A. Background

Merck Sharp & Dohme (Australia) Pty Limited (MSD) is one of the leading pharmaceutical manufacturers in Australia and one of the country's top firms for R&D investment.

Celebrating its 50th year in Australia this year, MSD is part of a sector – known as Elaborately Transformed Manufactures (ETMs) - which facilitates faster growth in real GDP than most other manufacturing sectors.

MSD was a participant in Phase 1 and 2 of the Factor F scheme from 1988-1999. Within the space of just 10 years, MSD went through a major transformation in direct response to an improved policy environment for the industry. It has:

- **built an international manufacturing base where none existed before:** This base represents a substantial platform for MSD to become the manufacturing hub for the Asia-Pacific region on behalf of our parent company.
- **embarked on major capital investment in high-tech manufacturing facilities:** This investment has resulted in new or upgraded manufacturing facilities which:
    - are equal to the best of the Merck secondary manufacturing facilities worldwide;
    - offers multi-skilling opportunities to our workforce;
    - employs state of the art techniques such as robotic technology; and
    - are capable of producing a large number of packaging configurations as required by the market.
- **Stimulated innovation, securing unique R&D opportunities which have placed Australia on a world platform**: A product of Australian research is now a significant contender in Merck's research pipeline.
- **created employment opportunities for highly skilled people**

In the decade to 1999, MSD was able to successfully compete against its sister subsidiaries in other countries, in order to win significant and strategically important export and R&D business for our Australian operations.

Although MSD has developed a manufacturing and R&D base here, the subsidiary is exposed to the dynamics of the international environment. If the local environment does not keep up with international standards, it is possible that the advances made here could be undermined. Once there is any loss, it is difficult, if not impossible, to win it back.

MSD's future success will depend on our ability to remain a "competitive" and leading subsidiary. A key element of our competitiveness (vis-a-vis sister subsidiaries) is the policy environment in which we operate**.**

While there have been a number of improvements to the policy environment since the early 1980s when disinvestment was occurring (such as the Factor F and PIIP schemes; patent term restoration; and the establishment of an independent pricing authority), it is our view that overall, the environment has deteriorated significantly compared to when PIIP was introduced, in part because the pricing issues are getting tougher and in part because other countries are proactively chasing pharmaceutical investment.

A new industry development program, which is far more substantial than PIIP, is critical to retain and build on what we have or else the industry will continue to go backwards.

B. The Productivity Commission's terms of reference: comments on key items

Examine the appropriateness of PIIP by: determining whether there is economic justification for intervention in the pharmaceutical industry; and articulating and assessing the arguments for and against PIIP. In particular, the Commission should determine whether the economic rationale for counteracting price outcomes under the Pharmaceutical Benefits Scheme (PBS) remains credible.

Price suppression/reduced activity:

MSD believes the economic justification for intervention in the pharmaceutical industry remains valid. The major impediment which constrains MSD's ability to increase activity here is the pricing and reimbursement environment. This dampens investment in all areas of our operation and delays ready access to new technology for Australian consumers.

The prices which we receive for our medicines are amongst the lowest in the developed world and fail to recognise the considerable R&D investment made. Some of our medicines are not able to be listed on the PBS because the low price offered would have a flow-on effect globally, or are listed much later than other OECD countries. In addition prices are eroded over time throughout our patent life. The adverse pricing outcomes for Australia versus other key OECD countries are well demonstrated in a project being undertaken by the Centre for Strategic Economic Studies at Victoria University of Technology. A paper which examines three therapeutic areas (peptic ulcer medicines; antidepressants; cholesterol reducers) finds that " in general, the real price of drugs in the USA tends to rise over time. In Australia however, after some tendency to rise in the first half of the 1990s, drug prices have fallen consistently since 1996-97. "[1]

The MSD following products have not been listed on the PBS because of unacceptably low prices: COZAAR, HYZAAR/FORTZAAR, MAXALT,. Another product, TRUSOPT, was listed in 2001, six years after it was first recommended for reimbursement by the PBAC. The delay in listing was entirely due to the low price offered.

For MSD's 6 top selling products, the average level of prices is 70% of EU average prices.

[1] "Demand and Price Dynamics within the Pharmaceutical Benefits Scheme" Working Paper No. 6, Pharmaceutical Industry Project –Equity, Sustainability and Industry Development Working Paper Series, June 2002. Centre for Strategic Economic Studies, Victoria University of Technology.

