

## **Submission by the Queensland Pharmaceutical & Nutraceutical Industry Forum for the Review Panel of the National Innovation System – dated 30<sup>th</sup> April 2008.**

### **Introduction**

The Queensland Pharmaceuticals and Nutraceuticals Industry Forum (QPNIF) is an industry led action group that acts as a united voice for the Queensland Pharmaceutical, Nutraceutical, Biotechnology, and Therapeutic Medical Devices Industries. This was an initiative commenced by the Queensland Government in early 2007, and consists of representatives of this eco-system including:-

- Pharmaceutical & Nutraceutical companies,
- Industry association representatives,
- Universities and their research institutions,
- The training and educational sector, and
- Government Agencies.

The objectives of the QPNIF are directly aligned with those objectives of government and include:-

- Connecting & engaging Industry & stakeholders with idea's and resources
- Promoting an innovating business and research culture.
- Building local and global markets for smart products, programs and services
- Developing, recruiting, training & retaining skilled people
- Improving and boosting productivity levels

### **Contribution to the Innovation Agenda**

The QPNIF would like to contribute ideas and recommendations to the Innovation Review Process. These idea's and recommendations have been provided at short notice due to the timing of the request for idea's. Any points of clarification may be directed to the Chair of the QPNIF, Dr. John Miller. Contact details for Dr. Miller are:-

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The Queensland Pharmaceuticals and Nutraceuticals Industry Forum supports the Innovation Review Process (IRP).

As part of the IRP, we notice that Senator Kim Carr has announced the reconvening of the Pharmaceuticals Industry Working Group (PIWG) and we welcome this announcement. As a key body that creates policy and develops strategies and solutions, we would ask that the QPNIF be directly linked to the PIWG to provide industry and stakeholder interests.

In addition, the QPNIF would like to make the following contribution to the IRP:-

## **Queensland Pharmaceutical and Nutraceutical Industry Forum Response to National Innovation Review April 2008**

The Pharmaceutical and Nutraceutical industries have particularities and potentials that require dedicated consideration by government in the course of analysing and updating our approaches to innovation. Collectively, the industries are significant employers. They also have a fundamental role to play in reducing the cost of preventing illness and treating disease in an environment where health budgets cannot continue to serve the populace as they have done for the last 30 years. Nor can the Government afford to continue to support the current disease treatment paradigm.

Ten years ago, Queensland had strengths in complementary medicine but lacked a true pharmaceutical base. This has changed as a result of \$600 million of government investment and an additional \$300 million from philanthropic sources. The ongoing success of our home grown firms like Bullivants (now part of the Symbion Health Group) and Herron (now part of Sigma Herron), coupled with our emergent health biotechnology firms means that Queensland firms have a real role to play in any discussion of Australia's future in innovation.

The pharmaceutical and nutraceutical industries in Queensland employ 20,458 people and contributed approximately \$1.7 billion to Queensland's economy in 2005-06. Some of Australia's largest complementary medicine and generic medicine manufacturers are based in Queensland. For example Symbion Consumer a division of Symbion Health, Australia's largest complementary medicine sponsor/manufacturer is based on Brisbane's north-side and employs 270 people. Sigma Herron, Health World, MediHerb and New Product Development add an additional 400 employees to the complementary medicines base.

Queensland's success in biotechnology means that firms like Peplin with a market capitalisation of \$90 million now consider themselves pharmaceutical firms rather than biotech start-ups. Progen is another company on the cusp of a complete drug development and delivery pipeline and with a market capitalisation of \$98 million will be another key player in Queensland's pharmaceutical future.

What makes the pharmaceutical and nutraceutical industries such unique places to engage in business? Both are characterised by extremely costly investments in manufacturing facilities, the dependence upon high numbers of skilled staff with various types of scientific and engineering training, extremely long lead times from product development to product release and existence within a highly regulated environment.

