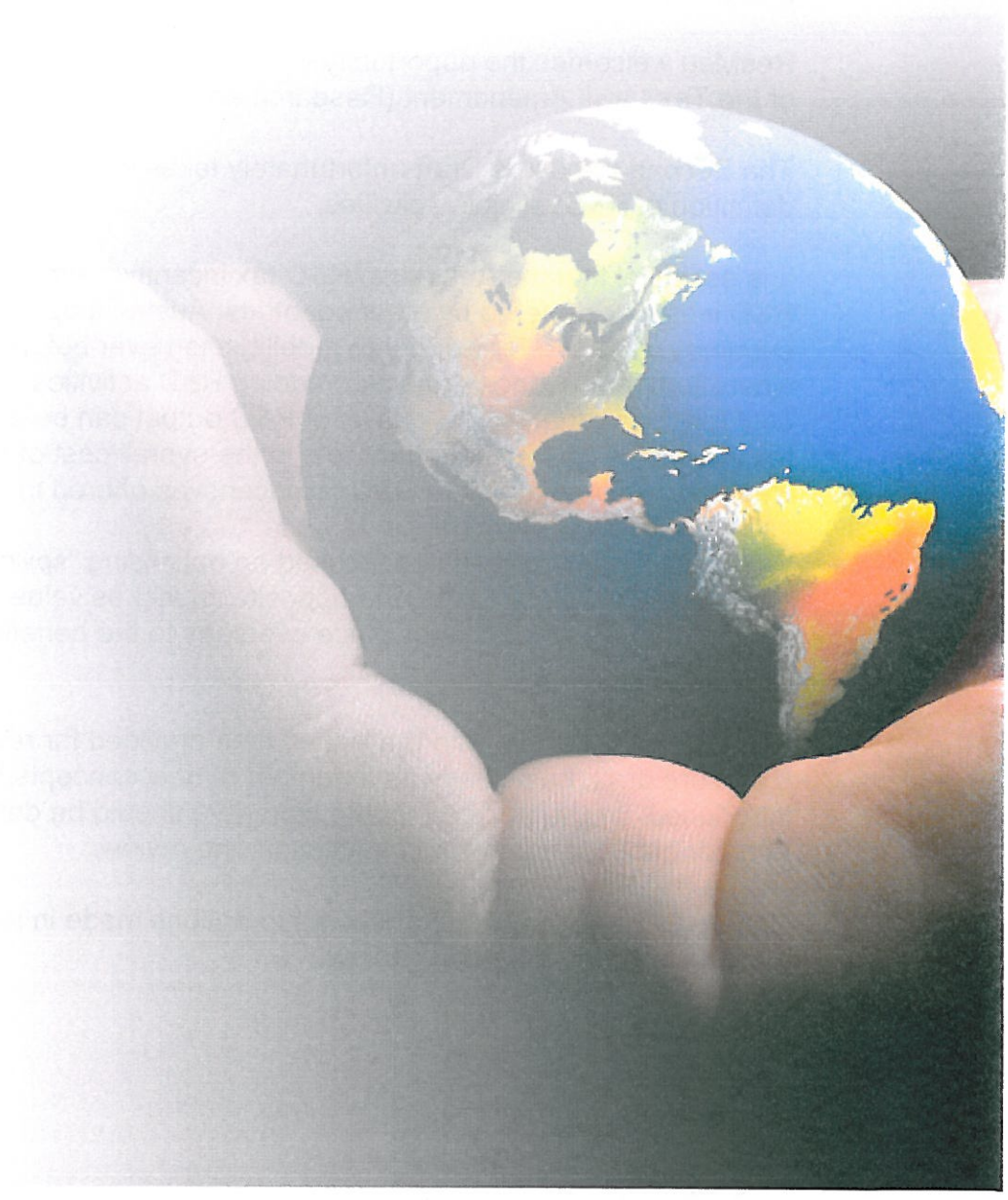

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INTRODUCTION AND EXECUTIVE SUMMARY

ResMed is a leading developer, manufacturer and marketer of products for the screening, treatment and management of sleep-disordered breathing (SDB) and other respiratory conditions. The company was founded in 1989 and since then has become one of the world's leading respiratory medical device manufacturers, exporting more than 90% of its production from Australia. ResMed is listed on both the Australian and New York Stock Exchanges.

Our focus is on continuous innovation to develop breakthrough products and technologies. As global leaders in sleep and respiratory medicine, we educate and raise awareness by sharing knowledge with patients, clinicians, industry professional and the broader medical community.

ResMed welcomes the opportunity to comment on the Second Exposure Draft of the Tax Laws Amendment (Research and Development) Bill 2010.

