NSW Department of State and Regional Development's comment on the Productivity Commission's Draft Research Report:

Evaluation of the Pharmaceutical Industry Investment Program.

Executive Summary

The NSW Department of State and Regional Development (DSRD) supports the continuation of an industry development program for the pharmaceutical industry.

The Pharmaceutical Industry Investment Program (PIIP) should be improved and redesigned in line with the principles outlined in the Pharmaceutical Industry Action Agenda. Ideally the new scheme should:

- Be a 10-year program incorporating a 5-year plan with an in-principle commitment for a further 5-years, subject to a review of performance and industry priorities and needs.
- Be open to more pharmaceutical companies.
- Have a number of entry points.
- Have entry based on competitive criteria.
- Encourage the establishment of regional or globally significant investments as well as R&D activity.
- Encourage participants to develop project partnerships with Australian small and medium-sized enterprises (SMEs) and research organisations in the pharmaceutical and biotechnology industry. SMEs may benefit from a scheme modelled on the Strategic Partnership Industry Development Agreements (SPIDA) Program.
- Help to fill gaps in infrastructure.
- Comply with WTO requirements.

With respect to the Productivity Commission's other recommendations, DSRD considers:

- The recommendation to abolish clause (f) should be reviewed. Clause (f) should be assessed against all of its original policy purpose, noting that if clause (f) and the PIIP were removed, there would be no way to reward local activity, adding to negative overseas head office perceptions of investing in Australia. If the Commission believes that the original policy purpose is still relevant, it should investigate methods in which the PBPA could put clause (f) into effect.
- The Commission should pursue its recommendation to allow multinational corporations to take advantage of the R&D tax concession. This would recognise the many benefits that these R&D activities provide to the economy. The Commission should review the costs and benefits of alternative options to encourage R&D by multinational companies in Australia, in the event that the Commonwealth deems expansion of the R&D tax concession is not appropriate.
- Any recommendation to amend Australia's intellectual property legislation should be dealt with by the Inter-Departmental Committee chaired by the Commonwealth Department of Industry, Tourism and Resources.
 - DSRD would be concerned with any changes that may weaken the integrity and international reputation of Australia's Intellectual Property legislation.

NSW Department of State and Regional Development's comment on the Productivity Commission's Draft Research Report: Evaluation of the Pharmaceutical Industry Investment Program.

The NSW Department of State and Regional Development (DSRD) supports the continuation of an industry development program for the pharmaceutical industry.

Any new program should be developed in line with the principles outlined in the Pharmaceutical Industry Action Agenda (PIAA). A whole-of-government perspective is required, including consultations and co-ordination with the States and their respective biotechnology policies in order to ensure that full value can be realised from any assistance provided. Legal and regulatory structures should be continually assessed and improved to world best practice, whilst factors inhibiting the growth of the industry should be removed or reformed.

The Pharmaceutical Industry Investment Program (PIIP), or its replacement, should be leveraged to motivate multinational pharmaceutical companies to develop productive linkages, and expand investment and other activities with the Australian health and medical industry sector, including biotechnology.

The boundaries between biotechnology and pharmaceutical industries have become less distinct. As pharmaceutical corporations continue their trend towards outsourcing activities, especially R&D, small biotechnology companies are playing an increasing role in the pharmaceutical industry. There are also commercial opportunities for the supply of goods and other services which are, and will continue to be, met by Australian biotechnology companies.

In a series of recent reports on issues affecting the global and Australian pharmaceutical industries it was noted that:

"Breakthrough advances in biotechnology have had a significant impact on core pharmaceutical technologies. Bioinformatics has resulted from the convergence of the distinctive technologies of biotechnology and IT. The impact of the shortening of the market exclusivity period has been to effectively truncate the product life of many new drugs. This both increased the pressure for additional drugs from pharmaceutical company product pipelines and intensified the search for new compounds from Biotechnology companies."

"Australian R&D, at least biology, is seen as world class, but constrained in gaining the attention of large pharma by 'tyranny of distance', and limited in funding opportunities from risk adverse Australian capital markets. In a continuing world of big pharmaceutical companies perhaps the best that can be hoped for is to gain research and drug development support at an early stage on a project by project basis from a large pharma by more actively pursuing overseas links."²

² Rasmussen, B., *Implications of Business Strategies of Pharmaceutical Companies for Industry Developments in Australia*, CSES Working Paper No 1. (Melbourne, 2002) Page 2.

¹ Rasmussen, B., *The Role of Pharmaceutical Alliances*, CSES Working Paper 2, (Melbourne, 2002) Page 1.

"In this environment the best option for Australian organisations is to form alliances with global pharmaceutical and biotech firms or provide specialised services to these firms. If in their emerging strategies the global pharmaceutical companies seek to outsource many more of their functions to companies that can offer economies, arising from specialisation or unique knowledge, over in house solutions, then the likelihood of Australian firms having some greater value added role in the total drug production process is increased." ³

Requiring PIIP program participants to develop project partnerships with small to medium sized Australian companies in the pharmaceutical and biotechnology industry is one way to assist in developing a strong Australian health and medical industry sector.

A program on which this could be modelled is the Strategic Partnership Industry Development Agreements (SPIDA) Program, which was coordinated by the Commonwealth Department of Communications Information Technology and the Arts.

