19 April 2010

Mr Paul McCullough
General Manager
Business Tax Division
The Treasury
Langton Crescent
PARKES ACT 2600

Dear Mr McCullough

Medicines Australia welcomes the opportunity to comment on the second exposure draft in relation to the new R&D Tax Credit program.

This is our third submission on the design and implementation of the new program. Our first was made in October, in response to the Consultation Paper, and our second was made in February, in response to the first exposure draft. The content of these earlier submissions, copies of which are attached for your reference, remains fully relevant to the current consultation process.

Medicines Australia greatly appreciates the Government's responsiveness so far to stakeholder concerns about the design and implementation of the R&D Tax Credit system. We are pleased that the second exposure draft is close to delivering a program that will likely boost commercial R&D in this country.

With respect to the second exposure draft, Medicines Australia strongly supports:

- the revised "Object" clause under section 355-5;
- the revised "meaning [of] core R&D activities" clause under section 355-25;
- the revised "excluded activities" clause under section 355-30; and
- the revised "expenditure not at risk" clause under section 355-40.

The revised "Object" clause eliminates the explicit reference to spillover benefits which appeared in the first draft of the legislation. This will reduce the likelihood of the legislation being misinterpreted, down-the-line, to mean that the tax credit is only intended to reward continuous incrementalism.

The revised "meaning [of] core R&D activities" clause clarifies one of the program's most important eligibility requirements and includes a new definition of "R&D activities" which better reflects the nature of commercial R&D, particularly as it occurs in the pharmaceuticals and biotechnology sectors in Australia.

The revised "excluded activities" clause states that the list of excluded activities will not apply to supporting R&D activities. We believe that this will reduce the risk of certain critical activities undertaken during the course of conducting clinical trials in Australia, such as "quality control" on experimental medicines which are administered to patients in clinical trials or "specialised routine medical care" given to patients during clinical trials, from being *a priori*

declared ineligible for tax benefits.

The revised "expenditure not at risk" clause clarifies that R&D undertaken in Australia on behalf of a foreign group member will be exempt from the expenditure not at risk provisions.

Medicines Australia also continues to strongly support:

- the removal of the requirement for ownership of resulting intellectual property to be held in Australia before a company can access the new tax incentive; and
- the Government's intention to provide comprehensive pre-claim guidance to claimants regarding the eligibility of their R&D activities.

That said, Medicines Australia remains concerned about the following elements in the revised legislation:

1. The current wording of section 355-35 suggests that supporting R&D activities will effectively be divided into two separate subcategories: those that are directly related to core R&D activities and those that are conducted for the dominant purpose of supporting core R&D activates. This will undoubtedly introduce significant (and unnecessary) complexity into the system and increase the compliance burden on companies. Such an outcome would contradict the Australian Government's intention of delivering a "more predictable and less complex tax incentive" and it could severely limit the number of companies that would consider the tax benefit as a cost-effective measure to increase R&D investment in Australia.

Therefore, Medicines Australia strongly recommends that only one of the two proposed tests for supporting activities be retained in the final legislation.

2. A feedstock rule has not been articulated at all in the revised legislation. Instead, section 355-460 simply states that "a feedstock adjustment is under consideration".

Consistent with our earlier submission, Medicines Australia does not believe that it is the Government's intention to treat experimental biopharmaceutical products that have been manufactured solely for the purpose of use in clinical trials as "feedstock output".

Even so, Medicines Australia strongly recommends that the final legislation explicitly recognise that:

- **investigational products administered to patients or otherwise used in the normal course of conducting clinical trials, as long as these products are not in themselves manufactured for commercial exploitation, are not subject to feedstock provisions;**

and

- **the resulting drug developed at the conclusion of a clinical trial is <u>not</u> deemed to be a direct output of the related R&D activity and therefore <u>not</u> subject to feedstock provisions.**

Medicines Australia believes that these remaining concerns must be addressed in order to make the new R&D Tax Credit system as effective and beneficial as possible. That said, and as stated earlier, the revised legislation for the new R&D Tax Credit program is much closer to delivering the kind of incentive that the Australian Government promised it would and the kind of incentive that would make Australia a more attractive location for global investment in R&D.

Medicines Australia remains fully committed to working with Government to make the new R&D Tax Credit system as effective and beneficial to R&D investment in Australia as possible.

We would be happy to meet with you to discuss this further if required.

Yours sincerely

Brendan Shaw
Chief Executive

Attachments
1. Medicines Australia Submission to Treasury on R&D Tax Credit Consultation Paper
2. Medicines Australia Submission to Treasury on R&D Tax Credit Draft Legislation

26 October 2009

Mr Paul McCullough
General Manager
Business Tax Division
The Treasury
Langton Crescent
PARKES ACT 2600

Dear Mr McCullough

Thank you for this opportunity to comment on the Treasury's consultation paper on the new research and development tax credit system.