Failure to secure PBS listing means there is no real incentive to run clinical trials here. This was our experience with a product called COZAAR. Had COZAAR stayed on the PBS, MSD would have been involved in the "RENAAL" clinical study and might well have extended a multi-million dollar trial called the Australian National Blood Pressure trial which began in 1994. COZAAR was the first in a new class of medicines to treat high blood pressure.

From a manufacturing perspective, the domestic volume which would result from a PBS listing gives us "critical mass" and the opportunity to push for export volumes. If there are no plans to sell a product here, it is harder to justify manufacturing.

The combined effect of the PBS process and price outcomes result in reduced local revenue and an inability to predict forecast growth with any confidence. This means we are not in a strong position to lobby our parent company for further R&D investment as we are unable to be confident about the return on that investment. Our investment in human resources, IT, and other aspects of our domestic operation is also unstable.

Examine, if it is found that intervention in the pharmaceutical industry is justified, whether PIIP is an effective form of intervention, or whether alternative interventions would be more efficient and effective. In particular, if a continuing need to counteract price outcomes under the PBS is established for post 2004, identify possible policy and program measures to do this, with an assessment of each option.

There are a range of possible policy and program measures to counteract price outcomes under the PBS. MSD believes a new industry development program is probably the most realistic option.

1. A new industry development program as proposed in the Action Agenda.

Industry's proposal for the design of a new program is attached as an Appendix to the Action Agenda. Key points from this proposal are below.

Principles of a new program

A new industry development program should be guided by the following principles:

1. an in principle commitment by the Government and Industry to a ten-year program beginning 1 July 2004, with firm commitments to the first five years of the program;

2. be accessible by all parts of the value chain;
3. build partnerships and collaborations among major companies, small firms and Australian research institutions;
4. improvements and increases in commercialising the outcomes of Australian research;
5. address gaps in infrastructure;
6. strengthen the investment by multinational pharmaceutical companies in Australia by encouraging the establishment of global hubs in R&D, manufacturing and services;
7. encourage high quality activities most likely to enhance the sustainability of the Australian industry and with most spin-off benefits for the Australian economy;
8. have flexibility to support substantially more companies than have been supported under either the Factor (f) Scheme or the PIIP; and
9. comply with WTO requirements.

Components of a 10-year industry development program

Industry proposes that the new program should be constructed as follows:

i. an entitlement scheme available to all firms that meet the eligibility criteria . Applications for new funding will be accepted annually.
ii. different payment rates for different types of activity with a specified maximum rate ;
iii. payments received by a firm may be taken as either actual price increases or as a lump sum.
iv. Companies to be rewarded for:
    - **Replacement** value adding activity for products and/or pharmaceutical-specific services which are regionally or globally significant and which meet certain criteria (e.g. increased export intensity; increased local value-added content of a company as a whole);
    - **Additional** value-adding activity in R&D, and in manufacturing;
    - Formation of linkages and partnerships along various parts of the value chain.

Industry Development Activity

It is proposed that the rewards which companies receive under the industry development program should differ according to the type of activity being undertaken, as shown in the table below.

This approach enables activities to be rewarded according to their contribution towards achieving the Action Agenda vision, with the highest level of reward being for growth activities which involve R&D partnerships or which have a clear global orientation.

Replacement local value adding activity for products and/or pharmaceutical-specific services which are regionally or globally significant and meet certain other criteria	X%
Additional local value adding activity predominantly for the **domestic** market	Y% (where Y>X)
Additional local value adding activity that is **regionally or globally** significant	Z% (where Z>Y)
Replacement R&D activity not involving local partnership and participation	X%
Replacement R&D activity involving **partnership**	Y%
Additional R&D activity not involving partnership	Y%
Additional R&D activity involving local **partnership** And participation	Z%

There is also reference to the need for targetted incentives for major investments such as actives manufacturing.

Definition of PVA

MSD believes that any new program should encourage companies to spend money and conduct activity in Australia. To that end, any definition of Production Value Add (PVA) should recognise the globalised nature of our industry which is dominated by multi-national companies. These companies compete in the international arena to attract value adding activity to Australia. The focus should be on measuring and rewarding activity that truly contributes to the growth of the Australian economy.

A definition of PVA should focus on **Local** Production Value Add (LPVA). The importance of "Local" is that it relates to local spend on goods and services, or "fully absorbed local cost of manufacture". This would exclude imported materials, including bulk active, but would include depreciation on plant and machinery.

This approach measures activity that is truly value add and is not confounded by influences such as exchange rate fluctuations and complexities of international transactions between affiliated companies. This approach is also attractive due to its simplicity and ease of administration.