Under the SPIDA program, international IT companies that wished to supply products and services to the Government market were required to demonstrate a commitment to the development of the Australian IT industry and report annually on progress. This included establishing strategic global or regional sourcing and/or outsourcing agreements with Australian companies. SPIDA activities also included:

- research and development;
- exports of Australian products and services;
- facilitation of new export market opportunities;
- Regional Headquarters investment;
- strategic investment;
- venture capital investment;
- skills development; and
- technology transfer.

Examples of Australian industry development facilitated though the SPIDA program include:

Intel & Legend Performance Technology
 Legend Performance Technology is a fully Australian-owned, Adelaide based company, specialising in manufacture and export of components for the IT industry. Through its relationship with Intel, it is able to prototype new memory products and anticipate market demands prior to the release of new motherboard families.

- Panasonic & Ring Australia

Ring Australia, in conjunction with Kyushu Matsushita Electric (KME), has locally developed a Computer Telephone Integration software package called Phone Manager, designed for Panasonic's Digital Phone Systems. Panasonic (through KME) also provided financial support for Ring Australia for the joint development of set-up software (dealer version) for Phone Manager.

³ Rasmussen, B., *Implications of Business Strategies of Pharmaceutical Companies for Industry Developments in Australia*, CSES Working Paper No 1. (Melbourne, 2002) Page 10.

A similar program for the pharmaceutical industry could provide benefits that include:

- Knowledge and technology transfer It could assist Australian companies with information on how different markets regulate and approve new drugs and the provision of industry contacts.
- **Training and skill development** It could help maximise Australia's human capability through education and training opportunities with multinationals.
- **Investment** Improved capabilities in local firms as a result of collaboration with multinationals would mean a more attractive environment for investment. Increasing levels of collaboration will enhance the marketing of Australia as a key location for R&D for future investment by multinationals.
- **Direct access to international distribution system** It would provide the opportunity for Australian SMEs to tap into comprehensive international distribution networks.

Any new scheme should incorporate incentives that encourage the establishment of additional regionally or globally significant investment as well as R&D activity that incorporates local partnerships and participation.

Focussing solely on R&D activities - as recommended by the Commission - may not be sufficient to allow Australian-subsidiaries to build and maintain sufficient critical mass to ensure their future viability. International studies also conclude that R&D activities are not undertaken in total isolation to other corporate activities. As the OECD noted in its report on globalisation of industrial R&D, "...[the] evidence points to an internationalisation of research and technology by MNCs that complements their manufacturing and sales activities in major markets ...the data suggests that foreign R&D investments tend to follow production abroad."⁴

More pharmaceutical companies should be allowed to participate. However, any expansion will need to be counterbalanced by the need to offer meaningful incentives to allow the scheme to fulfil an industry development role. This might require an increase in program funding and / or a limit on the nature of eligible activities.

Any new scheme should provide for multiple entry points during the life of the scheme and be long enough to provide certainty for business decision-making. Given the long time to develop products in this industry, the Action Agenda's proposal of a 10 year program, with firm commitments in the first 5 years and in-principle support for the following 5 years is worthy of serious consideration.

Other Productivity Commission Recommendations

Clause (f)

The recommendation to abolish clause (f) should be reviewed by the Commission.

In the Pharmaceuticals Benefit Pricing Authority ("PBPA") guidelines, factor (f) takes account of local activity when setting prices. The PBPA states that it has not

⁴ OECD, Globalisation of Industrial R & D: Policy Issues, (Paris, 1999). Pages 16-17.

taken local activity into consideration in its deliberations. The PBPA is considered that the PIIP scheme (partly) relieves it of its clause (f) obligations. However, just because it is not presently being enforced is not a sufficient reason for its removal. A more appropriate question is whether the clause is worthwhile. In answering this, all the reasons for its original inclusion in the guidelines should be reviewed and assessed. If these are still relevant, the Commission should investigate ways in which the PBPA could put it into effect.

It should be noted that if the PIIP scheme is dismantled – as the Commission recommended - the PBPA will again have to apply clause (f) in its determination. If, however, clause (f) is removed, it will reduce recognition of local activity and add to negative head office perceptions of investing in Australia.

R&D Tax Concession

DSRD considers that the Commission's recommendations to allow multinational corporations to take advantage of the R&D tax concession would recognise the many benefits that these R&D activities provide to the Australian economy. Their R&D activities provide benefits to the local economy by:

- Providing employment opportunities to skilled employees.
- Improving the skills of local researchers and managers in the latest issues affecting the global pharmaceutical industry.
- Supporting graduate and post-graduate training.
- Providing access to specialised research technologies and techniques.
- Collaborating with local biotechnology firms and research organisations.
- Increasing market size for local suppliers and service providers, providing greater business opportunities and potential for additional specialisation.
- Supporting bids for local manufacture of new products. There are increasing linkages being developed between R&D and manufacturing with a greater tendency for pharmaceuticals to be manufactured at the location they were developed.
- Showcasing Australian R&D capabilities in a global commercial context.

Given the benefits, DSRD would like to see the Commission further pursue this recommendation. It may also be beneficial for the Commission to review the costs and benefits of alternative options to encourage R&D by multinational companies in Australia, in the event that the Commonwealth deems expansion of the R&D tax concession is not appropriate.

Amending Intellectual Property Legislation

With respect to the recommendation on the amendment of Australia's intellectual property legislation to allow generic manufacturers to export generic versions of drugs whose patents have expired overseas, but remain in force in Australia, the Inter-Departmental Committee chaired by the Department of Industry, Tourism and Resources is the more appropriate forum to develop recommendations of this nature.

DSRD would be concerned with any changes that may weaken the integrity and international reputation of Australia's Intellectual Property legislation.