Summary

Medicines Australia:

- strongly supports the consultation paper's first principle, that the "location of ownership of the resulting IP will not be relevant" to companies' access to Standard or Refundable tax credits;
- supports the consultation paper's second and third principles, creating a two-tiered system that would allow companies with a turnover of less than $20 million to be eligible for the Refundable tax credit and companies with a turnover of more than $20 million to be eligible for the Standard tax credit;
- strongly believes that companies should be able to utilise the Standard tax credit to offset other tax liabilities, prior to carry forward;
- supports the consultation paper's sixth principle, that the definition of eligible R&D activities be changed to involve both innovation and high levels of technical risk, provided that:
  - the definition of these concepts remains unchanged;
  - they are assessed at the project level; and
  - the Government recognises that biopharmaceutical R&D activities (including Phase I, II, III, and IV clinical trials) involve both innovation and high levels of technical risk;
- strongly opposes the proposal to split eligible R&D activities into core and supporting activities, as this would be wholly inappropriate given the nature of day-to-day activities involved in the process of conducting R&D and inconsistent with the new program's stated goals: simplicity, predictability and stability;
- believes that the current exception that up to 10 percent of eligible R&D may be conducted overseas should be retained, and that pre-approval for this exception should be removed;
- strongly believes that the current list of excluded activities should be amended to remove any reference to "research in social sciences, arts and humanities" as eligible activities;
- requests specific pre-claim guidance for the biopharmaceuticals industry.

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Introduction

Medicines Australia represents the innovative pharmaceuticals sector in Australia, which brings new medicines, vaccines and health services to the Australian market and which, in 2008, generated approximately $4 billion in export earnings for the Australian economy.

The sector also invests hundreds of millions of dollars each year on research and development. In 2008 alone, it invested over $860 million.

Unfortunately, maintaining this level of investment in Australia is becoming increasingly difficult.

Australia is home to some of the world's best researchers and healthcare professionals and boasts a world-class research infrastructure, a stable socio-economic environment, a strong intellectual property system and an efficient regulatory regime. These are all factors that have contributed to the strong growth of overall investment by the pharmaceuticals industry in Australia; indeed, between 1998 and 2007, the global pharmaceuticals industry invested over $4 billion in research and development in Australia, at a standardised annual growth rate of 19 percent.

But these factors alone are no longer sufficient to continue to stimulate investment growth. Not only has growth effectively stagnated, it has in fact declined in several important areas of investment. In clinical research for example, recent industry investment has declined by more than thirty percent.

Several reasons can be given for this. The most important among them is the rapid transformation of developing countries such as India, China, South Korea and Poland as viable destinations for long-term investment in research and development. In the recent past, these were largely ignored as potential candidates due to their lack of local expertise and health care infrastructure, their under-developed intellectual property systems and their fluid socio-political environments.

However, the global environment has changed. Medicines Australia would like to emphasise that for global biopharmaceutical companies, as countries like India and China continue to transform themselves, the practical relevance of Australia's "traditional" comparative advantages has started to decline dramatically.

Medicines Australia believes that any significant loss of international investment as a result of continued declining competitiveness will have a decidedly negative impact on the future of biopharmaceutical research and development in Australia.[1] This must not to be allowed to happen.

The introduction of the R&D Tax Credit system is an important step in the right direction.

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[1] In clinical research, for example, multinational biopharmaceutical companies fund more than 70 percent of all ongoing clinical trials in Australia. A substantial loss of investment in this area will lead to a loss of thousands of high-value jobs and it will necessarily diminish Australia's overall research capacity.

This new program will replace an outdated system that was unpredictable, complicated and generally unrepresentative of the nature of modern commercial pharmaceuticals research and development activities. It is not surprising that the R&D Tax Concession program – even after the introduction of the International Premium[2] – proved to be wholly ineffective in attracting significant additional investment to Australia from global biopharmaceutical companies. [3]

In announcing the new program, the Australian Government has acknowledged that tax policy is an increasingly important area of competition between Australia and its global competitors, including several emerging economies. As the latter improve local research infrastructure, improve the quality of the local workforce, and, in general, close in on Australia's traditional comparative advantages, it is considerations such as the difference in relative tax burdens and the availability (and the relative competitiveness) of tax incentives that will help to influence global decisions on the placement of investment in research and development.

Of course, whether or not the new system is ultimately effective in influencing global decision makers depends entirely on its precise design and on the method of its implementation.

Design Principles

1. Principle 1

Medicines Australia strongly supports the consultation paper's first principle, that the "location of ownership of the resulting IP will not be relevant" to companies' access to Standard or Refundable tax credits.

This principle reflects the rapidly evolving nature of commercial research and development into an increasingly global enterprise. This is true both for the pharmaceuticals industry[4] and for most other knowledge-based industries.

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[2] As it was introduced in late 2007, the International Premium R&D tax concession was only beginning to have an impact. However, as it equated to only 4.5 cents support per dollar of R&D expenditure, the rate was seen as too low to attract the attention of multinational companies to domicile their R&D in Australia.

[3] This position was affirmed by the Pharmaceuticals Industry Strategy Group, which was formed in June 2008 by Senator Kim Carr, the Federal Minister for Innovation, Industry, Science and Research, to "develop a plan to attract investment in R&D, clinical trials and manufacturing activity in Australia." The Group's members were drawn from all segments of the bio-pharmaceuticals value chain, including leaders from the pharmaceuticals, biotechnology and generic medicines industries and senior union and Government representatives. In its final report to Government in December 2008, the Group stated that current R&D tax incentives in Australia are not "a strong incentive for investing in research and development in Australia."

