Submission to the Productivity Commission's Draft Report on the Pharmaceutical Industry Investment Program.

Eli Lilly Australia Pty Limited

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Contents

Executive summary

Eli Lilly Australia Pty Limited (ELA) is a subsidiary of Eli Lilly and Company headquartered in Indianapolis, Indiana, USA. Eli Lilly and Company is one of the top 10 research based pharmaceutical corporations in the world and within Australia. Lilly is committed to a continuous stream of innovation, resulting in a range of first in class or best in class prescription medicines and the acknowledged best pipeline of new compounds in the industry today.

ELA employs over 500 people in research and development, sales, marketing, distribution and general administration functions. Turnover in Australia is 2002 was in excess of A$250 million.

This represents substantial growth from 1997 when turnover was A$113 million with a workforce of approximately 300.

ELA is one of 9 participants in the PIIP and the only company whose PIIP activity is focused only on R&D activity. ELA committed to incremental investment of A$142.9 million over the 5-year period, with an investment incentive entitlement of $19.9 million. Currently, ELA is ahead of projected expenditure and has demonstrated the highest ratio of investment verus baseline of all PIIP participants with an R&D component. As such, ELA is in a strong position to comment on the draft report findings with regard to R&D investment. Because ELA has not participated in either the Factor F or PIIP programs in the area of production value added, comments in this submission are confined to the R&D area.

ELA believes the approach taken by the Commission in its draft report understates the benefits resulting from the R&D component of the PIIP. The econometric analysis which calculates the net cost / benefit to Australia from the PIIP is overly conservative for the following reasons:

- The Commission attempts to generalise across the small number of programs that have very different investment components (R&D versus production value added and different models of investment within R&D itself). The R&D experience is impacted by the fact that 3 participants have not met their incremental investment targets for various reasons. However, this should not damn the whole program in terms of ability to stimulate R&D investment.
- In doing so, the Commission assumes a low level of induction for R&D activity (45%). **The ELA experience suggests a level of 76% is appropriate for its specific program**. Even if a lower figure is considered appropriate across all the R&D participants, one could argue a figure between the 45% and 76% levels would be a more appropriate estimate than that used in the draft report.

- The Commission also assumes a very low level of spillover from *clinical* R&D activity (25%). **The ELA experience suggests a level of 37% is appropriate for its specific program**.
- The low assumptions used by the Commission in the draft report combine to produce the econometric result of a net cost to Australia from the current PIIP. ELA data supports the use of higher values for these key variables in the Commission's econometric evaluation. These may be somewhat unique to the model adopted by ELA for its PIIP activities but are nevertheless evidence of the effectiveness of the current program. These claims are supported in this submission and ELA believes the Commission should adjust these variables upwards for its final report.

ELA notes that the Lilly PIIP estimates provided in this submission (76% for inducement of R&D activity and 37% for clinical R&D spillover rate) are closer to the "most favorable scenario" estimates of the Commission (70% for inducement of R&D activity and 50% for spillover rates for clinical research).

ELA also believes the Commission has failed to make specific recommendations regarding the importance of the operating environment created by the Pharmaceutical Benefits Scheme and the Pharmaceutical Benefits Advisory Committee process. While the draft report makes reference to a significant body of input it received from the industry on this issue, no conclusion or recommendations are made. This submission provides comment on the fundamental nature of the issues confronting the industry at present. The draft report acknowledges the importance of "head office perceptions" of the Australian environment in shaping investment decisions, but fails to suggest solutions.

In contrast, the draft report does include a recommendation (8.2) that Australia's intellectual property legislation should be amended to allow generic manufacturers to export to countries where patents have expired, even if a patent is still in force in Australia. While this may seem a minor change to the intellectual property regime Eli Lilly and Company regard any erosion of the regime as undesirable and a negative factor in investment decisions. Such changes to intellectual property regime irrelevant to an evaluation of the PIIP and are not helpful to the issue of attracting further industry investment to Australia and ELA suggests it is removed from the final report.

Finally, the draft report suggests that IF government were to continue some form of industry investment incentive it should be focused on R&D activity. This submission supports this view and provides further comment on the evolving nature of collaborative R&D investment with significant potential for Australia's struggling biotechnology and biomedical commercialisation industries. However, this submission argues it will be inadequate to rely on existing generic R&D investment incentives at their current level.

