MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

30 July 2014

Dr Kathleen Dermody
Secretary
Senate Economics References Committee
Parliament House
CANBERRA ACT 2600

Dear Dr Dermody

Thank you for the opportunity to contribute to the Senate Economics References Committee's Inquiry into the Australian Innovation System.

Medicines Australia represents the research-based pharmaceutical industry in Australia, which has a long and proud history in this country, stretching back more than a century. Today, over 50 multinational pharmaceutical companies, along with around 400 locally-owned medical biotechnology firms, operate in Australia. Together, they employ approximately 40,000 highly-skilled Australians, invest more than $1 billion in research and development and generate nearly $4 billion in exports each year. Most importantly, they develop, manufacture and distribute medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.

For decades, the pharmaceutical industry has been a crucial component of Australia's innovation system. By investing in research and development partnerships, clinical development and high-tech manufacturing, the industry has not only facilitated and enabled the development and commercialisation of important Australian discoveries, such as the human papillomavirus vaccine for cervical cancer, but also brought high quality medicines and vaccines to consumers around the world. Today, patients in more than 30 countries rely on pharmaceutical products manufactured in Australia to maintain and improve their health.

Despite these successes however, the pharmaceutical industry's future in Australia remains uncertain. It faces a number of significant challenges which are threatening its future viability and its capacity to contribute to the health and wealth of this nation. For instance, whilst Australia's innovation system as a whole remains one of the strongest in the world, an increasingly unstable and unpredictable business operating environment is putting extraordinary pressures on companies and, in many cases, discouraging them from investing in Australia.

Unfortunately, this comes at a time of immense opportunity for this country.

Over the next decade, much of the growth in the market for pharmaceutical products will come from Asia, and Australia is uniquely placed to meet this demand. It is not only strategically located but also has a highly-skilled labour force, a mature distribution infrastructure, a history of excellence in research (including clinical research) and a long-standing and well-justified reputation for manufacturing safe, high-quality medicines and vaccines.

However, without an appropriate policy framework, Australia will miss out on this once-in-a-generation opportunity, despite how good we may look "on paper", and once lost, the challenge to recover will be so much greater.

Level 1, 16 Napier Close Deakin ACT 2600
Phone 02 6122 8500 Facsimile 02 6122 8555 www.medicinesaustralia.com.au

MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

On the other hand, with the right policies in place, like those described in this submission, Australia could potentially double its share of the global pharmaceutical market over the next decade. This would mean an increase in annual investment in pharmaceutical research and development to $2 billion and an increase in annual exports of pharmaceutical products to as much as $8 billion by 2024.

There are three key pillars of any future strategy to build a stronger pharmaceutical industry in Australia:

- Secure the existing investment we have in Australia to ensure it stays here;
- Encourage the development of Australia's local bio-pharmaceutical sector; and
- Attract new direct foreign investment to Australia.

Each pillar needs to be part of any future strategy to secure and build Australia's capacity across the range of health and medical technologies sectors, including the research-based pharmaceutical sector.

With this mind, Medicines Australia, in partnership with AusBiotech, which represents the Australian medical biotechnology sector, recently put forward a three step plan to build a stronger, more sustainable and more vibrant bio-pharmaceutical industry in Australia. The plan called on Government to:

Step 1: Ensure a stable, predictable and efficient business operating environment;
Step 2: Enable growth in Australia's local bio-pharmaceutical sector; and
Step 3: Enact globally competitive incentives to encourage investment in R&D, high-tech manufacturing, skills development and public-private partnerships.

We hope that a serious consideration of these steps, which are described in more detail in the following pages, would inform the development of this Committee's recommendations to the Senate in relation to ways governments can both facilitate and actively support the development of innovative industries like ours in Australia.

Medicines Australia also takes this opportunity to reiterate its support for the Budget proposal to establish a $20 billion Medical Research Future Fund. Such a Fund will stimulate collaboration between government, the wider public sector, and the existing pharmaceutical research and development sector. Medicines Australia is keen to work with Government to make this Fund, and the medical and health benefits it will deliver to future generations of Australians, a reality.

