Interview with Will Delaat, Chairman, Pharmaceutical Industry Council (PIC)

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2006 marked a major milestone, with the Pharmaceutical Industry Action Agenda transformed from a Government-industry initiative into an industry-driven agenda, and the resulting creation of the Pharmaceutical Industry Council (PIC).

Would you please introduce the organization, and tell us about the main milestones and achievements since you began your tenure as Chair of this in 2006?

The PIC was formed in 2006 as the peak body of the peak bodies AusBiotech, GMIA, and Medicines Australia. Its intent was to continue the Action Agenda after the first three years of the initial 10-year plan, with the goal of doubling pharmaceutical activities from2002 to 2012. Although doubling is a broad term, we hope to double the levels of exports, R&D investment, manufacturing, value-added activities, and clinical trials wherever possible. Overall, the PICâ??s creation was a sign and signal that Australia wanted a bigger focus on the industry in the future. Dr Graham Blackman, who is on the board of Medicines Australia, was a real champion of the Action Agenda, and after three years of chairing the implementation group he felt it was time for someone else to take over, at which point I was elected Chair. The PIC began by resetting the vision of the Action Agenda, reinforcing ideas of doubling activity by setting key milestones, and a restrategizing session to assess changes in the years since the Agenda began. In fact things had changed, with big pharma undergoing significant consolidationâ?? generic prescribing increasing, Biotech companies becoming more significant, with additional issues of PBS pricing reforms, and patent legislation changes,. At this point the PIC decided to place a strong emphasis on an industry development program to follow-up the current P3. By 2009, there needs to be a successor program, hopefully with more funds and that encourages partnerships between big pharma and biotechnology. With big pharma undergoing global rationalization, itâ??s important for Australia to retain its manufacturing presence, and to at least hang on to what the country has currently got. If there were a government scheme to at least reward the current levels of manufacturing, parent companies would notice the governmentâ??s commitment, even if not in the form of incremental investment. In other areas like clinical research, there are many elements in terms of attracting the various phases of clinical trials, quality and speed of research and approvals, and skill base to ensure the right labour force available. All these factors are a part of the PIC work plan, consisting of different subgroups, including an industry development taskforce which has been working on a program to follow P3. There is also an R&D taskforce, to assess the quality, skill, speed, and timeliness of the clinical trials approval process. The Pharmaceuticals Education Council, headed by Professor Graham MacDonald, has been surveying skills gaps, and is going through final stages of research and focus groups, identifying these gaps and where support and incentives are required, for example in creating and updating certain

university courses, and establishing a National Coordination Body to standardize courses available in different universities. Given how broad and abstract the initial goals of the PIAA were, there are many different ways to achieve them.

What role do you see the subsequent scheme to P3 playing in terms of solidifying the governmentâ??s commitment to the industry?

It has been difficult to come up with a scheme to meet all the stakeholder requirements: big pharma, local companies like CSL and IDT, biotechs, and generics all have their individual issues. Proposals were made to Ministers Macfarlane and Abbott in the previous government, and they required a very strong business case. As a result, PIC took proposals to a consulting firm to put through the analysis and projections for a given investment, and asked for $600 million over five years, assuming additional spillover and multiplier effects. Interestingly, the analysis did not come back very compelling, in regards to return on investment, and therefore did not get much traction. Along with the change of government, the proposals got lost in the shuffle. Now, however, they are being revisited with Minister Carr looking to boost manufacturing, innovation, and R&D. The PISG has been a useful vehicle to officially revisit these issues, and has a good representation of all different stakeholders. Iâ??m pleased to see the Ministerâ??s keen interest in the pharmaceutical industry, which he has called one of the cornerstone industries of Australia. Given that in exports, pharmaceuticals are second only to the automotive industry, I think this is an apt approach.

There are always questions regarding the interpretation and presentation of information, but in terms of fundamentals, is the pharmaceutical industry really something that will retain long-term strength in Australia?

Manufacturing will probably not be the future of pharmaceuticals in Australia. When the PIC revisited the future of the industry two years ago, we concluded that it would rather be in R&D. Nonetheless, it remains important to maintain manufacturing to see us through the transition. Thereâ??s a tyranny of distance being so far away from other countries, and big pharma companies are not going to have large production plants here solely for Australia and New Zealand; it canâ??t be justified, whereas in Singapore itâ??s easy to have a hub for the whole region, or in other countries like India, China, or South Korea. Tax advantages, like those available in Singapore and Ireland, are another factor. If Australia wanted to make a play to be a big manufacturing hub it would have to give significant tax incentives, even if it were across only a few industries. A theoretical approach would be to focus on creating a Special Economic Zone for pharmaceuticals, and set aside an area with special tax exemptions, but I donâ??t know if the government has an appetite for this type of decision. Treasury and Finance departments have not been ready to provide large tax incentives, compared to countries like Singapore, where because itâ??s not a big country must offer such programs for lack of many other opportunities. If the Australian government wanted to go down that route, however, feasibility studies would be necessary to gauge the responsiveness of HQâ??s to put large plants here even if they did have the tax incentives. It would be a big sell given the distance to other markets, even including Asia. John Howard used to say Australia punched above its weight in research and innovation in biomedical sciences, and looking at the research output and patents written in the biopharmaceutical sector there is far more per capita here than in other areas. There are tremendous skills in basic research, that just need to be translated into products that can be developed.

