MERCK SHARP & DOHME (AUSTRALIA) PTY LIMITED

RESPONSE TO THE PRODUCTIVITY COMMISSION'S DRAFT RESEARCH REPORT ON EVALUATION OF THE PHARMACEUTICAL INDUSTRY INVESTMENT PROGRAM

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A. EXECUTIVE SUMMARY

The Productivity Commission's (PC) draft research report *"Evaluation of the Pharmaceutical Industry Investment Program (PIIP)"* comes at a critical time for the industry. The operating environment has deteriorated significantly compared to when the PIIP was introduced, in part because market success based on PBS reimbursement is increasingly difficult, and in part because other countries are proactively chasing pharmaceutical investment.

Although the report notes various issues and problems arising from the reimbursement and listing system, the PC has not framed a recommendation to address these PBS-related problems.

Its key recommendation - that a new industry development plan is not warranted – essentially denies a solution to the problem, which is thus left unaddressed. This potentially leaves the industry in a policy vacuum.

Moreover, the PC's key recommendation has been reached by discounting uncertainties and dismissing delay, market access and perception issues**.**

The PC's report emphasizes uncertainties throughout, yet at each and every point – based on unfounded assumptions, very thin or limited evidence, and in the face of contradictory industry evidence (which it discounts as being biased, denying the legitimate interests of the industry in the process), it forms an opinion against the PIIP and the industry. MSD has outlined many examples of this flawed reasoning in an appendix to its submission.

If one were to consider alternative hypotheses or interpretations on even some of these points, fundamentally different conclusions would result, as was the case with previous PC reports into the industry.

The key areas of concern for MSD are:

- **the failure to make any recommendation regarding the impact of the PBS on company activities;**
- **discounting the link between price suppression and depressed activity, which operates in a very real sense from MSD's experience;**
- **the absence of substantial analysis about the linkages between the different parts of the pharmaceutical value chain**
- **the conclusion that manufacturing activity is of little significance; and**
- **the failure to analyse the cumulative effects of 15 years of industry development programs and recognise that without the Factor F scheme, there would have been an insignificant base on which PIIP could build.**

MSD would urge the PC to qualify some of its recommendations and findings, by acknowledging the uncertainties. In particular, MSD believes the PC should frame a recommendation relating to the problems identified around the PBS.

B. INTRODUCTION

Prior to considering the Productivity Commission's (PC) preliminary recommendations and findings, MSD asserts that there is strong justification for the PC to address PBS issues in its recommendations.

MSD believes this is critical because the PC's key recommendation - that a new industry development plan is not warranted – essentially removes a solution to the problem while leaving the problem unaddressed. This has the potential of leaving the industry in a policy vacuum.

In addition to pricing issues, the PC acknowledges on page 8.3, that the pharmaceutical industry has deep-rooted perceptions that the Australian regulatory process for listing a drug on the PBS is unfavourable, because of problems with:

- Delay;
- Volume restrictions;
- Complex administration processes that lack transparency and a process for review;
- Application of cost-effectiveness analysis which makes overly stringent demands for data to support its design, and which does not adequately reward all benefits; and
- A rapidly increasing drive for cost containment with the PBS.

The Productivity Commission then states,

> "*were the industry's perceptions to have validity*, the appropriate response would be to change the PBS's listing processes, which would promote the community's interest in having cost-effective access to safe and effective drugs, as well as reducing negative perceptions among the industry".

Unfortunately, the Productivity Commission fails to deal with this issue by concluding that "an assessment of these issues is beyond the scope of this inquiry".

We submit that an assessment of this issue falls squarely within the scope of this inquiry, and as such, should be addressed and form part of the recommendations.

The terms of reference require that the Productivity Commission, "….examine the appropriateness of PIIP by: determining whether there is economic justification for intervention in the pharmaceutical industry". In turn, the Productivity Commission must, "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*", and "*identify possible policy and program measures to do this with an assessment of each option*."

There is no requirement that "alternative interventions" be an iteration of an industry development program – they may equally take the form of a recommendation to review the PBS listing process. We seek such a recommendation.

If the Productivity Commission's final report recommends there should be no industry development program, MSD seeks an additional recommendation that the PBS listing process be reviewed as a matter of urgency in a manner that responds to the industry's concerns, addresses negative head office perceptions and promotes the community's interest in having cost-effective and timely access to safe and effective drugs

C. PRELIMINARY FINDINGS

i) Preliminary findings which relate to compensating for the PBS

Preliminary finding 3.1

Australia's PBS arrangements constitute only one of the several factors contributing to lower pharmaceutical prices relative to other countries. (page 3.14)

While MSD agrees that there are several factors contributing to price differentials, MSD maintains that PBS arrangements are the over-riding factor. This is supported by international empirical studies and by the conclusions reached by previous PC reports into the industry.

International empirical studies have found that pharmaceutical prices are lower than they would be otherwise, in the presence of price regulation. Schankerman[1] suggests that pharmaceutical prices are likely to be lower in the presence of stringent price regulation. Danzon et al [2] have found that strict price regulation lowers the price for older products and for products that are available broadly across international markets as compared to less regulated markets[3]. As the PC report notes, Ellison *et al*[4] found evidence to suggest that restrictive formularies (such as the PBS) do allow the purchaser to extract price discounts.

The PC has previously found evidence to suggest that the Australian institutional arrangements have assisted in keeping PBS prices low over time.[5]

The PC has also not examined how the PBS process itself may suppress prices.

The Pharmaceutical Benefits Advisory Committee's (PBAC) interpretation of a product's economic evaluation will result in a PBS price lower than one reflecting the full value of the benefits offered by the product for the following reasons:

- The PBAC has a clear preference for evidence from randomised clinical trials. The PBAC Guidelines state, "if claimed clinical advantages for the proposed drug do not have a basis in the results of randomised trials, they are unlikely to be accepted by

[1] Schankerman, Mark (1998) "How valuable is patent protection? Estimates by technology field", *RAND Journal of Economics,* Vol 29, No 1, Spring, 77-107 p 97-98

[2] Danzon, Patricia M., Chao, Li-Wei (2000a) "Cross-national price differences for pharmaceuticals: how large, and why?", *Journal of Health Economics,* Vol 19, 159-195

[3] Interestingly, Danzon *et al* (2000: 159) have found that competition between off-patent products is more effective in lowering prices in less regulated markets.

[4] Ellison, Sara Fisher, Snyder, Christopher M. (2001) *Countervailing power in wholesale pharmaceuticals,* July, MIT and George Washington University, Massachusetts and Washington, p7 http://www.econ.yale.edu/seminars/apmicro/am02/ellison-020227.pdf

[5] Productivity Commission (2001) *International pharmaceutical price differences,* Research Report, July, AusInfo, Canberra p90

the PBAC".[6] Claims of benefits from non-randomised trials, "will be treated with scepticism". [7] The PBAC's conception of relevant data is not consistent in its emphasis on information such as: treatment changes measured in the laboratory as distinct from clinical outcomes; subjective adverse effects; and definition of treatment endpoints.

- The PBAC Guidelines strongly discourage the inclusion of indirect costs such as productivity gains, [8] resulting in a partial estimation only of pharmacoeconomic benefits of products.
- At the time the producer is seeking PBS listing, it is not possible for the producer to have available evidence to support the full extent of the improved patient welfare offered by the new product. Many product benefits can be assessed only after the product is available in the market.

Thus, absence of clear evidence of a benefit is taken as evidence that there is no benefit at all. This conservative approach denies the producer a price that reflects any benefits for which evidence has not yet been able to be presented due to timing issues and/or high transaction costs associated with collection of these data. This is price suppression by PBAC process.

In addition to the price suppression that occurs under the PBAC process, once a product is listed on the PBS at a particular price, there are several dynamics that will cause the price of the product to fall further over time.