If you have any questions about statements in this submission, please do not hesitate to contact me on 02 6122 8500. Medicines Australia would also welcome the opportunity to appear before the Committee to expand on our views.

Yours sincerely

Dr Brendan Shaw
Chief Executive

Level 1, 16 Napier Close Deakin ACT 2600
Phone 02 6122 8500 Facsimile 02 6122 8555 www.medicinesaustralia.com.au

MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

3 STEPS TO A STRONGER BIOPHARMACEUTICAL INDUSTRY IN AUSTRALIA

Step 1: Ensure a Stable, Predictable and Efficient Business Operating Environment

Measures

- 'Do No Harm': commit to ongoing PBS policy stability.
- Ensure the predictability and efficiency of the PBS listing process.
- Implement all 11 of the Clinical Trials Action Group's recommendations within the next 12 months.
- Restore the R&D Tax Incentive to its pre 2014-15 Budget form.

Step 2: Enable Growth in Australia's Local Biopharmaceutical Sector

Measures

- Strengthen Australia's intellectual property system by maintaining a strong patent system and extending the term of data exclusivity from five years to 12 years.
- Restore the Employee Share Scheme (ESS) to its pre-2009 form.

Step 3: Enact Globally Competitive Incentives to Encourage Investment in R&D, Manufacturing, Skills Development and Public Private Partnerships

Measures

- Establish a tax incentive program, which builds on the R&D Tax Incentive, to encourage innovative companies to invest in R&D or high-tech manufacturing, thus bringing or keeping new intellectual property (as well as jobs, skills and production capacity) in Australia.
- Implement policies to encourage public-private partnerships in Australia.
- Give companies incentives to encourage them to invest in developing, educating and up skilling their employees.

Level 1, 16 Napier Close Deakin ACT 2600
Phone 02 6122 8500 Facsimile 02 6122 8555 www.medicinesaustralia.com.au

MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Explanatory Notes

1. **'Do No Harm': commit to ongoing PBS policy stability.**

   In 2007, Medicines Australia negotiated ground breaking reforms to the Pharmaceutical Benefits Scheme (PBS) with the then Howard Government. These reforms were designed to deliver ongoing savings to Australian consumers through the introduction of appropriate policy measures to capitalise on competition in the commoditised, multi-brand market for off-patent medicines and reduce prices paid by Government for these medicines. These reforms, which are on their own helping to deliver a sustainable PBS, were augmented in 2010 through a Memorandum of Understanding with the then Government. The result today is that PBS reforms since 2007 have delivered billions of dollars more in savings than originally predicted.

   But whilst these reforms are ensuring the long-term sustainability of the PBS, they are also creating unprecedented challenges for the research-based pharmaceutical industry in Australia (particularly because the savings generated from these reforms are not being adequately used to create headroom for the listing of new medicines). Many companies have already cut jobs, reduced R&D investment and shut down manufacturing facilities to cope with the impact of these reforms.[1]

   Additional reforms (or "savings measures") would only make it more difficult for the industry to maintain even the current level of investment, let alone increase it. What it needs now is stability and certainty in relation to PBS funding policies.

2. **Ensure the predictability and efficiency of the PBS listing process.**

   The Pharmaceutical Benefits Advisory Committee assesses applications for new PBS listings. Despite significant advances in medicine effectiveness, innovation and technology, positive recommendations for applications have plummeted in recent years, from over 80% to less than 50% over the three years to 2012. Although there was some improvement in 2013, increasingly now, even "positive" recommendations sometimes include unrealistic conditions that creates significant barriers to effective price negotiations and, ultimately, listing of new products on the PBS. This trend over the last four years has seen a serious erosion in the value placed on innovation, which, in turn, has eroded business confidence and made it harder for Australia to attract new investment.

   Predictability and efficiency in the listing process is critical to a stable investment environment for the bio-pharmaceutical industry in Australia.