[4] It is common practice for basic and preclinical research to occur in one country – for example, in the United States or India – and for product development through clinical research to occur, often simultaneously, in more than a dozen countries around the world.

This principle also reflects the enormous benefits that Australia derives from foreign investment in local research and development activities. For example, in a recent survey[5] of over 170 prominent principal investigators, researchers and study coordinators involved in clinical research in Australia, it was noted that foreign investment in clinical research alone not only supports thousands of high-value jobs in Australia, it is also directly responsible for:

- enhancing the uptake of new evidence into everyday clinical practice;
- improving the standard of care, and therefore, health outcomes;
- providing funds to supplement academic research projects;
- providing practical experience to researchers and study staff;
- providing global recognition for Australian researchers; and
- helping to retain researchers in the Australian health system.

In short, the consultation paper's first principle recognises the inherent value of the research and development process itself, notwithstanding the eventual "location" of ownership of the resulting intellectual property.

In this regard, Medicines Australia also supports the retention in the new scheme of the exception to the 'on own behalf' rules that currently exist for foreign-owned research and development projects. This exception should remain whether such activities are reimbursed by an overseas related entity or not.

2. Principles 2 and 3

In general, Medicines Australia supports the consultation paper's second and third principles, that companies with a turnover of less than $20 million be eligible for the Refundable tax credit and that companies with a turnover of more than $20 million be eligible for the Standard tax credit.

However, we note that in paragraph 35, with reference to the Standard tax credit, the consultation paper notes that "if a company's tax liability is zero, unused offset amounts cannot be applied to reduce other tax liabilities (such as GST)."

Medicines Australia firmly believes that in its proposed form, the 40 percent Standard tax credit will not influence a local subsidiary company's "above-the-line" profitability. This would significantly constrain a company's ability to leverage this opportunity to attract new investment from headquarters, despite the possibility that the proposed incentive may be more attractive "on paper" in Australia than in other competing jurisdictions.[6]

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[5] This survey was commissioned by the Research and Development Taskforce of the Pharmaceuticals Industry Council (www.pharmacouncil.com.au) and administered through the NSW Clinical Trials Business Development Centre, with the stated aim of understanding the value Australia derives from involvement in industry funded clinical research as judged by investigators and study staff and to clarify direct and indirect spill over benefits. Results of the survey are available at www.clinicaltrials.org.au.

[6] Medicines Australia conducted a survey of member companies in February 2008, requesting information on the current or expected utilisation of the 175 percent International Premium tax concessions. The survey showed that 70 per cent of member companies did not or would not utilise the tax concession because it would fail to have an impact on their operating profits.

On the other hand, if the new Australian tax incentive were to have an "above the (profit) line" impact, it would be significantly more likely to influence global investment behaviours. This is because tax incentives are commonly much more likely to be helpful in attracting additional investment in research and development if they have an impact on development costs and revenue margins.

Medicines Australia recommends that there be openness and willingness on the part of the Australian Government to consider options that it has so far discounted and in good faith [and with the common aim of increasing investment], negotiate with industry to arrive at a resolution that creates a more effective incentive.

For example, Medicines Australia recommends that allowing companies to apply offset amounts to reduce, at least in part, other tax liabilities (such as fringe benefits tax or general sales tax) may be one way to ensure that the Standard R&D tax credit can impact a firm's "above-the-line" profitability. But this option is categorically rejected in the consultation paper without a compelling rationale.

More specifically, the Government may consider one of the following two options with respect to the Standard tax credit:

- Option 1: Allow companies to fully utilise offset amounts against all taxes, but cap any claims at 25 percent per year if the company is in a tax loss position. Under this option, the credit can be utilised to offset liability against other taxes such as fringe benefits tax. However, only 25 percent of a particular claim would be claimable in any one year, with any excess being carried forward to be offset in the future in a similar manner if the company continues to be in a tax loss position. In essence the company will ultimately be able to fully utilise the credit over a four year time frame either against income tax or other taxes.

- Option 2: Allow companies to utilise up to a maximum of of 33 percent of a claim to offset against other taxes if the company is in a tax loss position. Under this option the remaining 67 percent could be treated as proposed in the consultation paper.

Medicines Australia would like to note that:

One company said, "This [International Premium] provides a saving in tax paid/payable and falls below the profit line on which the local entity is evaluated. The International Premium may assist in bringing some R&D projects to Australia but as the tax concession is below the profit line tax saving, it is not taken into account when evaluating the performance of the local entity. Unfortunately, this means we cannot leverage the Premium concession as effectively as we would like to."

The fact is that most Australian pharmaceutical companies are subsidiaries of multi-national corporations. For these companies, tax incentives must affect "above-the-line" profitability to influence global investment behaviour – specifically, the financial impact of incentives must be recordable as part of operating [rather than net] revenues and profits.