1. Brief overview of Eli Lilly Australia's participation in the current PIIP

ELA is one of 9 participants in the PIIP and the only company whose PIIP activity is focused only on R&D activity. Highlights include:

- ELA committed to incremental investment of A$142.9 million over the 5 year period, with an investment incentive entitlement of $19.9 million.
- Currently, ELA is ahead of projected expenditure by A$10.6 million and has demonstrated the highest ratio of investment verus baseline of all PIIP participants with an R&D component.

ELA has essentially three components to its PIIP participation.

1. The Clinical Outcomes Research Institute (CORI):
This was established here as part of the ELA PIIP program with the specific aim of supporting clinical research across the Asia Pacific area. Since establishment, the scope has changed somewhat, to focus more on Phase IV trials but over a wider geography (all the world excluding US and Western Europe).

As well as expanding the quantity of clinical trial activity being conducted within Australia or supported by Australia, CORI also expanded our clinical research capability. This is best described as vertical integration of all clinical research activities eg protocol design, IT development, database design, data collection, data analysis, statistical services and report / publication writing.

2. The Global Clinical Data Management Centre (GCDMC):
This component was established to meet corporate need for increased efficiency in processing individual patient data from clinical trials. However, PIIP was instrumental in capturing this opportunity for Australia. The centre receives clinical trial data (in the form of individual patient case report forms) from trials in many countries (mainly the Asia Pacific area, but also acts as an overflow processing centre for trials served by the other two Lilly centres of this type, in Indianapolis and Spain).

3. Technology Transfer:
This third component has probably been under sold by Lilly in the PC survey and the site visit, as it is a further significant source of "spillover" from our PIIP activity. This issue is expanded later in this submission.
There is a diverse range of activity captured here, including several innovative health outcomes projects involving external researchers and consultants. PIIP has been instrumental in attracting corporate investment to support these larger projects that have not been feasible for ELA prior to PIIP. The collaborative nature of these projects is important as it both increases the

spillover and adds learning relevant to the future nature of collaborative R&D opportunities for Australia.

Major projects include
a) A large longitudinal observational study in schizophrenia, conducted over 5 years in Dandenong, Victoria. This is a million dollar plus project.
b) A large survey based cost of illness study in diabetes (yet to feature in Lilly PIIP claims).
c) A multifaceted research collaboration in psychiatry centred on the University of Melbourne (just beginning to feature in Lilly PIIP claims).

2. The level of induction of R&D activity.

Page 5.1 of the draft report lists key criteria for effectiveness of the PIIP or similar schemes. These are

- **The program must have the right *sign* i.e. PIIP must *increase* Pharmaceutical activity.**
  As argued below, the ELA program has categorically increased R&D activity from a base level A$8.7 million to a peak annual figure forecast for 2003-04 of A$42 million. The question therefore becomes how much of this activity was in fact induced by the PIIP. This is further examined below.
- **The effect must be of sufficient *size*, given the resources spent on the program.**
  Here the draft report appears to avoid the fact that the effect size is, at least in the ELA case, considerable. The draft report introduces a range of variables that may contribute to the effectiveness of any incentive program. While these variables appear reasonable to consider, they do appear to be addressed satisfactorily in the ELA case. That is, *employment* resulting from the ELA program has been considerable (136 people to date at an average fully loaded salary of A$78,000). The *character* of the investment is a key aspect of the ELA program, as it involves not only a quantitative increase in the number and value of clinical trials, but also an investment in the whole continuum of clinical research capabilities (including protocol design, software development, database construction, data collection, statistical analysis and report writing). This depth of capability illustrates that the industry *can* respond to incentives by investing in sustainable infrastructure and skills.
- **The program, and not some other factors, should be the likely *cause* of the desired outcomes**.
  This is addressed below.
- **Measures of effectiveness should be *reliable*. For example, an assessment might show that a program increased industry R&D by 50%, but the results may not be reliable**.
  The draft report goes on to indicate that there may be such variation around this estimate that it is merely an artefact and unlikely to be repeated in the future. The ELA view is that the growth seen in its program is sustainable and reliable. However, the *variation in type of R&D program* across a small number of companies has led the Commission to ignore this example rather than to consider the elements that are reproducible and likely to respond to better designed eligibility criteria in any future R&D investment incentive scheme.

