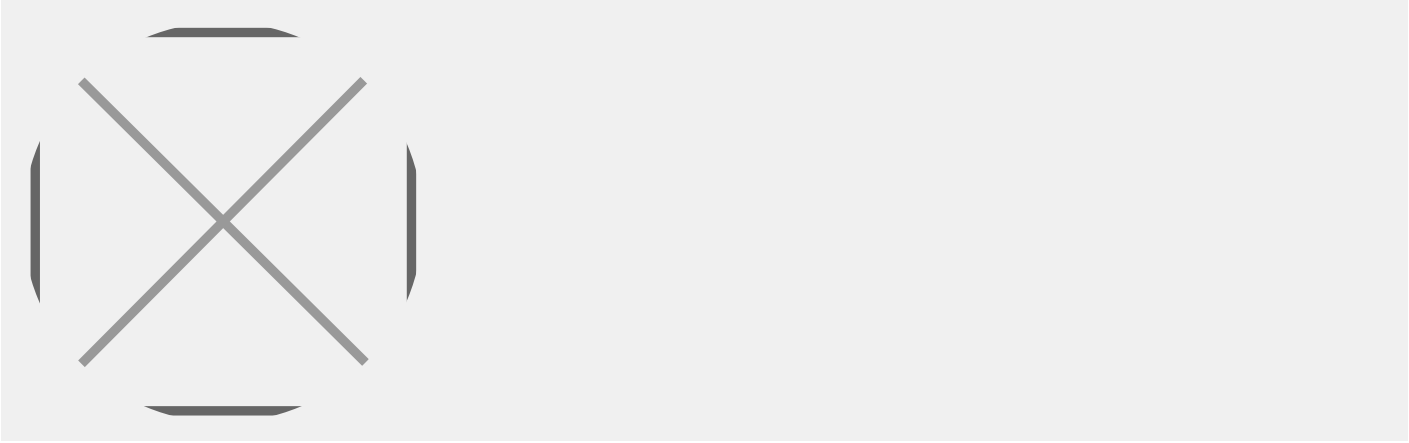
Interview with Brendan Shaw, Executive Director, Health Policy and Research, Medicines Australia



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Tags: Medicines Australia

To begin, would you please introduce Medicines Australia to Pharmaceutical Executive readers?

Medicines Australia is the association that represents the country's research-based pharmaceutical industry. With approximately 50 members, the organization comprises all major innovator companies, consisting of the significant American and European pharmaceutical players, in addition to some Australian companies like CSL and the Institute of Drug Technology.The organization's strategic framework falls under four headings: Access, Innovation, Image, and Leadership. These are broad terms, but everything Medicines Australia does comes back to them. Access covers everything concerning market access, from registration through to reimbursement, as well as bigger picture policy issues, such as how the government should spend on healthcare and broader economic trends. Innovation is about industry development, R&D, exports, and the like. Image concerns about the community's awareness of the value of medicines and the industry, by explaining the societal importance of pharmaceuticals to the larger community. Leadership comprises the role of Medicines Australia in being a good association, both in comparison to other associations around the world, and also to others in Australia.

In trying to be an effective association and fulfill these main objectives, what have been the main achievements and milestones in recent years?

The Pharmaceutical Benefits Scheme (PBS) is an important issue right now, and I would point to Medicines Australia's involvement as the main achievement of late. The PBS works in such a way