- The PBPA will frequently enter into *price-volume agreements* with the producer at the time of launch.[9] Price-volume agreements are commercial-in-confidence between the Government and the producer.
- *A product is tied to another product which has a price-volume agreement*. Any subsequent producer entering the market where the comparator product is subject to a price-volume agreement will be required to reduce its price when the price-volume agreement of the original product comes into effect. The subsequent producer is not privy to details of any future reduction in the price of the comparator.
- *The introduction of a competing patented product.* While the PBAC Guidelines do not preclude an equivalent product being listed on the PBS at an equivalent price, a lower price is preferable.[10] There are many examples where the entry of a new

[6] Commonwealth Department of Human Services and Health (1995) *Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee,* November, Australian Government Publishing Service, Canberra, p26
[7] ibid, p.59
[8] ibid,p.52
[9] Commonwealth Department of Health and Aged Care (2000) *Pharmaceutical Benefits Pricing Authority Annual Report for year ended 30 June 2000,* Ausinfo, Canberra, p6
[10] Commonwealth Department of Human Services and Health (1995) *Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee,* November, Australian Government Publishing Service, Canberra, p49

patented product has successfully provided the PBPA the opportunity to seek a price reduction from the producer of the original product.

- Where a product undergoes *a change to its PBS listing resulting in a greater target population*, the PBPA will generally require a price cut on the grounds of greater economies of scale in production.[11] The price cut will be requested despite the fact that an increase in Australian volumes will rarely, if ever, realise any economies of scale due to the small Australian market in the context of world wide consumption and manufacturing patterns.
- *The introduction of an off-patent competitor*. As in the case for patented products, the PBAC Guidelines do not preclude an equivalent product being listed on the PBS at an equivalent price. In practice, the introduction of an off-patent product results in a reduction of the benchmark price of between 10 – 35 percent (industry estimate).
- The PBPA administration of *reference pricing methodologies,* as part of its annual price reviews, results in ongoing reductions to the subsidised price of a referenced group. A recent independent review, conducted by Ernst & Young ABC and commissioned by the Commonwealth Department of Health and Aging, found the broadly used reference pricing methodology, 'weighted average monthly treatment cost' to have serious faults resulting in inappropriate price reductions.[12]

Given the above, MSD believes that PC should attribute some weighting to PBS arrangements. If it is found that PBS arrangements are an over-riding factor, this would change this preliminary finding.

Preliminary finding 3.2

Volume effects are likely to significantly counter the impact that price suppression has on pharmaceutical firms' profits. (page 3.18)

Volume effects will only counter the impact of price suppression to the extent that price is above marginal costs. As the PC report notes on page 3.4, it is still profitable for the manufacturer to enter the Australian market even if price is below average costs and is approaching marginal costs (providing certain other market conditions are met). The government has no power to force the industry to supply products in the Australian market at a particular price. Rather, the government is able to offer the industry listing on the PBS, associated with the payment of a subsidy to the patient, contingent upon the industry supplying the product at a lower price. Johnston [13] refers to this as the

[11] Commonwealth Department of Health and Aged Care (2000) *Pharmaceutical Benefits Pricing Authority Annual Report for year ended 30 June 2000,* Ausinfo, Canberra, p6

[12] Commonwealth Department of Health and Aged Care (2001b) *Review of WAMTC Method,* Volume 1, March, Ernst & Young ABC, Sydney, p3

[13] Johnston, Mark, Zeckhauser, Richard (1991) *The Australian pharmaceutical subsidy gambit: Transmuting deadweight loss and oligopoly rents to consumer surplus,* Working paper No 3783, National Bureau of Economic Research, Massachusetts
Johnston, Mark Andrew (1990) *Australia's pharmaceutical pricing strategy,* PhD Thesis, January, Harvard University, Massachusetts

'price-contingent subsidy'. It is, therefore, entirely possible, particularly where there are many products within a therapeutic class, that the PBS price may be approaching marginal cost. Thus, despite any possible positive volume effects, the firm's overall revenue will be adversely affected by low PBS prices.

There are several market conditions that act to reduce the subsidy effect including:

- Use of many PBS listed pharmaceuticals is restricted to specific patient types. Seventy five percent of new products in 1998 were listed on the PBS for uses that are more restrictive than those approved by the TGA.[14] The PC [15] also found evidence that volume restrictions are more prevalent for PBS listed products than in New Zealand and Ontario, Canada.
- The subsidy provided by the Australian government, as a proportion of the total price of the pharmaceutical product, is lower than the average of other comparable countries (excluding the US).[16]

Volume effects cannot be estimated from the available data but are probably not large because of the relative inelasticity of demand for pharmaceuticals and the above market conditions. While the effect on total return of lower prices paid for pharmaceuticals under the PBS is offset by higher volumes sold as a result of government subsidies to some degree, this has to date not been quantified with any accuracy.

Thus, the overall impact to the industry is indeterminate at best and unlikely to reflect preliminary finding 3.2.

Preliminary finding 3.4

If their profits are constrained by the operation of the PBS, the presence of liquidity constraints could, in principle, affect the activities of pharmaceutical firms, particularly those domestically owned firms not able to access global capital. However, given that there are better ways of overcoming liquidity constraints, they provide weak rationale for compensation to pharmaceutical firms. (page 3.27)

It is unclear why the PC has discounted the effects of price suppression on the financing capacity of MNC subsidiaries, in the face of a different conclusion from the Bureau of Industry Economics and a different experience on MSD's part.

When Therapeutic Group Premiums were introduced in 1997, this single price suppression measure wiped millions of dollars from MSD's profits on local sales. MSD was forced to reduce its discretionary expenditure. One of the affected projects was the

[14] Medicines Australia (2002) *A prescription for the health of Australia,* Medicines Australia, Canberra, p19
[15] Productivity Commission (2001) *International pharmaceutical price differences,* Research Report, July, AusInfo, Canberra ,p75-76
[16] Commonwealth Department of Industry, Science and Resources (2001) *Pharmaceutical Industry Action Agenda,* Discussion paper, Ausinfo, Canberra, p.10

MSD Research Foundation, which had provided untied grants to Australian researchers for a decade.

Preliminary finding 3.6

Country of origin pricing by other countries does not provide a credible rationale for compensation for PBS pricing in Australia. (page3.30)

In many of the Asian markets to which MSD exports, and the Middle East, Governments are explicitly or implicitly focussing on the price in the country of origin. It is because of this that Merck generally has a policy to establish a worldwide price for its products (the exception being its HIV/AIDS products).

Preliminary finding 3.7

Problems in PBS listing could have some effects on activity, but these are likely to have been small so far and would be best countered by measures other than an industry program. (page 3.35)

MSD agrees that a direct remedy is better suited to dealing with any PBS listing problems that may be affecting pharmaceutical activity. However, MSD suggests that this preliminary finding is not accurate. At best, the full effect is unknown.

While the discussion presented in the report on pages 3.31-3.35 provides a comprehensive analysis of the issue, MSD notes the following contributing points to the discussion.

- The contagion effect (as discussed in Box 3.5) is usually performed informally between countries. MSD's experience in negotiating with the Pharmaceutical Benefits Pricing Authority (PBPA) is that Australia will also informally benchmark Australian prices with overseas countries, when setting price - as per factor (g) of the PBPA factors. The informal nature of the inter-country benchmarking will make finding concrete evidence of its existence virtually impossible.
- The use of market penetration rates as a measure of market acceptance of a product must be considered in the context of time of entry in the market. The favourable penetration rates observed in the Australian market could be explained by pent up demand associated with launch delays into the Australian market. Under this scenario, doctors, aware of the benefits offered by new products available in the international market, will be extremely fast to use these products in the Australian market once they become available. It is also conceivable that Australian doctors are early adopters of new technology as is the experience in other areas eg. mobile phones.

Preliminary finding 3.8

While MNEs may possess additional bargaining power associated with the perceived desirability of pharmaceutical activities, this power is not likely to be very substantial in the case of Australia. (page 3.37)

In coming to this conclusion, the PC considered the degree to which firms will refuse to invest in a country with "excessive" price suppression. It cites New Zealand, commenting (page 3.36) that "other firms still undertake some R&D in New Zealand despite the adverse pricing and listing environment". This suggestion is both misleading and contradicts the Productivity Commission's earlier statement in this report (at page XVIII) that, "New Zealand, for example, has almost no pharmaceutical activity after firms left following years of low prices". As such, failure to counter price suppression carries a significant risk that firms would follow the same strategy as they used in New Zealand.