Further comments on the level of inducement:
Page 5.2 of the draft report goes on to state that a level of inducement of 100% is not credible. ELA agrees with this statement. However, the draft report goes on to acknowledge that it seems reasonable to attribute a level of inducement for R&D activity, but that "anecdotal stories provide little information for estimating inducement parameters though they provide extreme boundaries for acceptable estimates".

The draft report acknowledges it is difficult to obtain accurate estimates of inducement for R&D activity. The report then (in Section 5.4) attempts to do so via statistical analysis of spending by PIIP participants versus non-PIIP participants. Given the very small number of firms and the variability of their R&D programs under PIIP, this approach is questionable. Expert advice provided to Medicines Australia by Access Economics also questions the validity of this approach.

ELA suggests more attention should have been paid to the details of individual programs rather than attempting to "average" estimates of inducement for the whole PIIP. The failure of three participants to reach their R&D commitments reflects the nature of their R&D programs and changes in the strategic directions of two of these participants (Amrad and CSL), not a failure of the PIIP and suggests much could be learned from more careful assessment of the more successful programs to help shape criteria for any future R&D investment incentive. However, the performance of these firms undoubtedly impacts on the overall growth of R&D investment across the participating firms, leading to the statement on page 5.14 that "growth rates of R&D have been lower in PIIP firms than non-PIIP firms".

Again, ELA would suggest this reflects the variation in type of R&D undertaken and that more careful construction of eligibility criteria would have resulted in a more uniform pattern of growth.

As a result of these difficulties, the draft report uses an inducement rate for R&D of 45%.

In the ELA case, the inducement level is undoubtedly higher. There are several reasons for this:

- The base activity was that seen in many pharmaceutical firms in Australia i.e. a level of Phase III clinical trial activity that had grown over years but was beginning to show a reduction in the rate of growth (due to more countries participating in Phase III programs, many at lower cost than Australia). The type of trial activity was also typical at the time i.e. protocols received from corporate R&D groups, with the local role confined to identifying and contracting local investigators, monitoring trial execution and ensuring data was efficiently despatched to corporate R&D headquarters for cleaning and analysis.

- The rationale for CORI was to create a regional centre of excellence in clinical research that would service clinical trial needs in the Asia Pacific area. In addition, CORI would provide the depth of expertise to enable a more responsive process across the whole clinical trial continuum. This meant the addition of personnel to design protocols, develop software for database development, and provide statistical and report writing services.
- Over time, the effective operation of this continuum of clinical research services proved to be most valuable in "commercialisation trials" i.e. trials other than those primarily for registration purposes such as the traditional Phase III model. Commercialisation trials typically involve answering clinical and commercial questions related to drug doses, new indications, combinations or populations. They are also typically slow to execute and "commercialise" i.e. complete to the stage of publication in an appropriate medical journal. CORI has become an extremely efficient operation for such trials.
- Therefore the counterfactual is a continuation of the clinical research status quo. A number of the trials would have occurred in Australia without PIIP, but all other activity can be considered induced. Allowing for some increase in trial activity associated with pipeline products, ELA's best estimate of the level of inducement for CORI clinical trial activity is 73%. This can be validated as follows: As the table shows, the actual $ expenditure on clinical research over the period 1999-2002 has been $57.3 million. This is a 73% increase over the estimated expenditure for the same period in the absence of PIIP, based on historical growth trends.

Table 1: Comparison of estimated clinical research expenditure without PIIP with actual clinical research expenditure under PIIP

	1999-2000	**2000-2001**	**2001-2002**	**Total**
Estimated $ expenditure on clinical trial activity in the absence of PIIP (A$ millions)	10.0	11.0	12.1	33.1
Actual $ Expenditure on clinical trial activity with PIIP (A$ millions)	13.6	18.5	25.2	57.3

 # Using growth rate recorded from 1996-97 to 1998-99 of 10% per annum

- The other question with regard to inducement in clinical research expenditure is how much of the increase has been due to growth in global activity by Eli Lilly and Company due to product pipeline i.e. is similar growth occurring around the Lilly world?

