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Dear Tony

Please find attached ITR's submission in response to the draft research report evaluating the Pharmaceutical Industry Investment Program. The submission covers five main areas:

1. Relaxation of the R&D Tax Concession
2. Changes to the R&D Tax Concession versus a targeted industry-specific program
3. Design of a new industry program
4. Policy justifications for a new industry program
5. Conclusion

Should you wish for further information as to our response, please contact Craig Pennifold on 02 6213 7580.

Yours sincerely

Patricia Scott
Deputy Secretary

January 2003

Submission by the Department of Industry Tourism and Resources to the Productivity Commission (PC) in response to their draft research report evaluating the Pharmaceutical Industry Investment Program

1. RELAXATION OF THE R&D TAX CONCESSION

The draft report finds that the government should consider alterations to the R&D Tax Concession to allow greater access by pharmaceuticals companies regardless of whether the beneficial ownership of the Intellectual Property (IP) arising from the research is held in Australia and whether such a change should just apply to the pharmaceutical industry or to all industries.

There is little analysis on whether it is more economically efficient or effective to provide R&D support through the tax system via a generic program or through an industry-specific program. Clearly, ITR sees merit in the PC considering the advantages and disadvantages for the economy of reducing the impediments to multi-national enterprises accessing the R&D Tax Concession. We would like to make the following observations to assist your analysis.

It is reasonable that the PC has raised the question of improved access to the Tax Concession as a generic solution to spillovers in R&D. The issue has been raised previously and the view taken that, while a relaxation of the Concession would be to the benefit to the pharmaceuticals sector, it would reduce the benefits of the concession to Australia more generally. Moreover, the recommendation suggests focusing any relaxed R&D Tax Concession on a very narrow definition of eligible R&D, that is, pre-clinical R&D. Although the draft report is unclear on this point, implicit in the recommendation is the removal of clinical R&D from eligibility for the Tax Concession, which would reduce current entitlements.

The Second Reading Speech for the *Income Tax Assessment Amendment (Research and Development) Bill 1986* states that the R&D Tax Concession is designed to ensure that maximum benefits accrue to Australia from commercialisation of the R&D activities supported by the program. Control of intellectual property (IP) has been seen as a crucial element in maximising returns.

The IP-related requirements in the legislation ("on own behalf", s73B(9) of the Income Tax Assessment Act; the exploitation of R&D results "on normal commercial terms", and "in a manner which benefits the Australian economy", s39C and s39D respectively, of the Industry Research & Development Act) all aim to ensure this maximisation occurs. Although there are significant private benefits arising from IP ownership (as emphasized in the draft report), the research results are the major and most easily captured benefits. Exploitation of these R&D results for the benefit of Australia generates additional public benefits including, for example, royalty streams, licensing, exports and taxation revenue. The proposed relaxation of the existing IP requirements may compromise these benefits. In a recent landmark case, the Full Bench of the Federal Court found in favour of the Industry Research and Development Board, which issued a Certificate under s39M of the IR&D Act to the Commissioner of Taxation that R&D activities carried on by Bridgestone Australia Pty Ltd had not been exploited on normal commercial terms.

There would also be deadweight losses, because those currently ineligible for the Tax Concession would be able to access it if the requirement for IP ownership were relaxed. This deadweight loss across the economy would need to be included in the estimate of the net impact to the economy from the relaxation of the Concession.

A general relaxation would enable foreign-owned multinational enterprises in other sectors currently meeting these requirements to exploit IP-related benefits elsewhere than in Australia, potentially leading to a leakage of national benefits overseas without commensurate returns to the Australian economy. In this way, relaxing the IP rules for all industry sectors is likely to compromise national benefits and commercialisation outcomes. A ring fence option may not be sustainable in the medium to long term. ITR's general experience has been that ring fencing tax concessions to one sector is inherently problematic for a range of reasons. For example, in this sector, what would be the natural border line between pharmaceuticals and some biotechnology companies? There may also be increased compliance costs and other sectors might argue that they are being discriminated against. There are already calls from some sectors for a relaxation of the IP ownership rules.