Discounting the threat of reduced activity in Australia that might flow from a MNC by assuming that other MNCs would fill any displaced role is dangerous. As recognised, the pharmaceutical industry is a high level knowledge based industry and provides jobs to highly trained people. It is erroneous to assume that there is an oversupply of jobs in Australia for highly trained people, and this is reflected, in part, by the fact that there is "brain drain" from Australia to overseas locations. The reality is that if MNCs cease to invest in Australia, the highly skilled jobs that they bring will also be lost, and the highly trained people may leave Australia, taking their knowledge with them.

Preliminary finding 3.10

Overall, while the activity of some individual firms may be affected by PBS-related factors, it is likely that the aggregate effects are relatively small. (page 3.41)

This conclusion is based on the PC analysing each of the elements in a "siloed" approach. Table 3.4. summarises its conclusion for each of the elements.

Nowhere does it considers the cumulative effects of all the elements.

Preliminary finding 3.11

The rationale for assistance to the pharmaceutical industry based on price suppression is much less persuasive than conventionally claimed. Nevertheless, there are some links between the operation of the PBS and domestic pharmaceutical activity. However, these are unlikely to be substantial or generate large inefficiencies. (page 3.45)

Given the uncertainties inherent in the previous findings, the PC's conclusion that adverse efficiency effects are "small" is similarly uncertain.

MSD recommends that the PC revisit its preliminary findings under Chapter 3 in order to review the link between price suppression and depressed activity

ii) Preliminary findings which relate to head office perceptions

Preliminary finding 3.3

From an economic perspective, once a decision has been made to supply a market, the global location decisions should be determined by the comparative costs of production – pricing should be irrelevant. (page 3.24)

Preliminary finding 3.5

Head office perceptions of the Australian environment for pharmaceutical activity are influenced by price suppression and PBS listing problems, with possible effects on investment decisions in some cases. In general, however, it appears that large MNEs are deliberate and hardheaded in their investment allocation decisions, using decision-making processes that minimise long-run costs. (page 3.29)

Preliminary finding 4.3

It is implausible that mis-perceptions by head offices about Australian capabilities are widespread. Multinational pharmaceutical firms have had an involvement in Australia over several decades – many with production and research facilities. In any case, there are more efficient direct ways of dealing with mis-perceptions than subsidising activity.

Preliminary finding 3.3 appears to assume that there is only one decision made to supply a market with a particular product. This is not the reality. There are a number of decisions made over time, in line with the lifecycle of a product.

For any new product, usually only 1 or 2 manufacturing plants will support the launch worldwide. As sales volume grows additional plants commence manufacturing. In response to sales forecasts the total number of manufacturing sites will expand. These sites will later contract until such time as there are again 1-2 worldwide manufacturing sites as the product moves towards the end of its life cycle. All of the decisions regarding market supply could potentially be affected by "rules of thumb".

Preliminary finding 4.3 refers to "mis-perceptions". It is submitted that these perceptions are in fact accurate and that the PIIP is a vehicle, which attempts to mitigate the negative environment in Australia. As such, the reality has to change before the perception can.

In addition, Preliminary finding 4.3 is not supported by the PC's own analysis. The PC concedes that for smaller and less strategic investments, transaction costs of decision making may result in firms adopting rules of thumb to allocate new facilities. This is the precisely the position in which many MNCs operating in Australia find themselves. When decisions are being made between otherwise equal market regions, market access issues might well be the "tie-breaker".

In relation to preliminary finding 3.5, MSD agrees that the building of a new manufacturing facility necessitates a significant investment of capital and that decisions on the location of a new facility are quite reasonably made in a "hardheaded" manner.

However, the decision to enable an existing facility to commence manufacturing an established product is subject to the so called "rules of thumb" as comparatively, only small investments of capital are required.

MSD's experience with its blood pressure medicine, COZAAR, is illustrative of this. When the product was delisted from the PBS for pricing reasons, MSD was unable to attract additional export markets, such as Taiwan, and manufacturing volumes declined.

If manufacturing volumes are low (approximately 50% of MSD's local overall production is for the Australian PBS market), then opportunities for further investment decline. In the COZAAR example, the loss of volume translated into the loss of $8-10million total investment in a new packaging line. If volumes had been maintained, a new packaging line ($5 million) would have been purchased and another $3-5million would have been spent locally to install and validate the line. The new manufacturing opportunity would have created an additional 10 jobs.

This negative effect is multiplied every time a product fails to achieve listing on the PBS. Over the medium term, if we fail to achieve listing of new products, the cumulative effect could amount to a significant loss of investment in our manufacturing facility (eg. 10 small investment decisions would equate to $100m) but this investment will have been made in another manufacturing site overseas. The result will be a plant that contains obsolete packaging lines rather than state-of-the-art equipment.

For a manufacturing plant to be competitive constant maintenance and equipment upgrades are required. Unless the plant can keep pace with the technology upgrades occurring within the company, the plant rapidly becomes obsolete and unable to handle the new products within the R&D pipeline. This leads to a further and rapid erosion of the manufacturing base and makes the plant vulnerable to rationalisation

Thus barriers such as domestic pricing, transparency and expediency of regulatory procedures for product approval and reimbursement are key factors influencing decisions on investment in secondary production.

The PC, in chapters three and four, has partially assessed whether the industry's perceptions have validity. The validity of these perceptions has yet to be fully and correctly assessed.

In aid of this, a table has been provided (Appendix B) which summarises the problems with the processes of the PBS which plague the pharmaceutical industry daily and reinforce to global head offices that Australia is an uncertain and difficult location for investment. Such attitudes are reflected in "rule of thumb" decisions that detrimentally affect Australia.

MSD recommends that the PC give more credit to the validity of head office perceptions and their impact on activity

iii) Preliminary findings which relate to spillovers

Preliminary finding 4.1.

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. (page 4.6)

This conclusion is premised upon how one defines "spillovers". As conceded in this report on page 4.2, "the concept of spillovers is not clear cut and there can be controversy about what constitutes a spillover effect". It was further conceded on page 4.5, that "it is hard to infer the magnitude or type of spillover benefits that might occur from pharmaceutical FDI in Australia".

Consequently, the PC's conclusion that spillovers from the pharmaceutical industry are no greater than any industries is hard to accept, given that it is one of the most , high technology R&D intensive industries in Australia.

The PC acknowledges that the literature on spillovers tends to find a pattern of higher spillovers in "high technology" industries, yet the PC discounts this because "Australia's pharmaceutical industry is much less R&D intensive than the OECD average." (p.4.5)

Comparison with the OECD average hardly seems relevant when the level of R & D as a proportion of output for the pharmaceutical sector **in Australia** is almost four times the level for total manufacturing.[17] The R & D intensity of the pharmaceutical industry is one of the highest of all manufacturing industries. Business Enterprise R & D expenditure as a percentage of value added in Australia in 1997 was 23.3%, which is significantly higher than the high technology industry average of 15.1%.[18] These data show that the pharmaceutical industry has been a significant investor in R & D in Australia, despite being below the OECD average.

The terms of reference (p.IV) require the PC to consider "all those who contribute to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia, including the bio-medical sector." It is in the area of spillovers that the links between the different parts of the industry come to the fore.

The PC does not appear to have fully considered these linkages and the growth in outsourcing of R&D and partnerships and alliances.

The PC believes that if there is underinvestment in pharmaceutical R&D, the appropriate response is to continue to use the existing suite of generic programs rather than an industry specific program.

[17] *Industry Outlook 2000*, Department of Industry, Science and Resources, p 22
[18] OECD Science, Technology and Industry Outlook 2000, Table 27, p246.