  Analysis of clinical research spending in other Lilly operations around the world reveals that only two clinical research operations of any size recorded higher growth rates. These were China and Brazil, both Lilly operations that have been targeted as having potential for growth in clinical research and both coming off a very small base at the start of the period. This further reinforces the conclusion that PIIP has been responsible for attracting an additional share of clinical research into Australia.

  The following table shows the relative growth rates for clinical research expenditure across a wide range of Lilly operations, using Australia as the base level. Only China and Brazil have shown growth in excess of Australia.

Table 2: Comparison of growth rates for clinical research expenditure in a range of Lilly operations using ELA expenditure as the base for each time period.

Country	#1998-1999	#2001-2002	% Change	#1999-2000	#2001-2002	% Increase
China	0.23	0.57	151%	0.29	0.57	100%
Brazil	0.36	0.47	30%	0.38	0.47	24%
Australia	1.00	1.00	0%	1.00	1.00	0%
Spain	1.68	1.61	-4%	0.62	0.47	-24%
Germany	2.50	2.03	-19%	2.24	1.61	-28%
Mexico	0.59	0.47	-20%	0.62	0.41	-33%
Canada	1.77	1.34	-24%	0.57	0.36	-38%
Hungary	0.50	0.31	-37%	3.33	2.03	-39%
France	1.73	1.01	-41%	0.52	0.31	-40%
United Kingdom	2.41	1.36	-44%	2.29	1.34	-41%
Sweden	0.91	0.41	-54%	2.24	1.01	-55%
South Africa	0.91	0.36	-61%	3.24	1.36	-58%

- For the Global Clinical Data Management Centre, the ELA position is that this is 100% induced activity. A decision to add a third such centre was made by Eli Lilly and Company at about the time of the development of the PIIP. Initial consideration was to site the centre in Singapore, where Lilly had recently established an Ethno-Pharmacology Centre with considerable assistance from the Singapore government. Gaining entry into PIIP was a major factor in deciding to locate CORI in Australia (along with the usual investment considerations related to economy, workforce and regulatory environment).

- For the additional Technology Transfer component of the ELA program, the inducement level is harder to estimate. There is no doubt that some of the activity claimed under this area would have occurred without PIIP. One component of this is the novel nature of the outcomes research studies. The relatively high cost of these studies confirms that they would only have occurred on this scale with corporate assistance. ELA suggests an inducement level of 50% would be appropriate here.

Table 3: The net effect of estimates of inducement across the three components of the ELA program.

	Investment to date (1999 – Dec 2002) A$ millions	**Estimate of inducement (%)**	**Weighted estimate of value induced A$ millions**	**% Induced over total Lilly program**
CORI and related clinical research	73.3	73	55	
GCDMC	13.7	100	14	
Technology Transfer	10.3	50	5	
Total ELA program	97.3		74	76

Therefore, ELA argues the inducement figure of 45% used in the draft report for R&D activity is too low. While the ELA program does not reflect the entire PIIP, ELA believes the Commission should adjust its estimate upward to a figure somewhere between the current 45% and the ELA figure of 76%. ELA notes that the 76% figure is slightly in excess of the "most favourable scenario" figure of 70% provided in the draft report (Table 6.5, page 6.17)

3. The level of spillover of R&D activity.

The Commission defines spillovers as benefits from pharmaceutical activity accruing to third parties (such as R&D collaborators, suppliers and other pharmaceutical firms) that do not pay for these.

The draft report argues spillover from *clinical* R&D activity in the PIIP is low (25%). In the absence of specific evidence the Commission draws on estimates from literature, acknowledging there is very little that is specific to the pharmaceutical industry.

Pages 6.7 – 6.8 of the draft report provide a rationale as to why a low spillover figure is appropriate:

- Spillover rates can be expected to decline once the most promising R&D opportunities in an industry have been taken up.
- Lower rates are applicable when the R&D investment is an add-on to existing R&D measures. Given the lack of pharmaceutical-specific measures (other than PIIP) the Commission suggests "average" rates may be appropriate for use in regard to *pre-clinical* R&D within PIIP.
- Clinical trials are likely to generate lower spillover rates than preclinical R&D, due to the possibility of substituting other countries for Australia and the fact that benefits to participating investigators and institutions are likely to reduce with subsequent trials.