- under both options the underlying tax revenue position is neutral for the Government; and
- The Commissioner of Taxation is already empowered to ensure that there are economic reasons for a company being in a loss position (e.g. transfer pricing rules). Under Option 1, the credit cannot be used in full until the fourth year and as such the Commissioner has sufficient time to pursue companies through a normal audit program. Under Option 2, the 33 percent represents the tax concession portion of the credit and in this regard it is not an economic loss. Accordingly linking it to treatment akin to a tax loss is not justified.

Medicines Australia considers that structuring the Standard credit to be used against taxes other than income tax is a major consideration for subsidiaries of multinational biopharmaceutical companies in Australia. It will make the credit more visible globally and thus help attract further investment from global headquarters.

At this stage we do not contend that these are the only available options. We are, however, contending that these and other options must be seriously considered in order to make the new tax incentive as effective as possible.

Moreover, in relation to making the accounting treatment of R&D tax credits "above the line", we also request that the Government raise this issue with the International Financial Reporting Standards authorities, as we appreciate that this cannot be achieved by local authorities alone.

3. Principle 4

In general, Medicines Australia supports the consultation paper's fourth design principle, that "legislation for the new R&D tax incentive will provide support for the scheme's efficient and effective administration".[7]

However, in paragraph 47, the consultation paper notes that the new R&D tax incentive will require companies to distinguish between core and supporting research and development activities. This concept is repeated as the paper's seventh design principle, and a related question is raised on page 11.

Medicines Australia strongly opposes the proposal to split eligible research and development activities into core and supporting activities.

We believe that such a change – especially when associated with the introduction of variable rates of apportionment – is wholly inappropriate given the nature of day-to-day activities involved in the process of conducting research and development. It is also inconsistent with the new program's stated goals: simplicity, predictability and stability.

Some industries, including the pharmaceuticals industry, undertake non production trials to support hypotheses. Often the time cycle is determined by

[7] In a submission to the Treasury's Review of Australia's Future Tax System, Medicines Australia argued that the Government can significantly improve Australia's competitiveness by implementing a system of tax incentives that minimises compliance costs and maximises the (administrative) efficiency, efficacy, utility and the uptake of such incentives.

events completely unrelated to the time involved in setting up the trial or analysing the results. Costs then can be completely disproportionate to those associated with the "core" work. Yet both are parts of the whole program. Therefore, the issue of cost relativities is inappropriate.

If one of the Australian Government's aims is to keep the program "revenue neutral", it would be far better to clearly define those activities it would like to exclude from program eligibility and perhaps even set a specific limit on indirect costs such as overheads that can be linked to salary expenditure.

In paragraph 45, the consultation paper states that the Innovation Australia Board will continue to assess whether an activity is eligible R&D. Earlier this year, Innovation Australia undertook consultations on revised guidelines for developing R&D Plans. In its submission to AusIndustry and Innovation Australia, Medicines Australia supported the initiative to streamline and simplify these guidelines, in order to reduce the burden of compliance and encourage the (appropriate) utilisation of tax incentives. We believe that this remains an important initiative, and that it should be concluded (and the Guidelines for preparing R&D Plans updated) before the implementation of the new system in July 2010.

We also believe that comprehensive pre-claim guidance[8], as suggested in the paper – perhaps in the form of formal, non-binding pre-filing "opinions" by the Australian Taxation Office – will go a long way to eliminate some of the uncertainty associated with filing complex claims; this would give the incentive additional predictability and, therefore, enhance its effectiveness.

4. Principle 5

As a policy goal, Medicines Australia supports the consultation paper's fifth principle, that tax incentives should aim to encourage companies to conduct research and development that is "in addition to what otherwise would have occurred" and that "provides spillovers […] that are large relative to the associated subsidy."

Although this is an appropriate long-term policy objective, Medicines Australia believes that the Government must be very careful that, through the implementation of the new R&D tax credit system (including through downstream audits), it does not (advertently or inadvertently) create post-hoc restrictions that effectively only reward incrementalism.

In the 2008 survey of Medicines Australia member companies on the current or expected utilisation of the 175 percent International Premium tax concessions, one member responded that "This [International Premium] is based on incremental expenditure above a three-year rolling average compared to the Pharmaceuticals Partnerships Program which is based on a three-year fixed base. As such, the overall R&D expenditure would have to be much higher under the International Premium in order to achieve a similar

[8] Guidelines specific to the pharmaceuticals industry, as currently found in the Guide to the R&D Tax Concession, should be retained and updated.

entitlement. Given this expectation of constant incremental change, there will no impact on the success of our Australian subsidiary from this concession."

In the past, governments and governmental agencies (notably the Productivity Commission) have argued that public assistance for commercial activities, including commercial research and development activities, should "induce new activity" rather than activity "that would have occurred anyway".

Medicines Australia believes that emphasis on constant "new" investment contradicts the short- to medium-term aims of most commercial enterprises including the pharmaceuticals industry in Australia, which include maintaining existing capacity.

Furthermore, emphasis on "new" investment or "new" activity assumes that there is an intrinsic motivation for companies to maintain current investment levels in Australia. This is categorically untrue. Investment trends are dynamic, and recent trends in Australia are not positive. In fact, the entire "comparative advantage" / "global competitiveness" argument rests on the assumption that, without internationally competitive support, even existing investment will be diverted to more cost-effectiveness locations.