Both industries compete in a global market characterised by fierce competition and declining profitability as a result of key products coming out of patent protection. This creates a need for increased innovation to secure a future stream of product releases that can continue to create firm momentum. The global players have access to a variety of government and regional incentives in other countries that dramatically assist their ability to create value in a cluttered marketplace.

### **Current Innovation**

In Queensland and Australia, the significance of having an indigenous pharmaceutical and nutraceutical capacity is largely unrecognised by the broader public. The role product success can play in generating value for the rest of the population is highlighted by the returns the University of Queensland is enjoying as a result of the global penetration of Gardasil. Whilst the intellectual property is now owned by Merck and CSL, the University of Queensland's ongoing rights to patent royalties means that new facilities, support for the commercialisation of other intellectual property generated by university research and the like is now a reality. This in spite of tough negotiations by the Australian government to restrict the cost per dose of the vaccine to the Australian public which had far reaching implications for the global benchmark price set for the product.

The success of Gardasil has become iconic through the awarding of Australian of the Year to Professor Ian Fraser. However, his international reputation means that only last week a research team from Taiwan flew to Queensland to broker a joint venture with Professor Fraser and his research facility to honour a US\$500 million donation by a wealthy Taiwanese patron. Capitalising on the proportion of these funds that will find their way to Queensland means our nation stands a better hope of becoming a knowledge nation in action rather than just in name.

### **Collaboration**

What prevents us from moving quickly towards achievement of a dramatically improved vision for pharmaceuticals and nutraceuticals in Australia? Speeches\* by Senator Kim Carr, Federal Minister for Innovation, Industry, Science and Research in recent months have highlighted the need for Australia to change its culture. This has been replicated in our own travels to establish collaboration to achieve greater competition through our members in Queensland. We know that our future is dependent upon increasing our ability to compete with India and China (for example, by lowering our costs) whilst concurrently increasing our innovation to spearhead the development of new products that can be sold at a premium. Engaging with our members to establish a vision for how joint training, better supply chain management, improved infrastructure utilisation and the like is an ongoing battle. However, it can be achieved.

With a limited sponsorship from the Queensland government to bring like firms together to focus on overcoming common issues a much more cohesive, cooperative and opportunity focussed sector is emerging. The Queensland Pharmaceuticals and Nutraceuticals Forum is but one element of what has emerged over the last eighteen months as companies, research organizations, education and skill providers have begun to relate and collaborate. Access to small amounts of seed funds (in the order of \$10-\$40,000) that can be accessed by proactive business groups to fuel mechanisms for generating collaboration would increase the numbers of businesses taking their challenges in the global market more seriously. The use and access of such funds are critical in providing significant events and collaborative events and efforts to occur.

For example, a significant supply chain project that has the potential to save industry millions of dollars and which has possible national outcomes, arose from a small \$10K activity that generated a conversation. From this conversation a seed of an idea emerged, which became a project and then a full industry collaborative effort – this is truly the spirit and intent of the innovation process!

Based on the actions already achieved by our group we propose that the following issues still need to be addressed to take our industries into the next stage of development and prosperity:

## **Skills**

Australia, like all western nations is facing a skills shortage. Of even greater concern is the dramatic decline in the attractiveness of science and technology courses and careers in industries like pharmaceuticals. This means that our sector, a true knowledge sector, faces considerable challenges in attracting the current levels of staff required to undertake routine operations. Given the potential of Australia's biotechnology efforts to take their products to the world, we need to quickly address significant shortages in chemistry courses and programs.

What is more significant is the current inadequacy of university delivery models. Funding changes to universities mean that chemistry and pharmacy students spend less and less time in the laboratory. This means that new graduates do not have the requisite skills to perform in the workplace. That is why the QPNIF in conjunction with the Queensland government has launched this year the Vocational Graduate Certificate in Applied Biotechnology (Pharmaceuticals/Nutraceuticals). Whilst this new TAFE based training targeting university graduates is novel and has attracted great interest it has also exposed flaws in skills funding. Students electing to complete the VGC can count the six months course as a component of their university training. However, they cannot access a HECS like funding model to defer the costs associated with the course until they can afford to pay. This means that some students who would otherwise complete the program are not enrolling.