While these statements may be generally valid, ELA maintains that more in depth consideration of each participant's program would be useful, as the specifics will vary considerably. Although ELA cannot provide in depth evidence of the extent of spillover, there are some observations and comments that can be offered that further inform estimates related to the ELA program. ELA acknowledges it is difficult to generate accurate measurement of spillover rates. However, based on the observations below, ELA estimates the overall spillover rate for its PIIP program to be approximately 37%.

4.1 CORI and Clinical Research:
As indicated previously CORI has been responsible for both a significant increase in the quantity of clinical trials and the infrastructure / technology associated with clinical research in Australia. The initial phase of CORI operation (design and implementation of Phase III trials in Asia Pacific countries) would not have had significant spillover for Australia. The assumption of **25%** spillover rate is probably applicable to this aspect of CORI's operations. However, the focus changed in 2001 to non-registration (e.g. Phase IV) trials both in Australia and other countries within and without Asia Pacific. The design and implementation of these trials within Australia is relatively new, resulting in a greater spillover effect for investigators and

institutions than in other aspects of CORI's operation. For example, CORI designed the database required for a 10,000 patient survey of resource use and costs associated with type 2 diabetes. This project involved academic researchers and health outcomes consultants, both of whom have gained experience with this type of large survey-based costing approach.

CORI has also generated more work within the statistical analysis and publication functions than could be handled by its own staff (due to recruitment difficulties). This work has been outsourced, again providing opportunities for Australian consultancies to work on cutting edge clinical research projects.

In addition, CORI has been responsible for two significant developments in the area of software applications to clinical trials. One is CT-FAST, a program to facilitate data collection in trials. The second is in the area of statistical analysis, enabling the automation of a range of routine analyses conducted in all phases of clinical research. While neither of these software developments have yet been commercialised in Australia, the exposure of participating investigators and institutions to the data management tool has undoubtedly created a spillover in that these investigators are now familiar with the next wave of incremental improvement in clinical research practice.

The simplest way of attributing spillover rates across these phases of CORI activity is to relate rates to each year of CORI operation, as these roughly parallel the evolution in CORI's activity. Therefore, in this latter phase, a rate of 40% has been estimated for spillover rate (see table below).

4.2 Global Clinical Data Management Centre:
Here the spillover rate is again difficult to quantify. Because the Australian centre is the third in a series of Lilly installations worldwide means that suppliers (hardware, software and telecommunications suppliers, recruitment consultants) have definitely been exposed to cutting edge data management technology and staffing needs. In addition, the technology and process involved in this large-scale clinical trial data management project has been the subject of several conference presentations here in Australia, widely attended by the clinical research and biomedical research communities.

Finally, both CORI and GCDMC were recognised when ELA received two Innovation Awards (the Western Sydney Industry Awards and the Australian Business Limited President's Awards).

Given the whole field of medical informatics is increasing at a fast rate in Australia with clinical trial data management at the fore, it is a reasonable assumption that a moderate level of spillover is occurring from this aspect of the ELA program. ELA estimates a rate of 40% is appropriate here for the

initial two years (when the intensive set up phase occurred) then reducing to a lower level thereafter.

4.3 Technology transfer:
This area is the smallest of the components of the ELA PIIP activity and includes a diverse range of qualifying items. Intuitively spillover rates should be higher here than for clinical trial activity. However, they are difficult to estimate with any accuracy and there will be some double counting with the CORI and GCDMC spillover effects e.g. in relation to the health outcomes studies that have included activity across the three areas of the ELA program. Therefore a conservative view has been adopted and a spillover rate of 35% has been attributed to this area.

In summary, the weighted average of spillover has been calculated using the estimates explained above. This is shown in the following table and results in an overall estimated spillover rate for the ELA program of 37%. This is higher than the estimate attributed by the Commission for clinical research (25%).

