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General Manager
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The Treasury
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By e-mail: rdtaxcredit@treasury.gov.au

Dear Sir/Madam

Draft Legislation – "The new research and development tax incentive"

The following is Biota Holdings Limited (Biota)'s response to the exposure draft legislation and associated explanatory materials with respect to the new research and development (R&D) tax incentive.

Biota is a leading anti-infective drug development company, based in Melbourne and Oxford, UK. Biota has been responsible for a number of leading drug developments, including the discovery of Zanamivir, the first-in-class neuraminidase inhibitor for the treatment and prevention of influenza. This product is marketed around the world by GlaxoSmithKline as 'Relenza'.

Over the past decade, Biota has undertaken a number of R&D projects that has received support via the Federal Government's R&D Tax Concession program. Whilst Biota was unable to avail itself of the R&D Tax Offset (due to its large spend on R&D activities), the R&D Tax Concession has enabled Biota to undertake R&D activities in the knowledge that the financial risks associated with the development of new drugs are supported by the Federal Government. It is this support that has enabled Biota to maximise its investment in innovation and it is one of the reasons that Biota has been able to expand its R&D activities within Australia.

Biota understands the need for changes to be made to the current R&D Tax Concession legislation. Biota is in favour of the change to a tax credit plan as it aims to deliver benefit at times when innovative companies most need the assistance. When Treasurer Wayne Swan announced, as part of the 2009 Federal Budget, a scrapping of the old R&D Tax Concession program in favour of a 'better targeted, more generous, more predictable, less complex incentive for R&D activities', Biota welcomed the announcement and interpreted it as a real indication on the Government's continuing commitment to support innovation in Australia.

When the draft legislation was released, Biota was, to say the least, disappointed. The overriding concern is that the current wording of the proposed legislation appears to produce a result that fundamentally changes the nature of the R&D Tax incentive program. Instead of being more generous, more predictable and less complex, there is the real potential that genuine R&D activities (of the type conducted by Biota) will be deemed ineligible by falling foul of the Government's attempts to reign in expenditure under the current R&D Tax Concession program.

Biota is specifically concerned about the effect that the proposed changes will have on the following:

- The potential for Phased Testing associated with drug development to be classified as an ineligible R&D activity (either core or supporting);
- The Treatment of overseas R&D activities; and
- The application of the 'Expenditure not at Risk' provision and the retrospective assessment of eligibility.

We will explain our concerns on each of these matters.

Phased test as an ineligible R&D activity

In its draft form, the proposed legislation indicates that the following activity will not meet the definition of 'supporting R&D Activities':

- Activities associated with complying with statutory requirements or standards, including one or more of the following:
    - Maintaining national standards;
    - Calibrating secondary standards; and
    - Routine testing and analyses of materials, compounds, products, processes, soils atmospheres and other things.

As the Federal Government is no doubt aware, the development of a drug for use in the human population is a very structured process with a number of objectives, commencing with the discovery of a new compound capable of produce a desired outcome, followed by a series of investigative tests in order to ensure the discovered compound/drug works and does not produce an adverse effects to the intended recipient. The industry often refers to this as the trial and clinical trial process.

Most of the experimental trials start with some form of animal testing and, depending upon the results, progress to trials in humans. The trials will ultimately be broadened to include specific groups (e.g. children, elderly, different ethnic backgrounds, etc) to determine if the developed drug affects each group similarly and ensuring there are no adverse effects. Trials and experiments are conducted in order to meet minimum regulatory requirements both domestically and internationally prior to the drug being considered a success. These requirements by regulatory bodies require structured, standard routine testing in order to evidence the rigour of the scientific approach taken. Drug development cannot be considered successful if it has adverse effects on the target population and the results of these tests provide Biota, or its partner, with the data necessary to take the drug development to the next phase.

Biota is concerned that, based on the application of the proposed wording of the legislation as it stands, the Phased Testing associated with any drug being developed will be deemed an eligible R&D activity. As many of the experimental trials and tests conducted during Phased Testing include well structured and established tests, Biota is concerned that these activities will also not meet the necessary requirements to be considered as 'Core R&D Activities'. This is because Phased Testing use established technologies, methodologies and techniques that would potentially fail to meet the 'considerable novelty' requirement.

If the Phased Testing activities are considered as non-core activities and are ineligible to be considered as supporting activities (as per the conclusion upon application of the current wording of the legislation), the majority of the innovative R&D undertaken by Biota will be ineligible under the proposed R&D Tax Credit program.

It is Biota's view that this cannot possibly be the intention behind the revised legislation as it will direct drug development companies from Australia towards more supportive environments for innovation. **We suggest that the drug development trial and clinical trial process be clarified as qualifying expenditure in the final legislation.**

Eligibility of overseas R&D activities

Biota is concerned about the treatment of overseas R&D expenditure and the extent to which such costs are eligible to claim under the proposed R&D Tax Credit System.