However the majority of the programs that Government has on foot[19] are aimed at small to medium enterprises and are not able to be accessed by the large companies. Many are targeted at the early stages of the value chain to overcome identified market failures and are not designed to encourage alliances between large companies and small enterprises and researchers, or to recognise that manufacturing is important for development of the local industry

MNCs can play an important role in the continued development of the whole pharmaceuticals industry in Australia, with resultant spillover effects. None of the programs listed above are particularly strong vehicles for encouraging MNCs to commercialise Australian research and for forming partnerships with Australian participants in early parts of the pharmaceuticals industry value chain. This is where the strength of a programs like Factor F and PIIP lie. The Pharmaceuticals Industry Action Agenda provided numerous case studies of partnerships which have directly resulted from the existence of these industry development schemes.

MSD recommends that the PC review the evidence on spillovers from the pharmaceutical industry and remove the finding that spillovers might be less than in other industries

[19] Government has also established specific programs to assist in commercialising Australian research. These programs are targeted at different points of the path to market:

- Biotechnology Centres of Excellence, whose selection process is currently underway;
- NHMRC Development Grants, which provide funding for research at early proof-of-concept stage;
- Cooperative Research Centres (CRCs): for example the CRC for vaccines and the CRC for Asthma;
- Biotechnology Innovation Fund (BIF), to fund proof of concept proposals for biotechnology;
- Pre-seed Fund, to fund early stage commercialisation of R&D from publicly funded institutions;
- Comet: to fund business planning;
- Innovation Access Program, funding networking, technology diffusion/technology awareness;
- R&D Start, to fund specific R&D projects;
- the R&D Tax Concession, to encourage R&D; and
- Innovation Investment Funds, to provide venture capital.

iv) Preliminary findings related to the effectiveness and efficiency of PIIP

Preliminary finding 5.1

While the empirical results are mixed, on balance the preliminary analysis suggests that the PIIP has induced a significant amount of new R&D and value added activity among participants. However, it does not appear to have induced additional employment, investment or exports. (page 5.17)

This result should not be surprising given the PC's observation that "the subsidy equivalent of assistance under the PIIP is not large at around 3.5%" (p.3.41).

The industry's concern with the PIIP has always been that 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.

That said, the cost benefit analysis of PIIP is over a very short time frame in an industry characterised by long lead times. Outcomes from previous schemes like Factor F are still being felt, years after Government funding has ended.

For example, with the support of the Factor F scheme, MSD/Merck started developing a vaccine for the cervical cancer linked to human papilloma virus in 1991, in collaboration with Melbourne-based pharmaceutical company CSL Ltd and the University of Queensland. This vaccine promises to be a block buster product that improves global health.

This collaboration has been running for 12 years, and it is 3 years since MSD received any Government funding for the project. However, it is important to remember that MSD initiated this collaboration at a time when the Factor (f) program was running.

It is also difficult to accept the PC's findings that the PIIP "does not appear to have induced additional employment, investment or exports" (p.5.17).

The Australian pharmaceutical industry's outstanding performance as a role model of growth, employment and competitiveness was highlighted by the 1998 Centre for Applied Economic Research (CAER) Working Paper, *The Economic Performance and Contribution of the Pharmaceutical Industry in Australia: 1985-1995:*

The key findings of the report were that:

- growth in the pharmaceutical industry between 1985 – 1995 was triple that of manufacturing overall, increasing its share of GDP and contribution to domestic consumption.

- employment in the industry increased by nearly 4% p.a. between 1990-1995, compared to a negative employment growth rate in manufacturing and a number of other industries.

- labour productivity in the industry nearly doubled in the decade under review, together with employment growth. This is a strong indicator of the pharmaceutical sector's accelerating contribution to the economy compared with most others.

- export growth was strong in the pharmaceutical industry relative to most other industries. Overall export growth averaged 13.1% p.a. over the decade; while export increases were nearly three times larger than total manufacturing in the 1990 – 1995 period. Since exports indicate international competitiveness and increased trade revenue, this is important information about the role of the pharmaceutical industry in both Australia's manufacturing base and the international pharmaceutical's market.

- the level of R&D as a proportion of the output in the pharmaceutical industry was nearly four times the level for total manufacturing. In absolute terms, R&D investment growth substantially exceeded most industries.

As the CAER Working Paper quoted above indicates, the pharmaceutical industry in Australia has done well in the recent past when compared with other industries in Australia. At the individual company level, the study done by Access Economics[20] for MSD found that in 2000, MSD's expenditure was responsible for creating an additional 4,600 jobs through its supplier relationships and generated an extra $555m of gross output and an extra $280m of value-added output for the Australian economy.

Overseas studies have found that the industry has a higher multiplier effect than other key sectors. Statistics Canada estimates that the industry has an employment multiplier effect of 2.19 (compared to 1.27-1.95 for the Telecommunications Industry, 1.22 for the Banking Industry and 2.09 for the Insurance Industry).

Preliminary finding 6.1

The most likely (base case) estimate of the impact of the PIIP is a net social cost of about $40 million for the first three years of the PIIP. This estimate is relatively robust, as there is an 80 per cent chance that the estimated net social cost lies between $10 million and $70 million. In theory, favourable outcomes are possible, but are only likely in a very limited number of cases where the key parameter values are set at very optimistic levels. (page 6.18)

The PC 's analysis here solely reflects the incorrect assumptions made in early chapters, dressing them up as if they were scientific. In particular MARGIN will be an underestimate as MSD contends that the PBS **has** in fact had a major impact on activities and SPILLOVER is also likely to be an underestimate given the unconsidered benefits of **linkages** between the different parts of the pharmaceutical value chain.

[20]Access Economics. The Contribution of Merck Sharp & Dohme to the Australian Economy. Technical Report, 2002

D. PRELIMINARY RECOMMENDATIONS

Preliminary recommendation 7.1:

After the PIIP expires in 2004, a further pharmaceutical industry program should not be implemented. (page 7.2)

The PC has noted in several places that PBS issues[21] could be problematic but states that the solution to the identified issues is not an industry program. It also dismisses the option of paying world prices for drugs as "prohibitive".

MSD acknowledges that an industry program is a "second best" solution, and would be unnecessary with the right operating environment. However, if reform of the PBS listing processes - which the PC says is the proper course in some areas- is unachievable, then the PC's recommendation regarding a new industry program leaves the industry in a policy vacuum.

The PC's recommendation is also at odds with the Pharmaceuticals Industry Action Agenda endorsed by Cabinet in October, 2002, which recommends the development of a successor to the PIIP (Action 4). The Action Agenda document (at p. 54) notes that a successor program can be justified on the basis that:

- prices for prescription medicines under the PBS continue to be low in Australia and this use of government purchasing power discourages investment and activity in pharmaceuticals research, development, commercialisation and manufacturing;
- reduced industry activity decreases the desirable spillover effects - this in turn limits the opportunities for commercialisation of Australia's basic research and high paying jobs for graduates;
- Existing support programs do not drive the type of investment in R&D, manufacturing, services and partnerships that are essential to achieve sustainable growth.

MSD has lost manufacturing and R&D opportunities because we were not a successful PIIP applicant and - if there is no replacement program or substantial improvements in the PBS operating environment, we will continue to witness a slow decline in our local R&D and manufacturing activity.

[21] For example, "there is evidence that over the last 2 years, drugs with potential for large budgetary impacts ..have faced longer delays in listing…Were this correct, the appropriate response would be to reform PBS listing processes rather than have an industry support program" (p.XVII) "failure to achieve a listing would significantly damage sales and overall revenues…p.3.3"; "while it is generally accepted that Australian prices are lower than many other developed countries, it is difficult to measure by how much they are lower "(p.3.8) "Problems in PBS listing could have some effects on activity, but these are likely to have been small so far and would be best countered by measures other than an industry program" (p3.35); "were the industry's perceptions to have validity, the appropriate response would be to change the PBS's listing processes" (p8.3)

- Without a new industry development program, our R&D is likely to be confined to Phase III clinical trials. This will have an impact on other parts of the value chain because a strong locally based pharmaceutical industry is critical if the immaturity of the local biotech industry is to be addressed and its potential realised.
- In the area of manufacturing, there is likely to be a slow shut down of our manufacturing modules. Over time, export markets will be lost and all that will remain is packaging for only Australia. Our current state of the art plant will become outdated, unable to handle the new products in Merck's pipeline and vulnerable to rationalisation once its useful life is exhausted.