[1] There is no doubt that Government policies in relation to the reimbursement of new medicines have a decisive influence on investment decisions. Around the world, companies read signals from reimbursement agencies in different countries about the extent to which each of them value innovation. When countries develop a reputation for not sufficiently valuing innovation, then it generally becomes less likely that they will attract investment. New Zealand is a case in point, where the pharmaceutical industry has significantly reduced investment in large part because of the restrictive pricing policies in that country that have repeatedly delayed and devalued the adoption of new medical technologies.

3. **Implement all 11 of the Clinical Trials Action Group's[2] recommendations within the next 12 months.**

Clinical trials are a source of significant investment and jobs for Australia. According to a survey by the Pharmaceuticals Industry Council (PIC) in 2012, private investment in clinical trials in Australia (excluding investment in basic and discovery-stage research) reached approximately $650 million in 2011, with over 2000 individuals employed directly within companies in clinical research roles.[3]

Clinical trials also play a vital role in improving this country's healthcare system. They provide early and often free access to new healthcare technologies, which is estimated to save Australian taxpayers around $100 million each year in hospital and PBS costs.[4] Moreover, one of the main beneficiaries of private investment in clinical research in Australia are public hospitals, with more than 60% of all activity conducted there. This means that private investment on research is not only an additional funding source for Australia's public health system, but also a means of subsidising the delivery of health services to Australian patients. The higher the investment in the future, the higher the rate of additional funding, the higher the subsidy and, ultimately, the higher the benefit to Australian patients.

Unfortunately, Australia's share of global investment in clinical trials continues to decline.[5] According to figures from the Therapeutic Goods Administration, the number of new clinical trials in Australia declined by 34% between 2007 and 2010 and after increases in 2011 and 2012, clinical trial activity in Australia declined again in 2013, this time by around 9%.[6] It is for this reason that in 2013 the Strategic Review of Health and Medical Research in Australia (McKeon Review) called on Government to make clinical trial reform "an urgent national priority".[7]

The 11 recommendations made by the Clinical Trials Action Group (CTAG) in 2011 were designed to make the process of initiating and conducting clinical trials in Australia significantly more efficient and cost-effective. Unfortunately, more than three years after their release and despite some progress and repeated commitments, these recommendations have still not been implemented to the extent necessary to change the realities on the ground. Meanwhile, clinical trial activity in Australia has declined by more than 20% since 2007, with declining activity recorded in four of the last six years.

Clearly, urgent and positive action is required to ensure Australia remains a leading destination for global clinical trials investment.

---

[2] The Clinical Trials Action Group was established by the then Australian Government in 2009 to "help cement Australia's position as a good place to conduct clinical trials".
[3] Pharmaceuticals Industry Council, 2012, 2011 Survey of Privately Funded Clinical Research Activity in Australia.
[4] Commonwealth of Australia, 2011, Clinically Competitive: Boosting the Business of Clinical Trials in Australia, p. 16.
[5] Justin Chakma et al., 2014, Asia's Ascent: Global Trends in Biomedical R&D Expenditure, New England Journal of Medicine.
[6] Therapeutic Goods Administration, Half Yearly Performance Report(s), multiple years.
[7] Simon McKeon et al., 2013, Strategic Review of Health and Medical Research, Full Report, p.5.

4. **Restore the R&D Tax Incentive to its pre 2014-15 Budget form.**

   The R&D Tax Incentive, which was implemented in 2011 after three years of extensive community consultations, is specifically designed to increase R&D in Australia by making access to tax benefits more efficient and predictable.

   Under this system, unlike the one it replaced in 2011, there is no requirement for companies to demonstrate year-on-year growth in their R&D expenditure in order to claim a tax benefit.[8] There is also no requirement for intellectual property from eligible R&D projects to be held in Australia, which recognises the inherent value of the research and development process itself, notwithstanding the eventual "location" of ownership of the resulting intellectual property.