Given the convergence of so many of the scientific disciplines, greater sharing of curriculum in broader base degrees or common entry years would also benefit industry. To ensure the students and teachers/academics involved in the training were skilled to deliver what industry requires much greater attention needs to be given to industry rotations. TAFE and Universities constantly complain that they would love to provide more industry time for their staff. However, current funding models which are highly focussed on contact hours and completion rates do not adequately allow for professional development that keeps up with the rapid changes in technology in industry.

## **Research**

Universities and other institutions need to be provided with more funding to establish the evidence base for new discoveries. Companies small and large can get a glimmer of an attractive bio-active or other compound. Based on traditional medicines and other current research the basic efficacy of compounds can be established. The current model is that these are currently put to market in accordance with the guidelines in the Therapeutic Goods Act. However, in the past 20 years, very few new pharmaceutical or complementary compounds have ever come to the market in Australia, first in world under this model. New compounds elucidated and identified in Australia have seem commercialization undertaken overseas because of the lack of infrastructure and the probable costs involved.

Furthermore, extremely limited funds exist to study the evidence that accumulates as populations use complementary medicines over time and in conjunction with other medicines or activities. This means Australia lags behind countries like Germany, China, parts of the Middle East, Korea and India where a significant amount of public funding is being directed into the study of both the efficacy and potential health economics of incorporating complementary medicine into mainstream healthcare and functional foods. Until Australia adopts a correspondingly open framework for the exploration of all health modalities, we will continue to fund more expensive health options in an environment of chronic budget shortfalls. We will also miss out on export opportunities because we do not have all of the evidence required to market our products in some overseas markets.

Australia's diverse and clean climate could accommodate the mass cultivation and harvesting of many of the herbs that are used around the world today. Without support and innovation this facet of the industry will not develop. Our unique biodiversity means that Australia potentially has many indigenous plants and potential bio-actives that are uncharacterised and are not being studied. Additionally many of these plants are more drought friendly and could offer farmers new opportunities for revenue if they were more adequately explored and able to be marketed internationally.

### **Export**

AusTrade is currently a valuable resource for those exploring overseas markets. However, entering foreign markets in the pharmaceutical and nutraceuticals markets is a protracted and expensive business because of the need for evidence to meet overseas regulatory requirements, documentation and packaging, developed to meet individual country peculiarities. This means that significant numbers of our small nutraceutical companies do not have the funds to penetrate markets where potential take-up of their products is highest. AusTrade currently has just six officers working in support of firms from these sectors across Australia. Boosting their number and the funds available to support firms attending foreign tradeshows and performing the many activities associated with overseas registration and reimbursement procedures unique to our industry is warranted.

### **Research and Development**

The current R&D tax concessions are a necessary and important component of our national innovation system. All of our firms are R&D intensive simply because of the highly regulated market we operate in and the demands by our clients for evidence and product improvements. More support needs to be provided to very small firms in our sectors looking to establish their compliance systems so that they can track eligible expenditure and claim for the available concessions. At the moment, the barriers for Contract Manufacturer's accessing R&D concessions are just too high. The framework is too narrow and the money too small. I am not sure of any companies that would be accessing this scheme. Additional funds to provide incentives for universities to support small firms with further research where they do not have all of the requisite and at times extremely expensive equipment would give Australian firms an advantage in getting truly innovative products to market.

## **Clinical Trials**

Australia's clinical trial environment is recognised as high quality and good value. However, significant shortfalls exist in the availability of trained clinical trial managers and nurses and other practitioners that can perform these tasks. Queensland is attempting to assess and develop suitable programs, targeted at experienced graduates to enrich this pool of labour.