MSD recommends that this recommendation be removed or, at a minimum, qualified by reference to PBS problems

Preliminary recommendation 7.2:

If the Government wishes to continue to provide support to the pharmaceutical industry to address any effects of low PBS prices, any new PIIP should:

1. *provide subsidies for R&D only;*
2. *be open to pharmaceutical companies with products on the PBS;*
3. *have its total funding capped;*
4. *have entry based on competitive criteria than emphasise undertaking activity that would not otherwise occur;*
5. *include more than one entry point; and*
6. *have a duration of five to six years (six years would allow three entry tranches). (page 7.16)*

MSD agrees with some of the specific elements for a new PIIP which the PC has proposed (eg. points 2 and 5 above), however we question whether a PIIP which focusses on R&D alone will provide sufficient incentive to retain a sustainable industry in Australia

The PC has failed to recognise that for MNCs, there is a strong relationship between the presence of manufacturing and an R&D presence. Manufacturing brings "critical mass" to a subsidiary and there are links between the drug development process and manufacturing.

In MSD's unsuccessful PIIP application, we had proposed a Regional Technology Hub as part of our broader activity commitments. This hub would have supported the introduction of new products. Its role would have been to review the experimental manufacturing data and develop processes for upscaling formulation for use in commercial production. This would have provided information for use by all Merck manufacturing sites. The hub would have brought a level of technical expertise that is currently not available at MSD. For the Asia Pacific region, it would have moved activities from the US head office to a regional base.

This is effectively part of the bridge between R&D and commercial manufacturing. But to do this, one needs a manufacturing presence, and if such a presence does not exist, the technical expertise is lost as well.

This practical example is supported by research undertaken by the OECD which recognised that the internationalisation of research and technology by multinational corporations complements their manufacturing and sales activities in major markets. "*Much evidence points to an internationalisation of research and technology by MNCs that complements their manufacturing and sales activities in major markets .For most countries there is a strong correlation between foreign affiliate shares of R & D expenditures and their domestic sales. The more foreign affiliates contribute to national output, the more likely they are to perform R & D in the host country…..the data suggests that foreign R & D investments tend to follow production abroad. The more production is located abroad the more likely research and development is likely to be also*."[22]

On deciding whether manufacturing activity ought to be included in a modified PIIP, the PC speculates that "once plant capacity is in place, decisions to manufacture another line come at relatively little cost to a company. In this situation, the PIIP may induce additional PVA, but it does not necessarily result in a large benefit to Australia because it does not require the commitment of significant resources by the company."

The PC fails to acknowledge that since there is presently a global over-capacity for manufacturing, plants which are running at a fraction of their capacity are more likely to be rationalised than those that are busier. An industry program which rewards manufacturing activity would assist in ensuring that existing plants in Australia remain busy and thus are less at risk of being rationalised.

In considering the duration of a modified PIIP, the PC rejects a longer commitment (5 years followed by an in-principle commitment for a further 5 years) on the basis that "certainty beyond a five year period is difficult to achieve within a government program." The recent 15 year commitment to an industry development program for the passenger motor vehicle industry flies in the face of this suggestion. Furthermore, the governments of other countries such as Singapore have no difficulty with long term commitments.

MSD recommends that the PC revisit its conclusion on manufacturing activity

Preliminary recommendation 7.3:

Clause (f) should be deleted from the guidelines issued to the PBPA by the Commonwealth Government. (page 7.20)

[22] Globalisation of Industrial R & D: Policy Issues, OECD 1999, p 16-17.

The PBPA is required to give due consideration to the level of an individual company's local activity when recommending PBS prices.[23] As stated in the PBPA's annual report, the Authority's objective encompasses, "maintaining a sustainable pharmaceutical industry in Australian".[24] The proposed deletion of factor (f) would effectively remove any requirement of the PBPA to perform its required role in giving consideration to the level of an individual company's local activity.

Although clause (f) is not being enforced directly, the PIIP scheme was, in part, an attempt to recognize clause (f), which thereby relieved the PBPA of its obligation to consider clause (f). Should the PIIP scheme be dismantled, the PBPA will again have to examine how best to give effect to clause (f).

In exploring options for fulfilling clause (f), the PC considers paying world prices for drugs, and concludes "the increased cost to the budget and/or patients make this prohibitive." In order to properly conclude that the costs of such an option are prohibitive, this would require much deeper analysis and a consideration of whether the public would be prepared to pay a larger portion of GDP towards subsidising the PBS. At present, this is merely an assumption of the PC.

Removing clause (f) - in the absence of any consultation with the pharmaceutical industry or the public -would be ill advised.

Moreover, factor (f) refers to taking account of local activity. It has no connection to price suppression. Local activity need not be confined to R&D or manufacturing so there may well be reasons beyond industry development for keeping it there.

MSD recommends the removal of this recommendation

Preliminary recommendation 8.1:

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.

Recommendation is supported.

Preliminary recommendation 8.2:

Australia's intellectual property legislation should be amended to allow generic drug manufacturers to export to countries where patents have expired, even if a patent is still in force in Australia.

[23] Industry Commission (1996) *The pharmaceutical industry,* Report No 51, Vol 1, May, Australian Government Publishing Service, Melbourne p96

[24] Commonwealth Department of Health and Aged Care (2000) *Pharmaceutical Benefits Pricing Authority Annual Report for year ended 30 June 2000,* Ausinfo, Canberra, p5 http://www.health.gov.au/pbs/pricing/pbparpt.htm

MSD believes that this recommendation should be removed for the following reasons:

- as the report notes, the issue is being pursued by an Interdepartmental Committee (IDC) chaired by the Department of Industry, Tourism and Resources (ITR). The IDC has produced an Options Paper and has conducted public consultations. The PC should not pre empt the outcome of these deliberations
- it is unclear how the recommendation explicitly relates to an evaluation of the PIIP – it would appear to be outside the PC's terms of reference
- the recommendation itself is far wider than any of the options canvassed in the ITR Options Paper.

The PC notes that "the current patent extension requirements….appear to impede **inadvertently** Australian exports of generic products and favour foreign-based generic manufacturers" (p.8.6).

We would dispute the suggestion of inadvertence. The patent extension provisions were developed and enacted only after a 1993 announcement following which a number of options were developed which were the subject of consultation with industry and interested parties over a period of years. The generic producers had ample opportunity to alert the Government to any adverse impacts on their business. Secondly, whilst there is no evidence that a prohibition against exports was a specifically intended outcome of the legislation, there is ample evidence to suggest that was within the general contemplation of the legislature as reflected in the Explanatory Memorandum (EM) in relation to the Bill.

Language such as:
"The aim is to provide an 'effective patent life' or period after marketing approval is obtained during which companies are earning a return on their investment more in line with that available to inventions in other lines of technology'";

"A country's patent system is also an important factor in contributing to a company's decision on whether to invest or not. If Australia has a weak patent system relative to its competitors, there is risk that investment in research and development will be lost to those offering stronger patent protection.";

"The object of this proposal is to provide an 'effective patent life' or period after marketing approval is obtained during which companies are earning a return on their investment more in line with that available to inventions in other fields of technology. It is also intended to provide a patent system that is competitive with other developed nations"

Discussion in the EM - of what activities would be allowed during spring-boarding during the extended terms whilst ensuring compliance with the TRIPS agreement - are all

supportive of the proposition that an extension of all the usual rights of the patentee was intended.

The EM also stated it would be undesirable for Australia to be out of step with the periods of protection offered to most other developed countries as to do otherwise would send a highly visible and particularly strong negative signal about the Australian climate for innovation and research and development.

A summary of the substantive arguments which MSD put forward to the IDC are included in Appendix 3.

In looking at patent life, the PC concludes that the amendment to the *Patent Act* which allows for up to a five year extension to a patent, providing a maximum effective patent life of 15 years, has "resulted in a majority of pharmaceutical patents (up to 70 per cent) expiring later in Australia than they do in comparable countries".