   Above all, the R&D Tax Incentive **in its pre 2014-15 Budget form** provided an excellent and globally competitive incentive for both home-grown and foreign-owned companies to conduct R&D activities in Australia. In fact, a 2010 report by KPMG Global placed Australia, under its then proposed R&D Tax Incentive, at the top of its ranking of the most competitive locations for R&D investment, ahead of Canada, UK, Netherlands, Mexico, US, France, Japan, Germany and Italy.[9]

   Unfortunately, in the 2014-15 Budget, the Australian Government announced that it would cut the rate of the R&D Tax Incentive by 1.5% from 1 July 2014. According to the Budget papers, this would be offset by a 1.5% reduction in the corporate income tax rate for around 800,000 companies by 1 July 2015. Given that the stated purpose of reducing the corporate income tax rate is to "increase Australia's ability to attract investment", it seems counterproductive to implement other policies (such as a cut to the R&D Tax Incentive) which could seriously undermine the ability of Australian companies to attract investment in such a high-value area like medical research.

5. **Strengthen Australia's intellectual property system by maintaining a strong patent system and extending the term of data exclusivity from five years to 12 years.**

   There is a strong and enduring rationale for making sure that no new laws are implemented that would, in any way, undermine the ability of pharmaceutical companies to acquire and defend their intellectual property (IP) rights. The process of bringing new medicines to the market involves a high degree of risk. Only a small portion of promising research yields safe and effective products, of which only a fraction are profitable enough to generate the necessary investment returns. On average, the cost of bringing new medicines to market is approximately $1.5 billion, including the cost of unsuccessful research projects, and it can take between 12 and 15 years to complete the process.[10]

---

[8] Commenting on the design of the previous 175% International Premium Tax Concession, a Medicines Australia member company said in 2012 that "The International Premium was based on incremental expenditure above a three-year rolling average, so the overall R&D expenditure had to be much higher under the International Premium than the R&D Tax Incentive in order to achieve a comparatively small tax benefit. Given this expectation of constant incremental change under the old system, there was no impact on the success of the business as a result of the previous Tax Concession."
[9] KPMG, 2010, Competitive Alternatives: Special Report - Focus on Tax, p. 19-22.
[10] J. Mestre-Ferrandiz et al., 2012, The R&D Cost of a New Medicine, UK Office of Health Economics.

Compared with other areas of technology, the time taken to develop new technologies in the pharmaceutical industry is significantly longer.

Patents and other forms of IP protection allow innovative companies to invest in R&D, with the expectation that they will have a fair and reasonable opportunity to recoup this investment before others, who did not bear any of the initial risk or costs, are permitted to profit from new and improved products.

It is crucial for Australia to maintain a strong IP system. This will ensure pharmaceutical, biotechnology and other highly-innovative companies have confidence in the system and continue to invest (not just in R&D but also in high-tech manufacturing) in this country. Adopting proposals without notice, that are retrospective or attempt to curtail effective patent terms, as for example recommended by the recent "Pharmaceutical Patents Review", would significantly weaken Australia's IP system and severely damage the country's international reputation as an investment destination.

Medicines Australia fully endorses the McKeon Review's assessment that the best way to "protect valuable intellectual property" is by ensuring Australia's IP system is "strong, stable, predictable and harmonised with global best practice".[11]

Currently, the term of data exclusivity, which is an important element of Australia's IP system and an important indicator of the overall strength of any country's IP system, is just five years, compared to between eight and 12 years in most other OECD countries.

The data required by the Therapeutic Goods Administration before it registers a new medicine for sale in Australia is extensive. It is derived from years of basic and pre-clinical research, followed by numerous clinical trials involving thousands of volunteers and patients from around the world. Clinical trials alone cost on average of $700 million per medicine and can take up to 10 years to complete.[12]

Without the protection of data exclusivity, generic companies could begin relying on original data, which they played no part in generating, to bring competing products to market as soon as an innovative medicine is approved for sale, thus depriving research-based pharmaceutical companies of the opportunity to recoup their investment. This is especially harmful in cases where:

- an innovative medicine is approved for sale just before it is about to lose patent protection;
- patent protection is, for whatever reason, unreliable or insufficient, as may be the case with so-called 'biological' medicines; or
- a product is approved for sale after it loses patent protection.