The Second Exposure Draft unfortunately takes a narrow approach to the definition of R&D, eligible activities.

It is essential that the Australian R&D tax incentive remains competitive with R&D incentives offered by other countries. Australia operates in a global economy, with greater workforce mobility than ever before. The decision of where to perform long–term value adding R&D activities is largely a factor of cost (providing the level of quality of R&D output can be achieved) and R&D tax incentives play an important role in the overall cost of performing R&D. ResMed regularly monitors R&D tax incentives offered in key jurisdictions.

Whilst the exposure draft has focused on optimising "spillover" effects, it is significantly at risk of having the opposite impact as value adding R&D either does not take place, or takes place overseas to the benefit of other economies.

ResMed is concerned with the limited time provided for review of the Second Exposure draft, particularly as a number of new concepts have been introduced. It is submitted that the start date should be deferred to enable an appropriate opportunity for consultation and review.

ResMed's key concerns and recommendations made in respect to the Second Exposure Draft are detailed below.

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ResMed Submission

1. s355-25 Core R&D Activities

- ResMed submits that the proposed definition of Core R&D activities will significantly increase uncertainly and takes an extremely narrow approach to R&D. The existing definition of core R&D activities should be retained.

  Whilst the definition has been reworded, there is still effectively a requirement that the activities contain high levels of technical risk and considerable novelty to be present, without explicitly using these terms.

  Subsection 355-25(a) achieves the high levels of technical risk requirement by stating that core R&D activities are those "whose outcomes cannot be known or determined in advance on the basis of current knowledge, information or experience but can only be determined by applying a systematic progression of work".

  Section 355-25(b) achieves the considerable novelty requirement by stating that the activities are "conducted for the purpose of generating new knowledge (including knowledge about the creation of new or improved materials, products, devices, processes or services)".

  Either of these requirements can independently result in activities that are highly beneficial to the Australian economy.

  An example might be a manufacturing process that has high levels of technical risk due to semi-automation, but is not considered to be innovative. The project itself might generate additional engineering positions as well as the subsequent Australia manufacturing activity if the project is successful.

  To require that eligible activities consist of <u>both</u> requirements in 355-25 (a) and (b) would mean many projects would not qualify, despite having significant "spillover" benefits. To deny these projects eligibility is likely to result in either the projects potentially not being undertaken, or untaken in a jurisdiction where R&D incentives are available.

- Subsection 355-25(b) significantly limits R&D activities to the generation of new knowledge and excludes the most common form of commercial R&D involving the application of knowledge or information. This narrow approach fails to recognise that applying new knowledge is the most commercial common source R&D and will severely limit eligibility of R&D activities for the R&D tax incentive. It also largely recognises the "research" element and not the "development" element of R&D which is inconsistent with the overall purpose of the R&D tax incentive.

- ResMed also submits that for greater certainty, R&D activities that require regulatory approval (e.g. from the Food and Drug Administration) should be automatically considered eligible R&D. Any new product requiring regulatory approval will have "high-levels of technical risk" until regulatory approval is obtained.

2. s355-35(1) Supporting R&D Activities

- The definition of supporting R&D activities has been limited to "activities undertaken for the dominant purpose of supporting core R&D activities" where an activity is on the exclusions list or directly related to the production of goods or services. The proposed definition is significantly restrictive and increases uncertainty due to the subjective assessment required and the existing requirements should be retained.

- The transition of the "exclusions list" to supporting R&D activities with a dominant requirement represents a significant shift in the application of the "exclusions list". The exclusions list has a potentially much broader impact for both core and supporting activities.

- Activities associated with complying with statutory requirements or standards could have an extremely limiting effect for medical industries which are governed by the Therapeutic Goods Administration (TGA) in Australia and Food and Drug Administration (FDA) in the U.S. A large number of project activities could be interpreted as being for the purpose of complying with these statutory requirements. Whilst these activities may be directly related to core R&D activities, there may be uncertainty as to whether the activities meet the dominant purpose test. Similarly, clinical studies are often undertaken specifically to enable approval of a product by a governing body such as the TGA or FDA and therefore could potentially be excluded.

- Pre-production activities would also be excluded under the proposed "exclusions list". This is not reflective of commercial reality as any R&D that results in the development of a product needs to be tested to ensure it can be manufactured. Pre-production activities such as trial runs are an essential part of the overall R&D project.

- Further compliance costs will arise by requiring claimants to separately register activities as either core or supporting activities. ResMed submits that the current requirement of registering R&D activities should be retained.

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ResMed would like to thank The Treasury for their consideration of ResMed's submission.

B. Sandercock

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ResMed