The conclusion is then drawn that these revised patent laws are the cause of generic drug manufacturers' alleged disadvantage in export markets. This extension is not the main reason why patents expire later in Australia than they do in comparable countries. The main reason is that Australia's regulatory approval process is slower than in many countries, and in some cases, patents are filed later in Australia. The appropriate remedy is not to change the patent laws, but to remedy the regulatory processes.

Weakening of our IP laws will just add more fuel to the negative perceptions which our head offices already have of the Australian environment.

With an emerging Australian based biotechnology industry, it is in Australia's interest to strengthen, not undermine the pharmaceutical patent system. This is particularly the case given the Government's innovation agenda and its substantial commitment to growing an Australian-based, research and development oriented, biotechnology sector.

MSD recommends the removal of this recommendation

APPENDIX 1: UNCERTAINTIES AND UNFOUNDED ASSUMPTIONS

Page No.	PC Text	MSD Comment
XVIII	The PC states "Firms have strategic incentives to raise with government their perceptions of an adverse environment in order produce (sic) favourable policy changes."	The PC clearly discounts industry information on the basis that it must be bias.
XIX	"[T]hrough Invest Australia there already exists a general mechanism for encouraging MNE investment in Australia"	Invest Australia has not to date provided a tailored approach which would be necessary to address the issues facing pharmaceutical MNEs.
XIX	"It is questionable whether an industry-specific approach is warranted for harnessing any spillover and agglomeration benefits in the pharmaceutical industry"	This uncertainty should not be decided against the industry.
XXII	"There remains some uncertainty about the effect of PBS pricing on firms' activity levels, for example, in relation to the significance of possible unfavourable head office perceptions about Australia. Were the Government to give greater weight to this uncertainty, the issue arisis of whether there is scope to improve the PIIP."	We submit that the degree of uncertainty is much greater than alleged, and the Government ought to give it greater weight.
XXII	"Failure to renew this industry assistance measure is unlikely to have a significantly adverse impact on the industry [as] the industry is built on Australia's comparative advantage in certain niches, such as	Has the PC considered what would happen to the local industry if this comparative advantage were to be whittled away by the proactive incentives of other countries?

	clinical trials and as a flexible manufacturer of short runs for local and regional markets, [and] this advantage will persist in the absence of the program.	
1.7	"For many programs – and especially ones involving relatively small subsidy rates as in the PIIP – it is very difficult to assess net benefits with precision. Indeed, in recognition of its endemic uncertainties, cost-benefit analysis is open to what one economist has called 'cooking the books without heat'. Choice of assumptions can determine the outcome of the analysis."	If the PC used any incorrect assumptions, they have – by their own admission- arrived at the wrong outcomes.
3.3	In discussing the PBS and its effect on demand, the PC states, "the bulk of the total cost of benefit-paid PBS pharmaceuticals – some $4050 million or 84 per cent in 2000-01 – is funded by the Commonwealth Government."	These figures taken in isolation are misleading as it is not stated until page 3.19, that non-benefit-paid PBS listed prescriptions are not separated from benefit-paid PBS listed prescriptions. The true government contribution towards the cost of PBS listed prescriptions will range somewhere between 54% and 84%[25], and it would be more suitable to present this range. Thus the conclusion, that script volumes can be expected to be signficantly higher under the PBS, compared to unsubsidised demand (page 3.3) may not be as robust.
3.3	"Moreover, the existence of prescription subsidies will, unless countered by other regulations, typically push up the price set by manufacturers for specific drugs. For example, because of the ceilings on prices,	It is misleading to make this statement before introducing the reader to the "other regulations", including the comprehensive economic evaluation performed by the PBAC. As the preliminary report correctly states on page 3.6, legislation seeks to ensure that no new product is listed on the PBS unless it demonstrates an appropriate level of cost-

[25] Based upon data provided by the Australian Institute of Health and Welfare ("AIHW") 2002: 256, the lower range of government contribution can be calculated as follows. Non-hospital patient expenditure on pharmaceuticals over 1999/00 was $2.3 billion. This figure comprises the cost of non-benefit PBS prescriptions; the cost of private prescriptions not covered by private health insurance; and the cost of non-prescription pharmaceuticals. Thus, patient contributions to total PBS prescriptions will be somewhere between $0.7 billion (patient contributions of benefit-paid prescriptions for 1999/00) and $2.9 billion (total patient expenditure on pharmaceuticals over 1999/00). Given that the government contribution in 1999/00 was $3.5 billion, it can be calculated that government contributed as little as 3.5/{3.5 + 2.9} = 54%.

	a concessional patient is indifferent between equivalent branded drugs costing $400 and $3.60 (as are unregulated prescribing physicians unless they care about burdens on taxpayers). Unless there are cheaper competing drugs below $3.60 – and for most drugs there are not – a pharmaceutical manufacturer has an incentive to add large premiums to drug prices if they have the market power to do so."	effectiveness. Consequently, the reader would likely form the incorrect perception that taxpayers may be inappropriately funding a medicine priced at $400 when there is an "equivalent branded drug" costing only $3.60. Furthermore, and in contrast to the text, the manufacturer does not have the power to add large premiums to the price of medicines (except in TGP categories).
3.7	"The impact of reference pricing and other cost containment measures on the ultimate returns to a pharmaceutical supplier is somewhat mitigated by the capacity under current regulatory arrangements for the supplier to charge a higher price than the reference price, but with the patient paying the difference between the reference and selling price."	This statement would lead the reader to believe that suppliers can charge premiums whenever they wish. This is not correct. . In fact arrangements for suppliers to charge a patient premium applies only to 1/3 of products listed on the PBS and predominantly to off-patent products. As at June 2000 only 27 patented brands (or 1% of all brands listed on the PBS) charged a patient premium.[26] In addition, the PC has failed to explore whether charging a "premium" reduces the volume and thus return to the pharmaceutical supplier. In Australia, direct to consumer advertising is prohibited and thus the consumer, not being educated about the advantages of the "premium medicine", may be prone to select a less expensive competitor.
3.9	"It is important to examine price suppression for different classes of pharmaceutical products – new innovative pharmaceuticals (products with significant clinical benefits that have limited substitutes, 'me too's' (patented drugs that have close substitutes) and off-patent	The PC acknowledged that "the Productivity Commission's results replicate the finding of past pricing reviews", but fail to expand on these and instead go into detail around the fact that Australian generic prices are relatively highly priced by international standards. Perhaps the message is that generic medicines are priced too highly at the expense of patented medicines. Danzon *et al* have found that strict price regulation lowers the price for older patented products and for products

[26] Commonwealth Department of Health and Aged Care (2000) *Pharmaceutical Benefits Pricing Authority Annual Report for year ended 30 June 2000,* Ausinfo, p10 Canberra, http://www.health.gov.au/pbs/pricing/pbparpt.htm

	drugs (comprising generics and off-patent originator brands) – since the price difference may vary markedly by class.	that are available broadly across international markets as compared to less regulated market. In addition, they found that competition between off-patent products is more effective in lowering prices in less regulated markets. [27] In another study the same authors found evidence to suggest that the price of off-patented products did not always approach marginal costs, particularly in more regulated markets.[28]
3.11	The PC discusses what would happen if pricing were liberalised, and found through survey, that "the average price increase [for patented products] was 22 per cent and median 18 per cent", then concludes that "it appears that much of the difference between Australian and overseas drug prices cannot be traced to policy-induced price "suppression".	The conclusion is inconsistent with the survey results, which themselves are 6 years old. Thus, this ought not minimise the extent to which the PBS arrangements result in price suppression.
3.15 (Box 3.1)	In looking at the "puzzling story of generic drugs" [being that different countries maintain different prices for generic drugs over time], the PC develops two possible explanations, which it assumes must also hold for branded drugs. The two possible outcomes are: 1) a reduction in "the claim that international price differences only stem from differential buyer bargaining power", or 2) "price suppression may not have as	This leap from generics to patented products is unfounded. The market forces differ across the globe and thus account for varying prices of generics.