Table 4: Estimated Spillover from ELA PIIP Activity

	1999-2000 A$ Millions	Estimate of spillover rate %	Value of spillover A$ Millions	**2000-2001 A$ Millions**	Estimate of spillover rate %	Value of spillover A$ Millions	**2001-2002 A$ Millions**	Estimate of spillover rate %	Value of spillover A$ Millions	**Jul 2002-Dec 2002 A$ Millions**	Estimate of spillover rate %	Value of spillover A$ Millions
CORI and Clinical research	13.6	25	3.4	18.5	40	7.4	25.2	40	10.1	15.9	40	6.4
GCDMC	1.7	40	0.7	3.9	40	1.6	5.3	30	1.6	2.8	30	.85
Technology transfer	2.2	35	0.8	3.4	35	1.2	3.2	35	1.1	1.4	35	0.5
Totals	17.5		4.9	25.9		10.1	33.7		12.8	20.2		7.7
Total ELA PIIP expenditure $ Millions	97.3											
Total spillover estimated $ Millions	35.6											
Total spillover rate %	37											

4. The Pharmaceutical Benefits Scheme: impact on market access and pricing.

The draft report (Section 3) explores at some length the issue of price variation in Australia compared with other markets, questions whether or not this constitutes price suppression and also considers the overall impact of the pricing and reimbursement environment on head office decisions on investment in Australia.

It is not the intent of this submission to argue the issue of price suppression. However, ELA wishes to highlight several points.

- Several comparisons of international pricing have established that there is pricing variation between Australia and major OECD comparators. The commonly accepted wisdom on this is that this variation is less with innovative compounds and greater with "me too" compounds. This is assumed to be the result of the economic evaluation and cost-effectiveness requirements employed by the Pharmaceutical Benefits Advisory Committee (PBAC). While ELA agrees with this view our experience is that the PBAC process, accompanied by the various price control mechanisms that exist in Australia, is in fact becoming a downward spiral which will soon see the above situation unravel to the extent that prices offered by the government for PBS listing of innovative products will be unacceptable to corporate head offices, resulting in more innovative products not being marketed in Australia. The downward spiral results from the process being based on comparative cost-effectiveness. The prices of older comparator drugs steadily erode due to subsidy levels adjusted downward in line with generics (in the case of products in Therapeutic Group Premium areas, this is regardless of whether or not the branded product has yet reached patent expiry). This is coupled with increasingly high prices being sought for innovative drugs (especially biotech drugs) reflecting the increasing costs of R&D. Along with this pricing squeeze comes the trend toward increasingly restricted PBS listing. Companies are seeking restricted listings as they struggle to reach acceptable cost-effectiveness thresholds with high priced innovative drugs without basing economic evaluations on third line clinical use. The government equally seeks restricted listings to aid the cost containment policies driven by the central agencies. Faced with these restricted listings, corporate head offices are even less enchanted by the relatively low prices being offered to their Australian subsidiary.

- It is frequently argued that the above view constitutes a hollow threat by companies who would be unlikely to seriously withdraw investment

in Australia. ELA believes the New Zealand situation reinforces this is not a hollow threat. The Commission draft report acknowledges New Zealand provides some evidence of corporate behaviour in these circumstances.

- ELA is also well placed to comment on the future, having a pipeline of innovative products that is acknowledged as the best in the industry. In addition, ELA made a decision during 2002 to refuse PBS listing circumstances being offered by government for a major product for the treatment of type 2 diabetes (Actos, pioglitazone).Also during 2002 ELA became aware that an increasing number of countries in Europe and the Middle East are referencing Australian prices when setting reimbursement levels. While proponents of the PBAC process may claim this is evidence of its success, it can be also argued that the downward spiral described above couple with the higher prices needed for the next generation of innovative drugs will result in more corporate decisions to by-pass the Australian market.

- Clearly the solution to this issue does not lie in industry investment incentive programs. Progress is being made in improving the PBAC process and also in innovative approaches to risk management for new PBS listings. These need to be seen as part of an overall revision of pharmaceutical pricing and reimbursement in Australia which considers modifying the cost-effectiveness requirements so that they do not result in shutting new drugs out of Australia, as well as revised perceptions about the appropriate level of expenditure on drugs.