The likely impact of the proposed changes on R&D activity of Australian subsidiaries of foreign-owned pharmaceutical firms is difficult to assess. Issues, such as trends in R&D expenditure under current rules, scope for deadweight losses to the extent that R&D was already being done and not claimed, and the tax status of companies around the world, would all need to be addressed. The degree of uncertainty of impact in part is why tax instruments are rarely directed at specific sectors. From ITR's perspective, the current rules exist for a legitimate reason.

Moreover, any relaxation of IP requirements would need to factor in tax planning issues, as it would also increase the opportunities for aggressive tax planning. For example, IP requirements link into the enforcement of the "on own behalf rules". Among other things, these rules prevent tax exempts effectively accessing the Tax Concession through contracting out R&D to a taxable company. This is not to say alternative ways of enforcing these rules could not be devised. However, it is important to consider that the IP rules do have flow on effects elsewhere in the R&D Tax Concession.

2. CHANGES TO THE R&D TAX CONCESSION VERSUS A TARGETED INDUSTRY-SPECIFIC PROGRAM

The fundamental question to be faced is that, given the draft findings that R&D payments under PIIP have generated a net social benefit, would the response effect and overall cost effectiveness of facilitating R&D be greater through the suggested change to the R&D Tax Concession or through a targeted industry-specific Program?

On balance, ITR believes it is the latter. An industry program that takes account of the unique global nature of the pharmaceuticals industry and its approach to IP ownership, and is targeted to inducing additional R&D investment and its utilisation in Australia, would provide the best outcome for Australia.

The Industry, Research & Development Board, who has joint responsibility for the administration of the R&D Tax Concession with the Australian Taxation Office, has considered this proposal and concluded that it is opposed to the suggested changes to the R&D Tax Concession, including changes that might be specifically designed for the pharmaceuticals industry alone. Their letter is attached.

The Board has also expressed a preference for a targeted scheme for R&D in the pharmaceuticals sector, identifiable as an offset for the impact of the PBS and not restricted to those companies currently in PIIP.

3. DESIGN OF A NEW INDUSTRY PROGRAM

In relation to the design of a new program, ITR sees merit in most of the program design features contained in Recommendation 7.2. It draw on the better features of the PIIP that the report acknowledges has induced a significant amount of R&D and value added and where the R&D component has generated a net social benefit to Australia..

We are not however convinced that any new program should only be open to pharmaceutical companies with products on the PBS. Our reasons are:

- It is an unnecessary condition. To the extent the overall level of industry activity is suppressed, it is more efficient to target high value R&D directly, rather than through intermediaries.
- We need to encourage partnerships between pharmaceutical and biotechnology companies and drawing the distinction on the basis of PBS listings ignores the increasingly dynamic and interconnected nature of the industry. This was one of the key findings of the Pharmaceuticals Industry Action Agenda, endorsed both by Government and by the whole industry.
- Allowing greater participation of Australian companies will reduce the losses associated with providing support to foreign firms and increase the net social benefit to Australia.

4. POLICY JUSTIFICATIONS FOR A NEW INDUSTRY PROGRAM

The draft report challenges a number of the key rationales for the existing scheme. However, the PC would appear to have reached some unqualified but quite definitive conclusions that are not well supported by the analysis presented.

One example concerns Recommendation 7.1, which says there should be no replacement for the PIIP, but the report notes the data limitations in the analysis means there is a margin of uncertainty about the assessment that the effects of price suppression are too weak to warrant policy intervention (page 7.2).

PIIP and R&D

The report states that "while payments for value added are estimated to have resulted in a net social cost (of $49 million), payments for R&D have generated a small net social benefit (of $6 million)" (page 6.14). This benefit is derived from the expenditure of around $24 million on R&D in the first 3 years of the program, suggesting there is a good case for Government intervention in supporting R&D for the pharmaceuticals sector.

PBS and Industry Development

ITR accepts the argument that price suppression is not profit suppression, but is not convinced that the impact of the PBS in totality is positive for the sector. Reform of arrangements regarding listing would be a direct means to reduce deadweight losses.

