

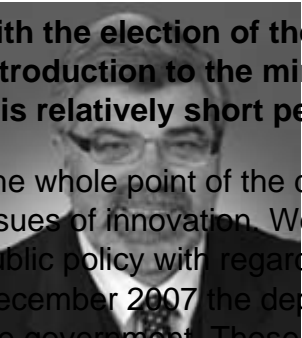
Interview with Senator Kim Carr, Minister, Government of Australia

21.02.2012

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Senator Kim Carr, Minister for Innovation, Industry, Science and Research was created in December 2007 with the election of the Labor government. To begin, would you please give a brief introduction to the ministry and highlight its most significant achievements and milestones in this relatively short period of time?



The whole point of the department is to refocus public debate and re-establish an agenda around the issues of innovation. We want to see a more integrated approach in terms of the development of public policy with regard to innovation in industry, science and research – hence the name. Since December 2007 the department has established a series of reviews of policy positions throughout the government. These reviews have been headed up by Dr Terry Cutler in the National Innovation System and into the Cooperative Research Centre by Professor Mary O’Kane, in the automotive by the former Premier of Victoria Steve Bracks, and in the textile, clothing, and footwear industries by Professor Roy Green. Within the department itself there are a number of review processes to establish industry development groups, and for pharmaceuticals is the Pharmaceutical Industry Strategy Group (PISG), concerned to ensure there is an effective response from industry working alongside government and the research sector to the challenges currently confronting the pharmaceutical industry, which are similar to many other countries in the developed world.

Speaking broadly, what role does the pharmaceutical sector play in the bigger picture of advancing Australian innovation?

The pharmaceutical sector is one of Australia’s most significant export industries, second behind only the automotive industry in size of contribution. It’s a major employer of labour and source of innovation and expenditure on R&D, and consequently a very important part of the Australian national innovation system. The manufacturing sector alone currently employs 15,000 people and exported \$3.9 billion dollars in 2007, second only to the automotive industry. We are concerned to examine the options available in terms of companies working with government to ensure the sustainability of the industry. In achieving just that, you mention the PISG. When you opened the new R&D centre for the biotechnology company Arana Therapeutics, you mentioned how the PISG will be tasked with the development of the industry’s 10-year plan.

What has the government learned from P3 and what do you expect its successor to resemble?

There was a review of the P3 program by Deloitte, whose findings suggested there needs to be significant revision to the program and it cannot continue in its current form. In Australia, like in other

countries, pharmaceuticals is one of the most R&D-intensive industries, and there are very long lead times in product development, taking 10-15 years and upwards of \$1 billion to go from discovery to point of market. We need to find mechanisms that encourage activities that are uncertain and risky, realizing that potential drugs identified through early R&D may never make it through, while remembering that there are risks but also enormous rewards and it's a highly profitable industry. Overall, multinational corporations have found Australia an important part of their global portfolios, with the country ranked 14th by sales in international terms and accounting for some 1% of global sales, which is significant considering our population. More importantly, the Australian medical fraternity is particularly strong, and by international standards has a huge competitive advantage in terms of being a highly-skilled and cost-effective place to conduct R&D. When this is combined with the strength of our infrastructure and workforce, and in particular the scientific workforce, Australia is in a very strong position. However, the industry is moving to change the style of production and we need to keep pace with that. Part of keeping pace with that are the PBS reforms.

You mention that Australia is a very profitable market for multinational corporations; what is your response to PBS reform criticisms at the apparent conflict between the government's desire to reward innovation, while sharply reducing the revenues that would otherwise be used to fund such innovation?

The PBS is a critical part of the architecture of the Australian pharmaceutical industry. The scheme, however, has two functions. One is to provide medicines at the lowest possible cost to the Australian people, and to ensure that the Australian people get good value for money. The second function is to ensure that there are sustainable industry development processes operating, and although there may be tensions between these functions, the Australian government is highly mindful that there are two and not just one.

You mention the high quality and strength of R&D, which many feel is the future of the industry, as opposed to waning manufacturing due to competition from more cost-competitive locales. What will be the future industry drivers?