[11] Simon McKeon et al., 2013, Strategic Review of Health and Medical Research, Full Report, p.226.
[12] J.A. DiMasi et al., 2003, The Price of Innovation: New Estimates of Drug Development Costs, Journal of Health Economics, 22(2): 151-185.

Extending the term of data exclusivity in Australia to bring it into line with global best practice, as explicitly recommended by the McKeon Review, would not only send a powerful signal to the international bio-pharmaceutical community that Australia is serious about investing in innovation but also allow local bio-pharmaceutical companies to better leverage their intellectual property assets to attract venture capital funding from foreign and domestic sources.[13]

6. **Restore the Employee Share Scheme (ESS) to its pre-2009 form.**

   The ESS, prior to the 2009 changes, notably the taxing of shares/options upon issue instead of when a profit is realised, provided significant support to innovative start-up biotechnology companies. The changes in 2009 removed important support and undermined the ability of start-up companies to attract high-quality staff.

   Once widely used in the pre-revenue biotechnology sector, the support of ESS was relied upon to attract quality employees by complementing cash remuneration and making salary packages more substantive and attractive, whilst also giving employees a vested interest in the success of their company.

   If tax is charged pre-success or pre-gain, the shares/options come at a cost to the employee, with the tax payable before any value is generated. This is comparable to paying income tax before you earn any income or paying tax in advance for an income that you may or may not receive. This method of taxation is a disincentive and disadvantages start-up innovative companies, especially during the establishment and development phases.

7. **Establish a tax incentive program, which builds on the R&D Tax Incentive, to encourage innovative companies to invest in R&D or high-tech manufacturing, thus bringing or keeping new intellectual property (as well as jobs, skills and production capacity) in Australia.**

   Countries all around the world are competing for investment in bio-pharmaceutical R&D and manufacturing. Most of them offer substantial incentives, such as preferential tax treatments, to attract the attention of global decision-makers.[14] Australia could much more effectively compete for investment by reducing the corporate tax rate to 10% under defined circumstances. This would encourage not only the development of new IP but also enable associated high-tech manufacturing to take place in Australia.

   One possible way to do this could be through the creation of a “Patent Box” system. Around ten countries now have this incentive in place, which allows a lower tax rate on profits from intellectual property. The “Patent Box” was recently implemented in the UK, providing a 10% tax rate on qualifying profit from patents, in contrast to the normal corporate tax rate of 21% (which is in itself is far lower tax rate than what is available in Australia). UK Government analysis indicates that the incentive has already led to significant benefits.

[13] According to the 2013 OECD Science and Technology Index, Australia ranks 19th among OECD countries in relation to the level of venture capital investment it attracts.
[14] According to the 2013 OECD Science and Technology Index, Australia ranks 17th among 18 (reviewed) OECD countries in relation to the level of direct government support for business R&D.

For example, GSK, one of the world's largest pharmaceutical companies, is centralising its pharmaceutical IP in the UK as a result of the "Patent Box", and has announced $800 million in new investment in the UK, including the first manufacturing plant to be built by GSK in the UK in almost 40 years.

A similar system in Australia with a low tax rate would be especially beneficial for the local bio-pharmaceutical sector, which currently transfers an overwhelming majority of its IP overseas for further development, commercialisation and manufacturing.

Another approach could be to take a lead from countries like Singapore and Ireland, which offer compelling case studies in the types of tax-based incentives that governments can offer to attract investment in the bio-pharmaceutical sector.

Singapore offers an exemption from corporate income tax for up to 10 years in return for investment in new R&D or manufacturing facilities; a 13% tax rate for up to 10 years for companies investing in existing manufacturing facilities; tax incentives for R&D investment; long-term loans for small and medium sized enterprises; concessionary tax rates for companies that relocate their headquarters to Singapore; and tax exemptions from qualifying income from overseas investments and projects. These and other incentives have ensured Singapore's place among the world's leading locations for investment in manufacturing and R&D by the bio-pharmaceutical industry. In the last ten years alone, Singapore has attracted over $50 billion in direct foreign investment in this sector.