[27] Danzon, Patricia M., Chao, Li-Wei (2000) "Cross-national price differences for pharmaceuticals: how large, and why?", *Journal of Health Economics,* Vol 19, 159-195 p159

[28] Danzon, Patricia M., Chao, Li-Wei (2000) "Does regulation drive out competition in pharmaceutical markets", *Journal of Law and Economics,* October, Vol XLIII, 311-357 p311

	many undesirable dynamic effects on global resource allocation to R&D as sometimes supposed"	
3.16	"[T]he average subsidy rate for benefit-paid pharmaceuticals is 84 percent."	As discussed above in this table, and acknowledged in the PC report, the average subsidy rate should consider the full range of PBS products, not just the benefit-paid pharmaceuticals. Thus, the average subsidy rate is somewhere in the range of 54-84 per cent.
3.16	"One pharmaceutical company indicated that it expects to sell four times as many drugs when they are listed on the PBS than when they are available privately at full cost."	The PC has used this statement, out of context, to support some degree of elasticity of demand for pharmaceuticals. The private market in Australia is presently ineffective as demand on the private market is likely to be negligible since a private market product must compete on price with a subsidised substitute (which in many cases may be inferior).[29]
3.16	In discussing revenue effects, the PC speculates, in the face of the "generally held [view] that pharmaceutical demand is relatively price inelastic", that "firms might make more revenue and, given low marginal costs for drugs, greater profits, from being in a low price but subsidised formulary, than to have 'free' pricing and no consumer subsidies." They further speculate that, "then it would not be clear that price suppression really harmed firms (that get listing for their products) at all relative to the monopolistic pricing	The PC assumes an unproven elasticity, then further fails to consider the effects of a subsidised, but volume restricted formulary (which is closer to our current environment).

[29] The price premium for the private market product will be disproportionately large for two reasons. First, the patient is only paying a co-payment, not the full price for the subsidised treatment. Second, the pharmacist and wholesaler mark-ups are unregulated in the private market and tend to be substantially higher than the regulated mark-up for PBS listed products. Other factors that make the private market less attractive to the producer as compared to the PBS market include: Doctors seldom discussing non-PBS options with patients as they assume patients will not pay the higher costs of a private prescription; and Australians sharing an underlying belief that all essential pharmaceuticals are available on the PBS. Such factors combine to make a private market in Austalia insignificant.

	benchmark – and this would invalidate the present rational for PIIP."	
3.18	In discussing revenue of a drug over its life-cycle, the PC states "it is critical to consider volume as well as price effects"	The PC makes many assumptions about effects on volume from PBS subsidies, but fails to support them with evidence (especially in light of the generally held view "that pharmaceutical demand is relatively inelastic"). They also fail to give due consideration to the impact that volume-limiting arrangements may have on revenue.
3.19 Box 3.2	Box 3.2 presents "back of the envelope calculations" that attempt to measure the revenue impacts of price suppression. The PC concludes that to measure revenue impacts of price suppression, it is necessary to consider both volume and price effects.	We endorse this conclusion, but suggest that the illustrative example could mislead the reader as the numbers used in the illustration are unfounded and potentially "out of the ball park". Relying upon such figures, the reader is likely to conclude that volume effects will offset any positive revenue effects that would stem from a hypothetical price increase. Such a conclusion may be incorrect and is not supported by the evidence.
3.20 (footnote # 31)	Discussing the Lewin Group (2001) survey, the PC all but discounted the results when it stated, "[q]uite apart from the usual problems associated with qualitative surveys of perceptions …, a significant drawback of such surveys is that they are likely to elicit strategic answers. MNEs would clearly prefer greater freedom to set reimbursement prices in all markets and their answers presumably reflect this."	Such assumptions are unfounded. This attitude is reflected throughout the report in the negligible weight attached to any evidence arising from industry sources. When presented with a wealth of industry evidence, uncontradicted by any other evidence, about factors influencing locational decisions, the PC still maintained that "these reviews were based primarily on the views of pharmaceutical firms and some empirical evidence relating to price differences. But, with the exception of the Commission's 1996 inquiry (IC 1996, pp. 321-50), they did not undertake in-depth analysis of the potential economic links between price suppression and pharmaceutical activity" (page 3.23).
3.23	The PC rejects the previously held view that the PBS buying arrangement represents a monopsony, but instead is an oligopoly. The PC then concludes, without evidence, that "it would appear strange in the context of these more realistic models of bargaining under the PBS that there would be any rational effect on Australian	A number of assumptions and models are used by the PC to conclude that price suppression has little impact on activity. Such assumptions and models appear to be erroneously given greater weight than industry evidence and existing empirical data.

	activity from price suppression directly."	
3.24	The PC concludes, in the face of existing evidence, that "the adverse effects of low Australian prices alone on global R&D is likely to be negligible given the small importance of the Australian market." "In these alternative characterisations of government purchasing arrangements, there do not appear to be direct links between low Australian prices and any adverse effects on Australian activity."	Such conclusions are unfounded on the body of available evidence and find their only support in the theories of the PC.
3.28	In discounting the significance of head office perceptions of the Australian environment as a factor for investment allocation, the PC states "[o]n the other hand, there is evidence that large MNEs are very deliberative and hardheaded in their investment allocation decisions, using complex models and decision-making processes that minimise long-run costs".	The PC does not state what this evidence is, that it relies upon to discount the overwhelming contradictory evidence from all subsidiaries consulted that "the adverse perceptions of the Australian pharmaceutical environment arising from the PBS arrangement" … "unless countered by some other advantage (such as the PIIP), would lead to reduced activity in Australia.
3.32	The PC proposes that "if the argument that price suppression is a major (indirect) source of restricted, delayed or non-listing … were robust, then it would be expected that it would be more severe in countries with greater degrees of price suppression." "Unfortunately, appropriate data to resolve the question are scarce." However, all available data indicates that "non-listing was an increasing problem for Australia relative to many other OECD countries", and that "Australia had the	After proposing its own test, and discovering that there is only evidence to support the conclusion that price suppression results in a reduced listing of new drugs, the PC proposes a "better indicator" which focuses on market share of drugs that are launched. This seems to make little sense and does not support the conclusion that there is not a severe problem with listing new drugs in Australia.

	lowest level of product launches of NMEs first launched in global markets between 1990 and 1999." The PC admits that "Australia tends to have a relatively low acceptance of NMEs as measured by the number of such entities", but then without any stated basis, assumes that the "better indicator of acceptance is the market share acquired by NMEs that are successfully launched". The PC then comments that there "appears to be little relationship between this measure of product acceptance and price differences", and thus concludes that, "while individual companies may sometimes encounter listing problems and volume constraints that affect MNEs, there does not appear to be a severe systemic problem associated with listing of therapeutically significant new drugs in Australia.	
3.34	"Where cost-effective drugs were not listed or subject to unreasonable volume controls, an industry program would be a largely ineffective and partial response to such a problem. While it might resolve some industry concerns, it would not help consumers get greater access to cost-effective drugs. Were the industry's listing concerns to have validity, the appropriate remedy would be to deal with these	The PC fails to acknowledge that PIIP payments can be used as actual price increases so that consumers can get greater access to cost-effective drugs

	problems at their root – reforming the listing process of the PBS."	
3.45	"[T]here could be some more complex links between suppressed prices and domestic activity – such as by generally damaging head office perceptions of Australia or intensifying liquidity constraints. While these arguments have some validity, it is far from certain that the effects they have would be large enough to warrant remedying."	In the face of this admitted uncertainty, the PC opts to not remedy the possible problem.
3.5	"Australia's TGA processes were recognised world-wide as of high quality – and this facilitated the supply of drugs from Australia to regional markets"	Although the standard of review facilitates the export of product to regional markets, the timeliness of review is slower than major competitor countries and may impede export. The PC fails to consider the element of timeliness and its adverse effect on long term manufacturing in Australia.
4.5	"It is hard to infer the magnitude or type of spillover benefits that might occur from pharmaceutical FDI in Australia".	What if it is high, and the PC has attributed the wrong weight in concluding that pharmaceutical spillovers may be even less than in other industries?
4.9 (Box 4.2)	In discussing agglomeration benefits, the PC states "[g]enerally, governments find it difficult to determine the extent of agglomeration benefits and industry has an incentive to exaggerate them."	The PC's attitude that industry can not be trusted and thus their evidence ought not be considered, shows through.
4.15	"Investments that are responsive to inter-governmental competition tend to be footloose (involve capital that can be relocated relatively easily). But the gains from footloose investment are often not sustained once assistance is removed and thus less likely to lead to net gains in the long run."	This is an unsubstantiated assumption. Furthermore, by making the assumption at this point in the text (combined with comments on page 4.14), the PC implies that pharmaceutical manufacturing facilities are footloose, which, even by the PC's own definition, they are not, as they cannot be "relocated relatively easily", and continue to provide employment and exports long after government incentives for their location have ceased.