The negative impact on investment from delays in listing on the PBS is referred to in the text, but finding 3.7 stops short of a specific recommendation, even though the analysis in the report suggests reform to the PBS listing process is the appropriate response.

Investment Decision Making

The report suggests that R&D, manufacturing and supply are separate investment decisions and companies should locate different parts of their business based on comparative costs (Finding 3.3). ITR's experience is that these decisions are interlinked. A company's existing level of Australian manufacturing will bear on whether they also decide to invest in R&D. The lack of critical mass helps explain our relatively low levels of pharmaceuticals R&D (versus peer nations), due in turn to the lower level of manufacturing and head or regional office presence in Australia.

This analysis principally applies to the foreign-owned multinational companies. Australian-based companies who do not have existing overseas plants/R&D facilities face relatively higher transaction costs in considering alternative locations for investment relative to existing locations in Australia.

R&D decisions should be less reliant on specific price outcomes, although companies will rarely undertake clinical trials in markets where they do not believe the drug will be listed.

Care also needs to be taken in measuring the impact of PIIP. Many companies argue that PIIP was important in anchoring their existing activity in Australia and in ensuring these activities stayed competitive in the global rationalisations that have been taking place. The data may therefore understate the performance of PIIP companies and of the program's additionally.

Definition of the Industry

Although the Terms of Reference for the report define the industry "as all those who contribute to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia, thus including the bio-medical sector", the analysis focuses mainly on foreign based multinationals undertaking end-use manufacturing. The strengthening linkages between the pharmaceuticals industry and the biomedical sector are not fully explored in terms of benefits from spillovers and partnerships and their implications for a new industry program

The report does not seem to fully take account of the benefits to Australia of the role of this industry in commercialising the significant public sector investment in health and medical R&D and in biotechnology, and to patients from being able to access the latest drugs early (eg through clinical trials). The health sector is one of the Governments National Research Priorities.

Spillovers

ITR is concerned that the report understates the spillovers from the pharmaceuticals industry in Australia. The international literature review is the basis of finding 4.1 that "there is no evidence to suggest that pharmaceutical activity leads to more spillovers than other industries. It might even be less than in some others." However, the analysis is not conclusive. At page 4.5 the report compares pharmaceuticals with other high technology industries, suggests that spillovers are higher in such industries, but states that the empirical findings are ambivalent.

The international literature on spillovers may also not reflect the situation in Australia. For example, the pharmaceuticals spillover rate could well be higher in Australia than in countries like the UK and Sweden that already have strong, integrated pharmaceuticals industries. Australia does not have strong links between the (mainly publicly funded) research base and broader industry.

The report concedes that linkages and clustering effects could be important, but nothing further is made of this in the assessment of PIIP or in the discussion of the design of a new program.

There is an assumption that clinical trials have few spillovers. While many of the benefits from clinical trials are appropriable by the enterprises sponsoring and conducting them, there are significant spillovers in emerging segments such as biometric and biostatistical analysis and clinical trial management.

We would also question the statement at 5.15 that PIIP has not driven links between the recipients and the rest of the Australian industry. A number of participants have built both the research collaborations with research teams/institutes/companies and the internal mechanisms to ensure this activity is linked to their global R&D effort (see earlier information provided). PIIP played a significant role in this activity.

Residual effects of previous programs

In comparing the performance of PIIP and non-PIIP companies, no account is taken of the residual impact of significant investments made under the Factor (f) program, raising the possibility that the longer-term benefits of the PIIP are understated.

This is particularly important for an industry with long investment lead times and where two Factor (f) Scheme participants, AstraZeneca and Merck Sharp and Dohme, attribute their significant manufacturing and export performance to their participation in that Scheme. Neither are PIIP participants.

Employment

The report finds that PIIP has not driven additional employment. However it needs to be noted that much of the employment growth that has occurred during the PIIP would have been in universities, medical research institutes and the Australian based biomedical sector rather than within participants themselves.

A wind-down of the pharmaceuticals industry activity will result in a leakage of highly qualified people to other countries. Those who found alternative employment in another Australian industry are less likely to create as much value by working outside their area of discipline. The return of specific Australian scientists and other highly skilled workers to Australia is a benefit that has been attributed by companies to PIIP.