Singapore has coupled these incentives with an aggressive approach to courting foreign direct investment through its Economic Development Board (EDB). Over the years, EDB has had a deliberate strategy of proactively approaching multinational corporations and selling the benefits of investing in Singapore to the boards of these companies.[15]

Ireland offers similar incentives. For example, a flat corporate income tax rate of 12.5% is a major incentive for biotechnology and pharmaceutical companies. Additionally, they pay no income tax at all on earnings from intellectual property where the underlying R&D is conducted in Ireland.

These and other incentives have allowed Ireland to become a major European, and indeed a global, hub for bio-pharmaceutical R&D and manufacturing. Currently, the bio-pharmaceutical industry in Ireland exports over $30 billion worth of medicines and vaccines every year, and manufactures 12 out of 25 of the world's top selling drugs. Usefully from a government perceptive, the bio-pharmaceutical industry has also become Ireland's largest payer of corporate tax. Such incentives have actually generated additional tax revenue for their governments by attracting additional tax-paying economic activity.

[15] Medicines Australia member company AbbVie, recently announced that it will invest $320 million in a new manufacturing facility in Singapore. Dozens of other earlier examples where Singapore secured new investments from large biotechnology and pharmaceutical companies also exist. In the late 1990s, Pfizer considered new investment in Australia and Singapore. The decision to locate the plant in Singapore rather than Australia was made in 1999 and the plant commenced production in Singapore in 2004. This decision was based almost entirely on the basis of comparative incentives.

Australia would benefit enormously from a well-targeted tax incentive to attract and retain R&D capacity and high-tech manufacturing capabilities, not just in the bio-pharmaceutical industry but across all innovative industries. We know this because favourable government policies in the past were not only a key driver of the rapid growth of the pharmaceutical industry in Australia but also created significant spillover benefits for the Australian economy at large.

In 1988, when the Australian pharmaceutical industry was facing massive disinvestment and an escalating deficit in the pharmaceutical balance of trade, the then Australian Government introduced the Factor F scheme, which ran from 1988 to 1999. Under Factor F, which encouraged companies to make significant manufacturing and R&D investments in Australia through notional price increases for products supplied through the Pharmaceutical Benefits Scheme, the industry's core capacity to conduct R&D and manufacture high-value therapeutic products for domestic and export markets skyrocketed. Over the 10 years of the program, the industry created more than 1000 new jobs and achieved a cumulative increase of over $600 million in additional R&D expenditure and approximately $4 billion in production value-add.[16]

Then in 1999, the Australian Government announced the Pharmaceuticals Industry Investment Program (PIIP) as a follow-up to Factor F. This 5-year program, with up to $300 million in available funding, operated from 1999 to 2004. In its 2003 review of the program, the Productivity Commission concluded that "PIIP has been effective in stimulating R&D and production value-add. It has also had broader benefits for the capabilities of the industry, for example, by shifting R&D to more complex areas".[17]

Whilst additional work with industry would be required to develop the current proposal further, Medicines Australia is confident that, based on both local and overseas experience, a well-designed, broad-based investment incentive could be a significant driver of long-term investment in high-tech manufacturing across many different areas of industry in Australia.

8. **Implement policies to encourage public-private partnerships in Australia.**

Encouraging public-private partnerships in Australia would not only reduce the large amount of duplication currently seen in research programmes across the country, but also enhance the pace of discovery and commercialisation.[18] In fact, various Australian reports (including the McKeon Review and the Productivity Commission's 2007 review of public support for science and innovation in Australia) concluded that Australia needs to radically improve on building partnerships between the public and private research sectors in order to drive innovation and help to successfully commercialise Australian discoveries.