Talking about Australiaâ??s strength in clinical trials, is it more early or late phase?

Australia is strong even at the basic level, like the Garvan Institute and the Walter and Eliza Hall Institute, and the Queensland Institute of Molecular Biology, consisting of people educated or attracted from overseas, and itâ??s a matter of translating that into commercial products. The

problem is with incentives, and the government has had to pay a lot of money to bring people back, because at high levels itâ??s not only a matter of quality of life, but a remuneration question that has necessitated grants to attract top people to Australia.

What do you anticipate will be the long-term impact of PBS reforms?

Weâ??ve taken some short-term pain for long-term gain in the innovative sector. Generics companies donâ??t necessarily agree, but from innovative companiesâ?? perspective itâ??s short term pain for long term gain. With the delinking that occurred between the F1 and F2 formularies, this provides long-term benefit as new products introduced to the market are protected from price erosion over the length of patent life, which was formerly not the case, when there were formerly price linkages to out-of-patent products. Another group called the Access to Medicines Working Group (AMWG) has been founded to deal with issues of accessibility, which are central to the PBS. I co-chair the AMWG along with David Learmonth, who is the Assistant Secretary in the Department of Health and Ageing. Although there are always competing views on the matter, AMWG is a vehicle for industry and government to improve access to new medicines.

One of the problems foreseen with PBS reform was that if comparator prices are lowering by 25% or more, and PBAC compares a new to an old drug, then how can a reasonable price be justified for a new product?

As a result, companies may decide not to bring new drugs to Australia. That is one of the issues in figuring out how to adjust the comparator so the new drug coming through has a reasonable price. In this respect the AMWG is working with the TGA, toward faster access and streamlining of regulatory and reimbursement processes, because at the moment it takes 12-18 months to go through the TGA process, and anything from 9-24 months to go through the reimbursement process.

With the whole process ranging from 2-5 years, weâ??re trying to reduce that figure to bring more certainty to companies introducing their products to market. Does Australia have what it takes to compete in biotechnology?

Australia can compete with other parts of the world, although of course when comparing to the west and east coasts of the United States, it may be difficult. However, given Australiaâ??s strengths in its research institutes, their spinoffs, and the private companies as well, there is great potential.

Where does the biggest potential lie in terms of niche focus areas in this sector?

Some of the biggest companies in this space are Cochlear and ResMed. CSL, Cochlear, and ResMed are all on the ASX, and the next level down from that has many biotech and smaller specialty pharmaceutical companies, like Pharmaxis and IDT, at different stages of commercialization. Of course, thereâ??s the importance of partnerships with big pharma, which is always looking out for the products that are being developed by smaller companies. Australiaâ??s biotech sector is strong and will continue to grow, with companies merging. Australia needs to work better together across the country, which is small in size although could benefit from the various hubs across the country competing as a nation against some of the larger hubs worldwide.

Is it the position of government to bring together those people?

Itâ??s an interesting question as to how far a government should intervene in the market. Governments tend to do best when they set the framework and IP legislation, and put money into basic research, which they do into NHMRC. Maybe in our industry there is need for an industry development scheme, but beyond that itâ??s up to the industry to look for linkages. There are linkages across Sydney such as BioLink which is an attempt to connect research groups across

Sydney and New South Wales, and create better collaboration between the states and federal government.

Looking to the next five or 10 years and bringing the Action Agenda to fruition, what do you envision as the sectorâ??s future?

Australia will do well to hang onto its current manufacturing, and although thatâ??s not a big achievement, itâ??s important to keep while the country goes through the transition phase, and maintain a good level of exports as we start to see the biotech industry mature. As this transition happens the industry will begin to support further future activity in bio-medical innovation, R&D and clinical research. Quickening clinical trials approval will also be important, and certainly the TGA is keen to reduce those times, which can be a great source of advantage. If Australia is perceived as a good place to do specialised manufacturing, with a fast and efficient TGA, markets could use Australia as a supply source. Further in the future there may be possibilities in convergence technology, combining biotechnology, nanotechnology, and telecommunications. In the future, a mobile phone connected to a heart monitor could stop heart fibrillation or administer appropriate drug treatment immediately, and this is where Australiaâ??s good device and biotech and research companies could play a key role. Of course, San Diego and Boston are thinking the same thing. In the shorter term, PISG will hopefully come out with some good ideas, because a substantial follow-up to P3 â?? which at an individual company level offered only $5-10 million over five years â?? is probably needed. As has been recently demonstrated with the Australian subsidiary of Toyota, the government is not shy about doing more for the automotive industry, and this should also be the case for the pharmaceuticals industry.

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