Apart from a new industry development program, other possible policy alternatives – in order to address price suppression - include:

(a) bringing Factor F to life in the PBPA's pricing decisions.
(b) better prices
(c) an innovation premium
(d) a scheme similar to the United Kingdom

These are explained as follows:

(a) Bringing Factor F to life

The sixth factor considered by the PBPA when setting prices is Factor F, the level of activity being undertaken by the company in Australia, including new investment, production, research and development. Currently the Department of Health defer this factor to the DITR, and the practical implementation of this factor has become PIIP payments. This is not satisfactory for non-PIIP recipient companies and for local activity not rewarded by PIIP.

'Bringing factor f to life' could be realised by inviting companies to quantify local activity in submissions to the PBPA. In turn, the PBPA could offer notional price premiums for PBS listed products in direct recognition of the local activity.

This would enable companies to use local activity to supplement the prices of products, particularly products where a company is struggling to achieve a satisfactory PBS price.

(b) Better prices for PBS listed products

Numerous studies have found Australian PBS prices to be low. The most recent comparison of Australian pharmaceutical prices compared to international prices was performed by the Productivity Commission (2001). The study made bilateral comparisons of the top 150 PBS pharmaceuticals to seven overseas countries. It found that Australian pharmaceutical prices are much lower than prices in the United States, Canada, the United Kingdom and Sweden. Australian prices were somewhat lower than prices in France and similar to prices in New Zealand and Spain. (Productivity Commission 2001: xvi)

The Australian system of referencing new prices to the prices of currently listed products will ensure that Australian prices remain low. This creates an adverse environment for industry investment.

Better prices for PBS listed products could be phased in over time. At the very least, CPI increases could be applied to a comparator product so that there is an "apples with apples" comparison between a new product and its comparator.

(c) Innovation premium

Where a product is considered innovative it could be eligible to receive a price premium. This option could be implemented under a variety of methods for example:
(i) a premium allotted by the PBPA akin to the Factor F premium as per (a) above;

(ii) provide better prices as per (b) above only to products that meet the definition of innovative.

(d) UK PPRS scheme:

In the UK pricing of in-patent prescription medicines paid for by the NHS is governed by the Pharmaceutical Price Regulation Scheme. This scheme places a profit ceiling of 21% return on capital employed, with a small additional allowance for innovation, but allows free pricing so long as profits remain within the specified bounds.

While MSD has not assessed the UK scheme, it may be worthy of review. It should be noted however any review needs to recognise that there are very different market conditions which prevail in the 2 countries.

Limitations of the PIIP program:

At $300m over four years, PIIP is not the compelling incentive required to maintain and grow the industry over the next decade- it may only slow down the level of disinvestment. There also appears to be minimal correlation between the companies who experience the most extensive price suppression and those who secured PIIP funding.

The limitations of PIIP have been well documented in the draft Action Agenda(p.37). The relevant extract is reprinted below.

"During the Action Agenda process the following issues were raised in relation to both the Factor (f) Scheme and the PIIP:

- only nine companies out of the thirty-odd companies that supply the PBS and have significant activity in Australia, are participants in the PIIP Program. A total of 17 companies participated in Phases I and II of Factor (f). This has meant, however, that the total funding provided under the Program was significant for the participating companies in contributing to activity and influencing decisions;
- the funding in both of the Programs was fully committed up front meaning that companies not ready to apply when the Programs were launched were unable to access the Programs for their duration. This meant, however, that the companies in the Program were provided with a high degree of certainty;
- that funding under both Programs was only provided to MNCs. In fact, under PIIP, 40% of funds are committed to companies that are Australian owned and operating in a global industry. The design of both Programs, however, encourages the participation of companies experiencing low prices through listing on the PBS rather than companies demonstrating reduced activity as a result of low prices;
- no funding was provided for capital investment through either of the programs. This has possibly contributed to some of the infrastructure gaps and lack of primary manufacturing capability identified in the Action Agenda process and may provide industry with the perception that such investments are not valued in Australia. However, through PIIP, participating companies were encouraged to make capital investments and to form partnerships through Broad Activity Commitments to embed MNCs in Australia. As funding was not tied to these commitments, there was no direct financial incentive for companies to do so. There are, however, some examples where partnerships were formed (such as AstraZeneca and Griffith University - see Case Study 1); and
- under the PIIP, funding has been at the same rate for all approved additional R&D and PVA, rather than graduated according to the value of the activity to the Australian industry or the difficulty of achieving additional activity. This has, however, resulted in simple and transparent program administration."