- In a submission to the Inter Departmental Committee on the PBS in 2002, Medicines Australia called for a White Paper on the future of the PBS. ELA urges the Productivity Commission to go beyond the comments in the draft report and recommend further in depth assessment of the PBS and its potential, now and in the future, to cause disinvestment by the industry in Australia.

5. Future incentives to invest in R&D activity in Australia

ELA believes thought needs to be given to the ongoing evolution of biomedical research in Australia and the nature of collaboration between industry and the biomedical research and biotech sectors. There is no doubt PIIP has stimulated a significant shift in the nature of R&D activity conducted by the industry in Australia. This is apparent in both the increases in activity other than Phase III clinical trials (e.g. early phase trials, partnering between pharma and research institutes to evaluate molecules from basic research) and in the depth of local infrastructure established for clinical research (e.g. CORI).

Work by the Centre for Economic and Strategic Studies at Victoria University reinforced the view that productivity of the Australian biomedical research sector (in terms of new molecules entering evaluation) is poor and the sector is seriously under funded. The long-term viability of the sector will require increased collaboration and funding from the pharmaceutical sector. While "good science" will find it easier to attract dollars the whole sector is becoming increasingly competitive internationally in terms of venture capital and indeed the noise level of "good science".

ELA believes there is significant potential to attract further R&D investment into Australia.

- The Lilly pipeline will ensure growth in clinical trials on a global basis.
- Economics of drug development will continue to drive process innovation in clinical research and ELA has demonstrated capabilities in this area.
- Australia has world-class researchers across the whole spectrum of biomedical research. ELA believes there will be further expansion of all phases of research in Australia. Steps taken in 2002 to resource a liaison position at ELA to work between Australian institutes / biotechs and the Lilly Research Laboratories in the U.S. are bearing fruit in terms of molecules being evaluated by Lilly.
- ELA is investigating the possibility of broadly based research collaborations with one or more universities or research institutes in Australia where a range of activity from discovery to early phase through to Phase III trials could be conducted. Lilly's global expertise in specific disease areas that align with Australia's national health priorities may be able to be bought to bear in this regard. ELA currently has one such collaboration underway with the University of Melbourne which spans basic research, clinical trials, outcomes and health services research, and education and training. However, ELA will not pursue other such opportunities vigorously without some indication of

the nature of R&D incentives that will be accessible to the industry post the expiry of the PIIP

ELA notes the draft report argues (page 4.13) that even if under-investment is a problem, an industry–specific program is not necessarily the answer. Apart from the question of cost-benefit of any industry specific program (dealt with elsewhere in this submission) the draft report states that an industry specific program must be superior to a generic program. The draft report suggests it is not clear if the pharmaceutical industry is sufficiently different from other industries to warrant a R&D support mechanism specific to it.

The draft report goes on to recommend use of the existing suite of generic programs rather than an industry specific program.

Eli Lilly does not have an issue with this per se, but reinforces the need for urgent further exploration of the ability of these programs to deliver on the opportunities that exist for significantly increased pharmaceutical collaborative R&D in Australia. This includes the question of tax concessions as well as the flagship programs such as the Collaborative Research Centres program.

ELA notes the conclusions of the Commission in the Review of Automotive Assistance (report no.25, Productivity Commission). In addressing the same question (the option of using generic R&D incentives) the Commission acknowledges there maybe inadequacies in these generic support measures. As with the automotive industry, consideration needs to be given as to whether reliance on existing generic support measures would be adequate to take advantage of the enormous opportunities in biomedical science that will be available in during the coming decade. ELA endorses the statement in the draft report that a case is made for review and improvement of the relevant generic programs and suggests that in their current form they are unlikely to adequately substitute for an industry specific support program.

Finally, ELA agrees with the suggestions made in Recommendation 7.2 of the draft report. Here the Commission lists six characteristics seen as desirable should government wish to continue to consider a further PIIP. The suggestion that entry to such a program should be competitive and emphasise activity that would not otherwise occur is a reasonable one. ELA advocates further dialogue with industry with regard to such criteria should government wish to pursue this option. ELA also supports the concept of a 6 year duration as a minimum requirement along with the concept of multiple entry points.