that any Australian can get medicines for a relatively small co-payment. The general co-payment is a maxiumum of A$31.30 per prescription, except for cases with a concession card, such as the elderly or those who have many prescriptions or are on welfare, whose co-payments a maximum $5 per prescription. About 80% of the prescriptions on the PBS go to concession card holders. In total, PBS spending amounts to over $6 billion per year, which is a significant amount by Australian standards. As a result, Australian governments have introduced various strategies to improve the PBS' financial sustainability as the country grows, because as is the case all over the world throughout the OECD, pharmaceuticals are a contributing factor to rising health care expenditures. After much debate in recent years, during 2004-05 the previous federal government decided to do something to get more out of the PBS in terms of value for money. One of the successes is that, from the outset, Medicines Australia decided to support the idea of PBS reform, and it was quite a strategic decision. Medicines Australia's members recognized there were pressures on the PBS and that the government wanted to change the PBS and get greater savings out of it. Medicines Australia chose to proactively support reform, rather than oppose it and keep things the way they were, with a therapeutic reference pricing system, whereby the government would pay for a treatment with a benchmark price and newcomers would have to left their value against it. In a way, what sparked Medicines Australia's proactive support and engagement in the PBS reform debate, was the former federal government's decision to introduce what was called the 12.5% generic pricing policy. Because the generics market in Australia was historically not particularly competitive, in part due to the operation of the PBS itself, the 12.5% price reduction policy was announced in 2004. This provided for mandatory 12.5% price cuts to a medicine and other medicines referenced to it the first time a generic brand of that medicine entered the market. However, the problem with a simple mandatory price cut like the 12.5% policy is its operation in a system like the PBS which operated on the basis of therapeutic reference pricing. When there is a reference pricing system that links the price of new medicines and old medicines together at the same price, a decrease of one medicine drags down the price of all, which created many problems for the government and patients alike. Consequently, this was not a good policy and there are few people around today who will actively support that original 12.5% generic pricing policy. With a view to reform the PBS, Medicines Australia engaged with government over a long period of time in many policy discussions. After much deliberation by the government with many stakeholders, the government announced major changes to the PBS in 2006 that involve splitting PBS medicines into two formularies, F1 and F2, where the former, F1, represents single brand medicines – which are mostly patented products but can include off-patent medicines and generics if there is only one manufacturer – and the latter, F2, mostly for multiple brands which includes originator and generic off-patent medicines, plus a handful of patented medicines deemed to be interchangeable with generics. The importance of this is that there are a range of regulated and market driven price cuts that will occur in the generic F2 market over the coming five years that will not affect pricing of products that are in the F1 market. In announcing the reforms, the government said that the twin

goals of PBS reform were to ensure the financial stability of the PBS through more competitive generic pricing, while ensuring Australians have access to new medicines in the future.The reforms include a range of other changes, including the creation of the Access to Medicines Working Group, or AMWG. The AMWG is a peak discussion group between Medicines Australia and the Australian government's Department of Health and Ageing and is designed to discuss and identify issues concerning the listing of new medicines on the PBS in Australia.The Minister of Health and Ageing, Nicola Roxon, acknowledges that there are many difficult changes ahead, recognises that there is some 'reform fatigue', and has indicated that she will be 'letting the dust settle' and not introducing any major changes to the PBS any time soon, because the industry has gone through much discussion and dialogue, and due to the length of the actual PBS reform policy it will take a few years to completely roll out. Over these years, there will be significant price cuts in the off-patent market. Incidentally, quite a few originator companies still play a major role in the off-patent market in Australia, because there hasn't been as much competition in the generics market as in other countries, nor the same degree of generic penetration you see overseas. Partly, the PBS reforms are designed to encourage such competition, and Medicines Australia fully supports a more competitive off-patent market. Medicines Australia thinks it's important to support reform for PBS to ensure the scheme's long term sustainability while ensuring patients will have access to new treatments in the future. On balance, PBS reform provides a good package, although some of Medicines Australia's members will experience large price cuts and it will be a difficult period to work through in the short term. For example, there will be a series of mandated cuts, the first occurring August 1, 2008, which will be an automatic 25% cut for medicines in the F2 category which have a high degree of competition, which there will be a 2% cut for all other F2 medicines on the same day, followed by additional 2% reductions in August 2009 and August 2010. Because companies have known about these cuts and their timing since November 2006, while they might not like them they can at least prepare and plan for those cuts. In the longer term, over and above the mandatory cuts in F2, there will be a system of price disclosure operating, similar to the Category M scheme that operates in the UK. In addition to the mandated cuts just mentioned, from now on companies who bring new brands of medicine listed on the PBS (essentially generic brands) must disclose the actual pharmacy selling price in the market to the government. This is designed to ensure that the price the government pays for the medicine reflects the actual price the product is being sold in the market. For example, if the official government reimbursement price is $100, but the company is selling to the pharmacist for $30, this must be disclosed to the government, and over time the government's official reimbursement price will fall accordingly. Such a fall will be weighted depending on market share of the different brands. I personally expect this to affect more and more off-patent medicines over time. In categories with lower-competition medicines, the first price cuts from price disclosure come into effect in 2009, and medicines with the highest competition will be affected starting 2012.In terms of encouraging the types of innovations your members are responsible for, how would you rate the government's commitment