[16] Commonwealth of Australia, Industry Commission, 1996, The Pharmaceutical Industry in Australia.
[17] Productivity Commission, 2003, Evaluation of the Pharmaceutical Industry Investment Program.
[18] According to the 2013 OECD Science and Technology Index, Australia ranks **last** among OECD countries in relation to the connectedness of businesses and public sector research organisations, including universities.

Already, there are numerous examples of successful collaborations between global pharmaceutical companies and Australia academic research centres:

- The recently launched Lung Health Research Centre (LHRC) is taking a multi-disciplinary approach to developing treatments for a range of lung diseases such as lung cancer, asthma, chronic obstructive pulmonary disease and cystic fibrosis. The purpose of the LHRC is to leverage the existing capabilities in the area of respiratory diseases in Australia to develop new treatments in partnership with the private sector, in a way similar to the ongoing collaborations between Cambridge University in the UK and global bio-pharmaceutical companies such as AstraZeneca.

- The ongoing collaboration between GSK and Monash University demonstrates a successful, mutually beneficial partnership for the investigation and development of new processes, products and devices to be industrialised. The partnership provides students at Monash University the opportunity to utilise state-of-the-art facilities and develop their real-world skills, while at the same time giving GSK a competitive edge with access to world-class researchers and facilities to enable innovative industrialisation capability. The collaboration has seven projects currently under development, from "proof-of-concept" to Phase III clinical trials on new products and formulations.

- Janssen-Cilag, a subsidiary of Johnson & Johnson, collaborates with a number of universities and biotechnology firms in Australia to develop early stage research, including a current collaboration with the UniQuest -- the main research commercialisation company of the University of Queensland -- to progress early stage novel research into pain and rheumatoid arthritis, and a partnership between Janssen and Australia-giant CSL to progress research around a molecule with potential treatment applications in haematological cancers and autoimmune diseases.

Actively encouraging public-private research partnerships through appropriate policy measures, (such as the European Innovative Medicines Initiative (IMI)[19]) could eventually facilitate the creation of several self-sustaining medical research hubs across Australia, which integrate research excellence and enable best-practice translation of research into the delivery of innovative healthcare solutions as efficiently and as quickly as possible.

Currently, there are several informal medical research clusters across Australia, notably in Melbourne, Brisbane, Adelaide and Sydney. Unfortunately, these clusters have, in most cases, been unable to capitalise on their successes in basic research due to a lack of policies intended to actively encourage industry co-location and involvement in wide-ranging collaborative research and commercialisation projects.

[19] The IMI is a joint venture between the EU and the European Federation of Pharmaceutical Industries and Associations (IFPMA) that funds innovative partnerships between industry and academia to encourage innovation in healthcare. The IMI is currently supporting over 40 separate collaborative R&D projects, in areas such as immunisation, antibiotics and processes for discovering and developing new medicines.

9. **Give companies incentives to encourage them to invest in developing, educating and up skilling their employees.**

Like other high-tech industries, growth in the pharmaceutical industry in Australia is being hampered by the persistent shortage of skilled workers. The workforce needs of the industry were the subject of a detailed study in 2008 by the Pharmaceuticals Education Council (PEC), which brought together both industry representatives and senior academics from Australian universities.[20]

The PEC found that there is a considerable shortage of specific skills required not just by the pharmaceutical industry but all knowledge-intensive industries in Australia. The report identified gaps across the value chain, and especially noted that many recent university graduates lack basic research, project management, clinical trial design, interpersonal, marketing and negotiating skills, all of which are critical to the business of bringing new products to market.

These findings were broadly supported by a Medicines Australia survey which found that bio-pharmaceutical companies in Australia routinely have to import labour to meet shortages in several key areas such as clinical trial management and business development.

Unfortunately, given the already high cost of doing business in Australia, it is difficult for companies to invest in up-skilling their workforce. As such, incentives such as tax breaks and/or grants would not only allow companies to train their workforce but, in doing so, also add to Australia's general pool of skilled labour.

[20] Pharmaceuticals Education Council, 2009, Report on Skills Gaps in the Pharmaceutical and Biopharmaceuticals Industries in Australia.