4.17	The PC concludes that, information failures or incorrect perceptions are not best targeted by a PIIP-type program, but rather by measures that aimed more specifically to deal with information or perception problems.	The assumption is that the problem is merely one of perception, when in fact the problem may be that through the PBS, Australia fails to reward innovation.
7.2	"[T]here remains a margin of uncertainty about the diagnosis that any effects of price suppression on domestic activity are too weak to warrant policy intervention."	Once the body of evidence is examined, and the bold assumptions are taken as mere assumptions, this uncertainty grows and ought not be decided against the industry.
7.6	In looking at a modified PIIP, the PC stated "it is debatable, however, whether the 'perceptions' rationale warrants support for production".	The PC concedes that this is not conclusive.
7.8	In considering company eligibility for a modified PIIP, the PC speculates that, "subsidised R&D activity in biotechnology firms may also directly substitute for R&D activity that would be lost as a result of adverse head office perceptions by pharmaceutical MNEs about Australia."	This theory about direct substitution of R&D is unfounded and fails to recognise that R&D continues throughout the commercialisation continuum. R&D required in the latter phases is exceptionally costly, and has been shown to be beyond the resources of most biotechnology firms. The main avenue for permitting this later stage R&D is through collaborations with MNEs. If the MNEs have a poor perception of Australia, they will be less likely to site R&D investment here. Thus, the PC's theory about directly substituting R&D of biotechnology firms for that of MNEs is flawed.
7.18	"Moreover, adoption of the preferred recommendation (not to continue with a pharmaceutical-specific program) would not represent the cessation of government assistance to the industry, or indicate that the Government did not value the important contribution of the pharmaceutical industry in Australia"	We wholly disagree. Cessation of the program would remove all government assistance to the pharmaceutical industry and would send a clear message to MNEs that Australia is a non-supportive environment which would further damage the perception of Australia as a viable place to invest.
7.18	"The pharmaceutical industry typically	The benefit derived by the pharmaceutical industry from such programs

	benefits from the suite of generally available Commonwealth Government programs and State Government assistance)."	is negligible. Most are targeted at earlier phase R&D and are not consistently available to MNEs.
7.20	"Given that each of the options to implement a clause (f) objective would be inappropriate, the clause is at best redundant and at worst detrimental to the interests of the community. This is one gordian knot that can safely be cut."	It is disconcerting that the PC would recommend deletion of clause factor (f) on the grounds that it can find no suitable mechanism for its implementation and give no consideration to the rationale for the inclusion of this factor. The PC recommendation is wholly unfounded on evidence. Consultation has not occurred and options have not been fully explored and analysed.
8.6	"Allowing generic manufacturers to export to countries where the patent had expired would not materially undermine patent protection in Australia. Moreover, as long as the export-destination countries had a sound regime for the protection of intellectual property, exports from Australia should not raise adverse perceptions about the commitment of Australia to protection of intellectual property."	This is complete speculation and unfounded on any evidence.

APPENDIX 2: THE PRICING AND REIMBURSEMENT SYSTEM AND HEAD OFFICE PERCEPTIONS

Element of the pricing and reimbursement system	Consequence	What this conveys to Head Office
Delays in listing or failure to list	• Products get to market later than in comparable countries, and have less time to recoup investment. • Threats of delay function to force prices lower. • Australian manufacturing loses opportunities to export to markets that select countries that list earlier • The following MSD 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.	Australia is slow, uncertain and opportunistic.
Volume restrictions	• Producers see reduced revenue combined with increased risk and uncertainty. • MSD's product for asthma, SINGULAIR has volume restrictions in addition to a range of prescriber restrictions	Australia is heading down the New Zealand path, and does not value the pharmaceutical industry's contributions to the economy or health outcomes.
Complex pricing and reimbursement process	• Unlike the position in EU, UK, or the USA, companies in Australia cannot be confident that their drug will achieve listing. • Creates uncertainty in revenue forecasts for forward planning purposes.	Australia is not a simple place to do business.
Lack of transparency and	• Makes it difficult to forecast and to report on the progress of PBAC/PBPA applications to head office.	Australian business environment is uncertain and government decisions

process for review	• Recommendations of the PBAC are not appealable. • Pricing discussions are complex and have been made more uncertain by the Department of Finance and Cabinet (for products more than $10m) being added as hurdles but not having had their roles defined.	are unpredictable.
Price determination using economic evaluation	• The PBAC's interpretation of a product's economic evaluation will result in a PBS price lower than one reflecting the full value of the benefits offered by the product. • PBPA process for determining price is poorly defined and documented. • Creates uncertainty of pricing outcome and domestic sales revenue. • Special approval from head office is often needed to accept such low prices eg SINGULAIR, VIOXX.	Australia does not reward innovation and presents a difficult environment.
Ongoing pricing reviews	• Quantum and timing are often unknown and require work to defend price. • Creates uncertainty in revenue forecasting. • Frequently reduces prices which then have to be communicated to head office • For MSD's 6 top selling products, the average level of prices is 70% of EU average prices	Australia is an unpredictable place to do business and presents a difficult environment.
Listing process detracts from private market	• Negligible private market as doctors are unwilling to prescribe new treatment for which eventual reimbursement and prescribing criteria are unknown.	Australian environment prevents adequate reward for innovation on the private market
Increasing drive for cost containment with the PBS	• All the problems above are being exacerbated. • Increasing uncertainty in achieving PBS listing	Australia is heading down the New Zealand path and will continue to become a more difficult environment.

APPENDIX 3: WHY PATENT LAWS SHOULD NOT BE AMENDED TO FACILITATE GENERIC EXPORT DURING THE PATENT EXTENSION PERIOD

- The premise - that expiring patents in major US and European markets will provide huge export opportunities for Australian generics producers - is hard to understand, given that the US and EU markets have very competitive and strong national/regional generics producers.

- Even if the estimate of an additional A$2.2 billion in export revenues over 2001-2009 is correct, it puts at risk a far more significant export effort from the research based manufacturers. MSD alone will manufacture exports to that level of value ($2.2b) in half that time frame, given a supportive policy environment.

- There is also the possibility that an Australian based generics manufacturer could be competing for business against an Australian based innovative manufacturer in the same overseas market, with potential loss of export dollars for the innovative manufacturer. For example, MSD Australia continues to manufacture branded products for global markets once a patent has expired.

- If the PC's recommendation were applied to existing patents, there is potentially the taking of property rights without compensation and the Commonwealth may be liable to compensate patent holders.

- the recommendation could potentially place Australia in breach of its obligations to the WTO. Whilst any patent extension beyond 20 years is at the discretion of WTO Member States, it can be argued that once a patent is on foot (whether it runs for 20, 22 or 25 years) TRIPS requires full patent protection to accrue

- It flies in the face of the Government's original commitment (when it introduced the 1998 changes) to allow a minimum of 5 years to pass before any evaluation of our patent regime occurred.

- The recommendation effectively sanctions "stockpiling", which was found to be inconsistent with TRIPS in the recent World Trade Organisation Canadian case (WT/DS 114/R). Specifically in that case the Panel found that the stockpiling exception constituted a substantial curtailment of the exclusionary rights required to be granted to patent owners under Article 28.1 of the TRIPS Agreement and as such that it could not be considered a "limited exception" within the meaning of Article 30 of the Agreement. This position was supported by submissions from Australia.