Program objectives

The report examines the justifications for having an industry program such as price suppression, changing the perceptions of multinational enterprises; spillovers, the benefits of agglomeration, and the strategic nature of this industry one by one. While individually each may not justify a program, no assessment is made whether the combined benefits would outweigh the costs.

PIIP has multiple objectives. In announcing the PIIP in 1997, the then Minister for Industry Science and Tourism said:

- "the pharmaceuticals industry is a "knowledge based, technology intensive industry which is uniquely placed to commercialise the results of long term investment in medical research" and
- "The Pharmaceutical industry is a major employer and the Government wishes to encourage these companies to plan their future investment with confidence. Our decision is designed to encourage the companies to invest, develop and create additional skilled jobs for Australians."

It is clear that the Government had the objective of promoting of investment, R&D and skilled employment in mind in developing the PIIP. This was also the objective behind its predecessor, the Factor (f) Scheme.

Biotechnology, including pharmaceuticals, is one of the Government's top three investment priorities.

Having no scheme to replace PIIP is likely to result in a loss of capital with a commensurate reduction in manufacturing and R&D activity and employment.

5. CONCLUSION

In summary, ITR would welcome a detailed analysis in the final report of the option of relaxing the R&D Tax Concession. Our preliminary analysis, and the conclusion of the IR&D Board, is that this option is not the preferred course.

With the R&D Tax Concession route closed off, and with the sector generating spillovers and net social benefit to Australia, some intervention by the Government is warranted. The rationale for that intervention is strengthened by the perception that Australia is a hostile environment for pharmaceutical activity including the higher costs from our regulatory environment (delays in listing etc) and price suppression.

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INDUSTRY RESEARCH AND DEVELOPMENT BOARD

INDUSTRY TOURISM RESOURCES

Ms Tricia Berman
General Manager
Innovation Policy Branch
Department of Industry Tourism and Resources

Dear Ms Berman

The IR&D Board notes the Productivity Commission's Draft Research Report *Evaluation of the Pharmaceutical Industry Investment Program* and offers the following comments on those matters raised in the report that reflect on programs that are the Board's responsibility.

The Board believes there is general merit in the view that any successor incentive to the Pharmaceutical Industry Investment Program should focus on R&D and Innovation.

However, the Board believes that fundamental objections can be raised to Preliminary Recommendation 8.1,viz:

- *"Consideration should be given to providing greater access to the R&D Tax Concession to pharmaceutical companies for research conducted in Australia, regardless of whether the beneficial ownership of the intellectual property arising from the research is held in Australia."*
- *"As part of this consideration it would be important to determine whether such a change should just apply to the Pharmaceutical Industry or to all industries."*

These objections are:

Distortion of the Concession

Special terms of access for a particular industry sector to the R&D Tax Concession, which is a broadly based entitlement incentive scheme, has scope to undermine the integrity of the concession and its policy purpose. It also may encourage behaviour that seeks to exploit the special terms of access.

Costs to Revenue

The costs to revenue of special access for the Pharmaceutical Sector are unknown. The suggestion that similar terms of access be offered to all industry sectors will have additional unknown cost to revenue. These costs should be modelled.

Excessive Reliance on Intangible Benefits

The proposed removal of the requirement for Australian IP ownership may have the effect of placing a much greater reliance on indirect benefits to Australia. These may be difficult to measure and define, and should not be given predominance over direct tangible benefits.

An alternative to broadening the R&D Tax Concession, a targeted scheme for R&D in the Pharmaceutical sector, was raised in the Report. The Board believes that this approach is preferable and notes that it specifically retains its identity as an offset to the effects of the Pharmaceutical Benefits Scheme. It has the additional advantage of enabling all potential beneficiaries in the Pharmaceutical sector to participate, in contrast to the currently restricted set of companies afforded access to the Pharmaceutical Industry Investment Program.

Yours sincerely

SIGNED

Professor Don Nicklin AO
Acting Chairperson
Industry Research and Development Board

17 December 2002