In most industries, including the pharmaceuticals industry, the immediate aim is to halt the decline in investment in Australia.

5. Principle 6

Medicines Australia supports the consultation paper's sixth principle, that the definition of eligible research and development activities be changed to involve both innovation and high levels of technical risk.

This change represents a significant tightening of the eligibility criteria, and although it will undoubtedly lead to a significant reduction in the number of activities claimed by claimants in general. However, Medicines Australia believes that the change from an 'or' test to an 'and' test (requiring research and development activities to involve both innovation and high levels of technical risk to be eligible) should allow the Government to achieve its objective of providing Australian firms and the community with additionality and spillover benefits.

Therefore, we support this change, provided that the Government recognises that the majority of research and development activities undertaken by biopharmaceutical companies in Australia (including Phase I, II, III and IV clinical trials) do involve both innovation and technical risk.

In addition, we recommend that the current definition of "innovation" and "high levels of technical risk" remain unchanged, as these concepts are well understood by companies.

Finally, we recommend that the 'innovation' and 'high levels of technical risk' criteria should apply at the project level and not at the activity level. This would ensure that all relevant research and development activities remain eligible.

6. Principle 7

Medicines Australia strongly recommends that "supporting" research and development activities should not be limited in any way. Savings from the proposed change to the definition of eligible R&D activity, and the discontinuation of the 175% Premium and International Premium concessions will provide sufficient cost reductions to Government to offset any additional cost of introducing the Standard and Refundable tax credits. In other words, these measures will achieve the revenue neutrality desired without requiring limitations to support activities.

Furthermore, besides the significant compliance burden in distinguishing between "core" and "supporting" R&D, we believe there are issues with the options proposed, as set out in our response to Design Question 4 below.

Design Questions

Question 1: Should there be any exceptions to the general rule that eligible R&D activity must be conducted in Australia?

Response: The current exception that up to 10 percent of eligible R&D may be conducted overseas should be retained. We also recommend that the "cap" be set at an automatic level and that pre-approval not be required under the new program.

Australian-owned biopharmaceutical companies are increasingly conducting clinical trials overseas, including to meet registration standards of overseas regulatory agencies. Even so, Australia remains and will remain the overwhelming beneficiary of this research – even if it is conducted overseas – through downstream manufacturing and intellectual property gains.

Question 2: How should the new R&D tax incentive treat R&D expenditure that is currently deductible at 100 percent?

Response: Medicines Australia questions why certain deductions were non-enhanced under the current *Concession* scheme. For example, why can a company acquire the services of a person skilled in a particular field and claim their salaries and on-costs at a concessional rate, yet if that company purchased the outputs of such a person's work as "core technology" to facilitate further development, not only is the cost of that technology denied a concessional rate, but it is also subject to "apportionment" treatment?

We believe that there should be no differentiation on rates of enhancements. If such items are seen as directly related expenditure, they should be put in the same basket as all the other recognised directly related expenditures.

Then, as a second step, the Australian Taxation Office may decide which items, if any, to exclude.

Dual rates simply result in complexity.

Question 3: Should payments made to associate entities only be eligible for the new R&D tax incentive where they are paid in cash?

Response: Medicines Australia agrees that payments made to associate entities should only be eligible for the new R&D tax incentive where they are paid in cash.

Question 4: Should supporting activities:
(a) be capped as a proportion of expenditure on core R&D?
    (i) If so, what would be the appropriate proportion?
(b) only be eligible where they are for the sole purpose of supporting core R&D activity?
(c) exclude production activities or dual role activities?
(d) only be eligible on a net expenditure basis?
(e) attract a lower rate of assistance than core R&D?
    (i) If so, what would be the appropriate rate?

Response: Although we do not agree that "supporting" research and development activities should be subject to limitations, in response to the options set out above and specific to the pharmaceuticals industry, we make the following comments:

(a) Capping

If classified as "supporting", a large amount of presently eligible research and development expenditure might then be subject to reduced benefit under the proposed "capping" of expenditure on "supporting" activities.

Given the proportion of "supporting" activities will vary from project to project, it will be impossible to predict in advance the benefit under the R&D tax credit for any given project under this option.

(b) Sole purpose / Dual-role activities

Many of the activities undertaken by biopharmaceutical companies reflect activities which serve multiple purposes. For example, clinical trials are conducted in order to:

- generate new knowledge concerning a drug;
- generate data for the purposes of seeking registration; and
- provide a treatment option to patients who have exhausted other treatment options.

Whilst there may be a multiple purposes, this does not mean that the process of drug research and development is not innovative or that it does not involve a high level of technical risk.

(c) Net expenditure

This option presents a major concern for biopharmaceutical companies; it would essentially act as a disincentive to the successful completion of an R&D project. This is counterintuitive, because whilst the potential benefit to the

company of successful drug development is great, the spillover benefits to the community from successful development are immense and include:

- new medical treatments;
- international prestige;
- export revenue (for Australian-based successes); and
- publication of scientific breakthroughs, ensuring that additional research can build on the success of initial breakthroughs.