The current pressures on the health system mean that any form of clinical trial, whether it is a complementary medicine or pharmaceutical are not given priority in hospital and clinical settings. Providing incentives and visibility for clinical trials and their effect on our economy and potential boosts to revenues within the health system is long overdue. This is but one of the many changes to culture required to ensure clinical trials can occur in timeframes similar to our overseas competitors. Ensuring common national paperwork, recognition of ethics reviews in one jurisdiction to another across multi-site trials and a real emphasis for clinical and ethics committees to meet regularly to discuss not just clinical trials but effective and emergent practice, would make our health delivery more innovative and ultimately more cost effective.

## **Innovation going forward**

Our health systems currently contain many highly innovative staff and programs. However, there is limited opportunity for their innovations to find a way to a commercial partner to be taken into other markets or further developed. The culture of sharing, taking local innovation into commercial settings and leveraging local knowledge with industry expertise does not exist in anything but pockets in Australia. Compared to overseas health systems where these practices are the norm, it means Australian health authorities are missing out on revenue, skilled staff and opportunities to obtain recognition for their efforts and our industry from novel ideas.

The length of time taken to bring a new product to market in this sector is considerable. On average, a drug from lodging of a patent (note not beginning of the research exercise) often takes 12 years to get to market with patent protection lasting only 15 years. Funding of the research and clinical trial phase for any individual drug or compound runs into the hundreds of millions of dollars. Creating opportunities for the public to share the risk and potentially reap the gain is necessary. Obstacles to this exist.

For companies set up in the early phase of the commercialisation process, losses are inevitable. It is more than likely that as promise is shown by research the original company structure will be bought out or merged with allied companies with useful intellectual property. Thus, these firms do not over the long-term meet any of the criteria for carrying forward losses and offsetting them against both operational profits and ultimate capital gains. To expand the base of people prepared to invest in these sorts of companies this situation needs recognition and remedy. It would also expand the pool of potential investors if losses could be claimed in the year they are earned. It is understood that the mining lobby has been making much more visible claims for many years because their investment cycle and risk profile is similar to that experienced in the pharmaceutical sector. Any progress of their claims would need to be matched by considerations for this industry.

## **Governance**

Finally, at a policy level government still makes distinctions between pharmaceuticals, nutraceuticals, biotechnology and functional foods. In many cases these sectors are handled by disparate agencies with competing agendas and this complexity compounds the amount of paperwork and liaison required by companies attempting to participate in policy development. It suffers from many interface issues and simply does not make sense. Firms are increasingly recognising that these labels are irrelevant. Biotechnology firms are usually participants in the early phases of drug development, in other words they are players in the pharmaceutical industry. Similar arguments can be made for other sub-components. If we are to get serious we will begin to gain recognition for the “Life Sciences” sector or some other more useful description that can cope with the complexity of the many firms that have a role to play in our future industry development. If we do not, then we risk innovation, development and commercialisation moving offshore where costs are lower and recognition and support are correspondingly higher.

With the change in government a number of initiatives have been suspended or abolished. Our industry is a complex one that requires dialogue. Having industry action agendas and other meaningful opportunities for detailed conversations focussed on solutions that will be owned by industry and truly accommodate our needs is the only way forward. We would appeal for such mechanisms to continue.

## **Summary**

The current National Innovation Review “recognises the vital role innovation plays in boosting productivity and international competitiveness, and re-iterates the Rudd Government’s commitment to fostering innovation across the economy”. Previous innovation challenges have revolved around specific industries or sectors. The Queensland Pharmaceuticals and Nutraceuticals Industry Forum (QPNIF), is uniquely placed to help target and drive innovation not through specific industries or linked sectors, but through a linked eco-system of industry, research, training and skills development.

Prepared and submitted by John Miller, Chair of the Queensland Pharmaceuticals and Nutraceuticals Industry Forum.

\*Speech given to the Auspharma 2008 Medicines Australia Conference on the 8<sup>th</sup> April, Hotel Realm, Barton ACT.