In general terms the main drivers of pharmaceutical R&D are the quality of the scientific and medical research base and infrastructure, the strength of intellectual property protection regimes, and the effectiveness of regulatory approval processes which allow R&D trials to be undertaken in a cost-effective manner. Australia has a world-class research base with 0.3% of the global population producing 3% of global medical research. The strength of our infrastructure and research training program is highlighted by the fact that we have six Nobel laureates in medicine, and medical research discoveries have a long history in this country, even going back to the days of penicillin. With an ongoing track record of success in this field, I'm highly confident Australia will maintain this competitive advantage. In terms of clinical trials there are areas we could do better, and we're working with our research community to strengthen management processes through the NCRIS to enable us to be more attractive to further clinical trials. Australia will remain a highly competitive place to engage in the pharmaceutical industry. In terms of the manufacturing issue, the quality of production and cost effectiveness of Australia's manufacturing facilities remains very, very strong and will continue to do so.

On that note of industry development, we've heard that Australia will not be competing in an 'incentive war' of sorts with the likes of Singapore, Ireland, or emerging economies. What is the theoretical rationale behind this position? On one side, there is an idea of lowering costs, and on the other, increasing benefits. Why has the government chosen the former over the latter and what does it say about Australian economic policy?

I would first like to note that the government does provide substantial industry support, most notably through the P3 and PBS. Looking at PBS, 93% of prescriptions filled in Australia are funded through that scheme, which involves annual subsidies of \$5 billion. Obviously, PBS reform is a matter of considerable interest and will be a question discussed through the Pharmaceutical Industry Working Group. The business model is changing for pharmaceutical companies, with increasing cost of development and outsourcing for R&D and the global cost-cutting strategies of international firms, and we have to pay attention to the fact that falling revenues in the face of increasing competition from generic drugs has changed the approach some of these companies are taking. There are clear oversupply questions emerging in terms of worldwide manufacturing, and Australian manufacturing operations are facing competition from new plants which have been funded as a result of direct subsidy support by other governments. I was recently in the US and was advised that a plant that had been scheduled to come to Australia had gone to Singapore on the basis of a complete, total, and permanent tax-free holiday. I don't know if that's a sustainable strategy for any government to follow, and I can assure you it's not a sustainable strategy I would recommend for the Australian government.

Where do you see the most significant areas going forward in creating that sustainable advantage?

Australia's big strength is going to be in high-value, niche manufacturing. We will be moving to ensure we are able to take advantage of new technological breakthroughs, and leveraging our scientific infrastructure to provide a significant competitive advantage in that field. We need to work closely to provide support in funding basic biomedical research, and with the industry in providing effective IP protections and effective and efficient market regulations, and answers to market access questions. Additionally, the government wants to ensure the pharmaceutical industry's expenditures on R&D are maintained, and has opportunities to achieve this through the taxation system, where the Cutler Review will provide advice on those questions. We will be talking to the industry regarding a replacement for P3, and opportunities for the industry to tell us what it sees, because this is about investment attraction, and ensuring the competitiveness of the industry in Australia and the integration with respect to the biotechnology industry and researchers are maintained. I believe there is cause for optimism but it will depend very much on whether the industry will work with the government, and all the indications suggest to me that this is what the industry wants to do. It's important to note that not all companies have the same business model. Recently I was talking to the decision makers in major pharma companies in the US, and some companies are talking about moving offshore, and others about expanding, so there is no particular model that applies. What we need to do is ensure all companies, particularly those who want to move into biological drug development, are given every opportunity to do so, and provide support in that area, taking steps to ensure the necessary prototyping arrangements are in place to assist biotechnology companies to move through from early stage R&D to market. There is clearly a change in attitude as companies move from chemical drugs to biological drugs, and we'll need to work with industry to see how that change occurs.

What is your final message to Pharmaceutical Executive readers?

The Australian industry is in good shape, and there is opportunity in Australia for the industry to prosper, but it will require new investment. Government wants to work closely with industry to provide the business case for new investment, and the whole focus of the Australian government is to focus on innovation as the fundamental foundation for prosperity. The capabilities this country has to offer will be apparent to companies, and although we won't be able to compete on the same basis as some other governments, the country has enormous opportunities in the quality of our workforce and science, and the reliability of our product development and the capacity to ensure the safety of our products. We want to use Australia as a foundation or base for access to Asia, but on a firm foundation of reliability and quality. We will take steps to ensure more direct relationships with

regulatory authorities in other countries, so we regulate plants, not necessarily just products. In this way, it's possible to see enormous opportunities to build on the strengths of the Australian innovation system that will be offered to international investors.

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