(d) Lower rate for supporting activities

This option does not remove the administrative burden of the (arbitrary and subjective) process of individually analysing activities for their status as "core" or "supporting". Should this be implemented however, we recommend a 37.5% rate of support, in line with the existing R&D Tax Concession.

Question 5: Should the current list of activities excluded from being considered core R&D be:

(a) amended in any way?
(b) extended to exclude activities from being considered supporting activities?

The innovative pharmaceuticals sector draws on all fields of research, including the social sciences, to address scientific questions that will be part of the understanding how disease works and the types of health interventions that governments can make to improve health outcomes for their citizens.

Medicines Australia strongly believes that the global competitiveness of the Australian pharmaceuticals industry would be greatly enhanced if incentives are applied to the full range of research that will be required throughout a product's lifecycle.

Australia's existing income tax system takes a narrow interpretation of science and specifically excludes research in the social sciences and the humanities. This is in stark contrast to the definition of R&D used by the OECD, which is:

"creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture, and society, and the use of this stock of knowledge to devise new applications."

The exclusion of social sciences places Australia at a disadvantage in the growing fields of science, including:

- epidemiology;
- pharmacoepidemiology;[9]

[9] Epidemiology is the study of the incidence and distribution of diseases, and their control and prevention within a given population. Pharmacoepidemiology is the study of the utilisation and effects of drugs in large numbers of people, particularly adverse effects. Both epidemiology and pharmacoepidemiology studies advance our scientific knowledge by identifying factors impacting public health related to a specific disease. These studies use systematic investigation methodologies with unknown outcomes.

- health economics research (including health technology assessment);
- outcomes research;
- cost-effectiveness; and
- pharmacoeconomics.[10]

Exclusion of research in the social sciences and humanities as eligible expenditures under the new R&D Tax Credit program will impede the industry from exploiting the developing expertise at Australian universities (and internally in companies themselves) in drug use and health outcomes studies (pharmacoepidemiology), post-marketing surveillance, and pharmacoeconomics, which are all key elements for making Australia a more attractive place for investment in new areas of scientific innovation.

Medicines Australia contends that studies in these new areas of science meet the same essential tests that all scientific qualifying work demonstrates: activities that are systematic, investigative and experimental that involve innovation and technical risk and are done for the purpose of producing new knowledge or improvements. And these areas of science are gaining ever-increasing importance. Governments here and abroad are demanding that such studies be completed to assist them in their decision making on approving new therapies.

Therefore we recommend that the current list of excluded activities should not be extended to supporting activities and that it is amended so that research in social sciences, arts and humanities may be eligible for the R&D Tax Credit.

Conclusion

Medicines Australia's recommendations concerning general corporate tax policy stem from a basic belief that a globally competitive taxation environment is absolutely critical to the viability of all aspects of Australian biopharmaceuticals industry; from research and development to the manufacture and sales of innovative products and services. In turn, the global flow of investment dollars is more dynamic now than ever. The change has been, and will continue to be rapid, and Australia will continue to face fierce competition from other nations (particularly in Asia) as the destination-of-choice for investors. If Australia fails to change rapidly and radically also, it will be left behind. The Government must ensure that we can at least retain and continue to attract foreign investment in innovative and knowledge-intensive industries, in which Australia can credibly hold a long-term competitive advantage. Tax reform is a vital component of the policies needed to sustain Australia's long-term competitive advantages in such industries.

[10] Health economics is the formal analysis of direct and indirect costs and benefits that are a consequence of a health care intervention, program or strategy. Outcomes research is the scientific study of the effects of medical care on individuals and society focusing on the effect of therapeutic treatments on endpoints such as survival, quality of life, satisfaction with care and cost. Pharmacoeconomics is concerned with the impact of pharmaceutical products and services in individuals, health systems and society, as well as the description and analysis of the costs. These three branches of science advance our scientific knowledge by proving or disproving a particular therapy's benefit to society. The cost effectiveness of these therapies remains unknown until such studies are performed.

Medicines Australia congratulates the Australian Government for taking the important step to improve and update tax-based incentives designed to support research and development activities in Australia. The new system, if designed and implemented properly, has the potential to make Australia one of the most competitive locations for such investment.

We caution the Government that if the new Tax Credit system requires companies to distinguish between core and supporting activities, this would not simplify the system but rather add a tremendous compliance burden on companies, the cost of which could well be higher than the benefit gained.

Moreover, without an above-the-profit-line impact, regardless of how competitive it may look “on paper”, the new program will not be able to achieve its aim of increasing overall investment in research and development in Australia. This is why it is so important for the Government to be open to good faith negotiations with industry, to find solutions that achieve the goals of all parties involved.

It is important that the new system achieves its stated objectives. Medicines Australia is fully committed to working with Government to find ways to ensure that it is as effective as possible.

Thank you again for the opportunity to contribute to the design of the new R&D tax credit. Medicines Australia looks forward to active and ongoing dialogue with Government on all aspects of tax policy in Australia.