Biota previously lodged an 'Application for Registration of Overseas Activities' with Innovation Australia for one of its programs. This application included the significant costs associated with clinical trials required to be conducted outside Australia. Despite the fact that Biota was able to demonstrate the activities could not be conducted in Australia and the net benefit Australia would receive from the project, the Application was rejected. Innovation Australia rejected the Application on the basis of the guidelines released subsequent to the initial application. These guidelines stated that if the overseas activities exceeded 50% of the total project (which for drug development projects, is quite common), the overseas activities will be deemed not to form part of a larger Australian project and will therefore fail to meet the criteria for consideration for overseas registration.

Most of the development cost will be born by a global pharmaceutical company in later stage clinical trials, yet Biota's cost does not qualify given that Innovation Australia's current view includes the spend of the pharmaceutical company in its assessment of the "50%". Biota is of the view that such an arbitrary 50% ruling does not take into account the commercial requirements of drug development whereby later stage clinical trials will almost always occur overseas, the benefit the project will provide the Australian economy and the fact that it will never enable any Australian drug development company to successfully access these provisions.

The release of the draft legislation does not clarify whether this 50% rule will be retained by the Board. The draft legislation (at subsection 28B(2)(c)) simply states that such activities must meet the requirements specified in the regulations made for the purpose of this paragraph (being with respect to activities to be conducted outside of Australia). This lack of clarity or guidance makes it difficult for Biota or any drug development company to clearly identify the extent to which expenditure on overseas activities will be eligible under the proposed regime. Biota is concerned that, in the absence of specific guidelines, the parties like Innovation Australia will default to the old 50% rule, a situation that significantly disadvantages drug development companies in Australia. **We believe that the legislation should better acknowledge the need for overseas trials to progress new drugs, rather than act as a penalty to the innovation commercialisation process.**

Expenditure Not At Risk

The standard operation practice with the pharmaceutical industry is to enter into a partnership arrangement as the discovered compound or drug enters Phased Testing. While the commercial terms of the partnership can vary, a common practice is for the partner (generally a large multinational pharmaceutical company with enormous financial resources) to cover the majority of the later stage Phased Testing costs. In return, the Australian company that discovered the initial compound and undertook early stage drug development (and who retains the intellectual property) receives progressive milestone payments and ongoing royalty payments if the drug is ultimately successful.

Section 355-405 of the draft legislation states that an R&D entity cannot deduct expenditure if, when it incurred the expenditure, it had received (or could reasonably have expected to receive) consideration as a direct or indirect result of the expenditure being incurred. If this situation occurs the entity can only claim so much of the expenditure that is in excess of the consideration. Subsection (3) then goes on to state that, in determining whether consideration has been incurred, the ATO can take into account anything that happened or existed before or at the time the expenditure was incurred and anything that was likely to happen or exist after that time.

Based on these definitions, Biota has grave concerns about the application of this section, specifically:

(a) the partnering arrangements that Biota enters into will have a consequential effect in that the revenue Biota receives through the sale of the drug (if successful) will need to be netted off against eligible R&D expenditure; and (if this is correct)

(b) Biota will not be able to determine if netting off is required until a number of years after the otherwise eligible R&D expenditure was incurred and incorporated into its Income Tax Return, effectively making the R&D Tax Credit System a retrospective program.

Given the broad meaning attached to the phrase 'consideration as a direct or indirect result of the expenditure being incurred', and the regulatory bodies' predisposition to interpret the legislation in a manner that restricts rather than enables R&D activities and R&D expenditure to be deemed eligible, Biota is of the opinion that there is the real risk that this section could be used as a means to reduce the level of eligible R&D expenditure claimable. At the extreme end of scale (albeit a very real concern), Biota may be forced to net off every dollar of R&D expenditure ever incurred (including preliminary and pure research in new compounds) against every dollar of revenue that it receives from royalties made via the sale of a successful drug product.

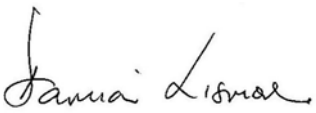
Biota is concerned that it is feasible that consideration in the form of royalty payments from Biota's partner may be considered as an indirect result of incurring the R&D expenditure. If this interpretation is correct, then Biota may be required to net these royalty payments off against expenditure it had incurred in the early drug development stage even though this expenditure could have been incurred a decade earlier. This outcome cannot be the intention of this legislation as it runs at odds with the Government's stated objectives**. We believe that the new legislation should provide absolute certainty and not leave companies potentially open to retrospective adjustments.**

Summary

Biota is engaged in innovation in drug discovery. We have a real and genuine concern that one or more of the three situations set out in this response will eventuate if the draft legislation is enacted in its current form. If this were to occur it would have an immediate and material impact on Biota and its ability to undertake R&D activities in Australia. We encourage Treasury to carefully consider these concerns as well as the submissions put forward by the larger Australia business community to ensure the requisite level of support is available to companies undertaking genuine R&D activities for the benefit of Australia.

If Biota can be of any further assistance in developing a world class R&D incentives program, or if Treasury would like to discuss these matters in person, please do not hesitate to contact me directly on (03) 9915 3721.

Yours sincerely



Damian Lismore
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