If you have questions about views expressed in this submission, or if you require further information, please do not hesitate to contact Deborah Monk, Director of Innovation & Industry Policy at Medicines Australia, at: deborah.monk@medicinesaustralia.com.au or at 02 61228500.

Yours sincerely,

Brendan Shaw, B.Econ (Hons.) PhD.
Acting Chief Executive

5 February 2010

Mr Paul McCullough
General Manager
Business Tax Division
The Treasury
Langton Crescent
PARKES ACT 2600

Dear Mr McCullough

Medicines Australia welcomes the opportunity to comment on the Exposure Draft in relation to the new R&D Tax Credit program.

This is Medicines Australia's second submission on the implementation of the R&D Tax Credit program. Our first was made in October, in response to the Treasury's consultation paper. The content of that submission, a copy of which is attached for your reference, remains fully relevant to the current consultation process.

Medicines Australia would like to take this opportunity to once again congratulate the Government for taking an important step to improve and update tax-based incentives designed to encourage commercial research and development activities in Australia. We remain confident that the new system, if designed and implemented properly, has the potential to make Australia one of the world's most competitive locations for such investment.

Medicines Australia would like to reiterate our strong support for the removal of the requirement for ownership of resulting intellectual property to be held in Australia before a company can access the new tax incentive. This correctly reflects the rapidly evolving nature of commercial research and development into an increasingly global enterprise. It also recognises the inherent value of the research and development process, notwithstanding the eventual location of ownership of the resulting intellectual property.

In addition, we strongly support the Government's intention to provide comprehensive pre-claim guidance to claimants regarding the eligibility of their research and development activities. This could significantly assist companies to limit the risk of a potential failure to receive tax benefits for expenditure on research and development activities.

Whilst we commend the Government's intent to deliver a "more generous, more predictable, and less complex tax incentive", we do not believe the legislation achieves this intent in its present form. We have the following concerns about the draft legislation.

1. Exclusions List

The draft legislation extends the existing Excluded Activities list (via the repurposing of the former s73B(2C) of the Income Tax Assessment Act 1936 (ITAA 1936)) to apply to both core and supporting activities. It states that expenditure on a number of activities (listed under subsection 355-35(2) of the Exposure Draft), including the following activities (amongst others), will not be eligible for tax credits under the new program:

- **quality control**;
- pre-production activities including demonstrating commercial viability, tooling up and **trial runs**;
- **routine collection of information**, except as part of another activity that is an R&D activity; and
- 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 analysis of materials, components, products, soils, atmospheres and other things**.

Although we do not believe that it is the Government's intention to exclude activities involved in conducting clinical trials from eligibility, Medicines Australia believes that language in the draft legislation (particularly those words that appear above in bold) potentially eliminates all clinical trials from eligibility as they are performed for in connection with regulatory requirements of the Therapeutic Goods Administration for the registration of prescription medicines.

The need for the exclusions list is reduced by the impact of the introduction of the 'dominant purpose' test for support activities. That is, where activities on the exclusions list are not for the dominant purpose of supporting core R&D activities, they will not be eligible. In instances where they are carried out for the dominant purpose of supporting core R&D activities, they will be an integral part of the process and should be eligible as supporting R&D activities.

Consider for example, manufacturing medicinal products for clinical trials which requires thorough quality checks before such products are administered to patients. Quality control in this circumstance would be an inextricable part of the overall research and development activity. As such, Medicines Australia strongly argues that quality control during the production of investigational medicinal products, by itself, is a legitimate supporting research and development activity, one that should be [potentially] eligible for tax benefits under the new program.

2. Augmented Feedstock Provisions

Here again, we did not believe that the intention of the draft legislation would be to treat experimental pharmaceutical products that have been manufactured solely for the purpose of use in clinical trials as "feedstock output". However, the current language does not make it clear that such materials are in fact excluded from having an impact on eligible (i.e.,

claimable) expenditure on pharmaceutical research and development activities.

For example, where a company conducts new research on a medicine that has previously been registered (such as an approved lung cancer medicine which is being trialled to determine effectiveness in bowel cancer), then this medicine has a market value and will be caught by the augmented feedstock provisions notwithstanding the fact that the company will not receive any payment for the use of this drug in the new research.

With respect to both the exclusions list and augmented feedstock provisions, it is vital to avoid confusion among claimants and assessors. Unclear legislation that is open to interpretation would not only undermine one of the new program's central objectives, which is to deliver a predictable benefit to companies conducting R&D in Australia, but it could also (we believe unintentionally) exclude large portions of biopharmaceutical research and development in Australia from program eligibility.

Submission Recommendation

Medicines Australia strongly recommends that the final legislation **explicitly** recognise that:

- activities that are undertaken during the course of conducting clinical trials, and that would otherwise satisfy the requirements of being either core or supporting R&D activities, are not *a priori* excluded from eligible R&D activities; and
- investigational products administered to patients or otherwise used in the normal course of conducting clinical trials, as long as these products are not in themselves manufactured for commercial exploitation, do not constitute a "feedstock output".
- The resulting drug developed at the conclusion of the trial process is <u>not</u> deemed to be a direct output and therefore subject to the augmented feedstock provisions.
- Furthermore, in the event that the proposed augmented feedstock provisions remain in place, we request that additional activities such as labour and plant depreciation are quarantined.

3. New Definition

The requirement for 'considerable novelty' in place of 'innovation' further restricts eligibility of potential claimants, whilst also increasing uncertainty by replacing a well understood and clearly defined term. Innovation is a familiar and well understood term and is similarly well recognised both internationally and in Australia. There will also be subjectivity and thus further complexity in how 'considerable' is measured. This shift in definition seems to favour the early stage basic R&D common in academic settings over innovation closer to the commercialisation phase.

Submission Recommendation

We therefore submit that the term 'considerable novelty' should be removed and the term 'innovation' be inserted into the legislation.

4. Expenditure Not At Risk

Section 355-405 of the Exposure Draft sets out that where expenditure is not at risk (for example, if there is guaranteed return) then the R&D entity is not eligible for a notional R&D deduction.

Our concern is that unlike the provisions for the existing International Premium Concession and the new "on own behalf" rules set out in the Exposure Draft, there is no clarification that R&D undertaken in Australia on behalf of an foreign group member will be exempt from the expenditure not at risk provisions.

This is important as transfer pricing rules dictate that if a party carries out R&D activities for another group member then the party for whom the R&D activities are being carried out must effectively pay an arm's length amount for those services.

Accordingly, there is no point in allowing foreign members of a group to own intellectual property arising from Australian R&D activities unless the expenditure at risk rules are relaxed in such instances. Failure to do so will eliminate R&D tax credit claims for R&D undertaken in Australia by foreign group members.

Submission Recommendation

We would suggest that an additional subsection is set out under section 355-405 to confirm that where the R&D entity is carrying on R&D activities for a foreign group member, the expenditure at risk provisions do not apply to the R&D entity carrying on R&D activities in Australia.

5. Objective

The draft legislation states that the objective of the new Tax Credit system is to "encourage industry to conduct R&D activities that might otherwise not be conducted because of technical uncertainty, in case where the knowledge gained is likely to spillover to the benefit of the wider Australian economy."

As noted in our first submission, past experience dictates that governments should be especially careful about institutionalising the concepts of "spillovers" and "additionality". Although these are appropriate policy objectives, their explicit inclusion in the objectives of the legislation creates the danger that the new R&D Tax Credit system will (either advertently or inadvertently) only reward "incrementalism". Clearly, this would be contrary to the short- and medium-term aims of most commercial enterprises, including the

pharmaceuticals industry in Australia, which include maintaining existing capacity.

Furthermore, Medicines Australia would like to reiterate that an emphasis on "activities that might otherwise not be conducted due to technical uncertainty" continues to wrongly assume that there is an intrinsic motivation for companies to maintain existing R&D capacity in Australia and/or bring new R&D investment to Australia. While it is true that companies have [commercial] incentives to invest in R&D to improve their competiveness and / or ongoing profitability, it is by no means certain that the same incentives will drive companies to locate their R&D activities in Australia. As the Government's objective is to increase R&D investment *in Australia*, it should be noted that the "commercial motivation" argument may be entirely irrelevant. Put differently, *so long as they conduct research and development*, the profitability and competitiveness of modern firms does not depend on where they conduct R&D. To ensure that Australia captures as much of the global research and development investment flow as possible, the legislation must reflect that its primary objective is to attract investment which could just as easily have gone to competitor countries. This may be done simply by deleting a few words from the draft legislation as noted above.

Submission Recommendation

Medicines Australia strongly recommends that the stated objective of the new program should finish at the word "activities", that is, the objective should only be to "encourage industry to conduct R&D activities", without any further qualifications.

6. Above the line

Medicines Australia remains extremely concerned about the apparent inability of the new tax credit system to have an above-the-profit-line impact for companies claiming non-refundable R&D tax credits. As noted in our previous submission, regardless of how globally competitive the new program looks on paper, it will not be able to achieve its aim of increasing overall investment in R&D in Australia without having the value of the tax credit considered in company R&D investment decisions. Generally, a company makes these decisions on the basis of above-the-line items.

Submission Recommendation

It continues to be extremely important for the Government to be open to good faith negotiations with industry and the relevant accounting bodies to attempt to find solutions that help achieve the goals of all parties involved.

7. Core versus Supporting Distinction

Medicines Australia strongly recommends that the Government reconsider its decision to require companies to distinguish between core and supporting activities. This would certainly not simplify the system; in fact it significantly increases the complexity for companies. The determination of whether an activity is core or supporting would be a subjective process and would add a

tremendous compliance burden on companies, the cost of which could well be higher than the benefit gained through tax credits.

Submission Recommendation

Remove the requirement to report activities annually, split between core and supporting activities.

Medicines Australia is fully committed to working with the Government to make the new R&D Tax Credit system as effective as possible and we look forward to active and ongoing dialogue with the Government on all aspects of the system's design and implementation. We would be happy to meet with you to discuss this further if required.

Yours sincerely,

Brendan Shaw
Chief Executive

Attachment: Medicines Australia Submission to Treasury on R&D Tax Credit Consultation Paper