to fostering an attractive business environment for such activities?Senator Kim Carr of the Ministry for Innovation, Industry, Science and Research has recently announced the formation of the Pharmaceutical Industry Strategy Group (PISG), which seeks to understand what the government needs to do to develop this industry. This is an important step and signals the new Australian government's keenness to ensure Australia remains a key player in the global pharmaceutical industry. Senator Carr is conscious of the global rationalization occurring with multinational pharmaceutical companies and changing markets, and recognizes the importance of keeping Australia in action and ensuring Australia has its niche in the market.

Governments always seem willing to help; to which concrete initiatives would you point as examples of this willingness?

Senator Carr has established the PISG to receive ideas, understand issues and drivers, and create a dialogue with Medicines Australia members and other parts of the pharmaceutical sector to determine the best approach to encouraging the industry in Australia. Other than this there are many examples, but one of the most notable occurred with the last Labor government that was in office until 1996. That government implemented a long-term $1 billion program called Factor F to support R&D, exports, and manufacturing. The program reenergized the industry, which in the late 1980s was heading south on all indicators – in investment, employment, and exports – and there was a resurgence into the 1990s that coincided with the program. Since Factor F helped develop and consolidate the industry, two smaller programs focused on R&D and exports, the Pharmaceuticals Industry Investment Program (PIIP) and Pharmaceuticals Partnership Program (P3), have been introduced, although with lesser impact than their predecessor. For example, P3 is relatively small, representing $150 million over five years. Although companies did participate in the program, it was quite small in terms of what the industry needs, which is to send a signal to the international industry that Australia is serious and wants to play an important role in global pharmaceuticals. Overall, the new government elected last November has shown promising early signs, by establishing and committing to the PISG. Such actions are also supported by Prime Minister Kevin Rudd, who has signalled he is keen to maintain and develop Australia's manufacturing industries. He has made statements like "we want Australia to be a place where we make things," stressing unambiguously a commitment to a strong manufacturing sector. Although early days, these are good signs that the new government is keen to develop a strategy for the manufacturing sector generally, and the pharmaceuticals industry. Medicines Australia will be involved in this process very strenuously and working towards developing the best strategy for the pharmaceuticals industry.

What are the most important issues facing Medicines Australia's members?

Obviously PBS reform, with the many upcoming changes, is at the top of mind. The industry is prepared to change and adapt to a new environment, which it can do and signalled that it is

prepared to do, as long as that environment is predictable and certain. PBS reform has been good in this respect, and this has been a managed process. Medicines Australia has always said PBS reforms were about ensuring patient access to new medicines, and we argue that the reforms are not yet finished. While the reforms in the generics market are locked in, the industry is keen to see evidence that the reforms will also achieve their goal of ensuring patient access to new medicines in the future and improving the listing of new medicines.Educational events and the industry's relationship to these is another issue. The first report on this topic came out in March 2008 and is a world-first, in which the association has collected information on every educational event conducted by our member companies, and put a lot of effort into communicating the results to the general public. While challenging, this was a success story, in so far as demonstrating complete transparency and in demonstrating the commitment of Medicines Australia members to responding to changing community expectations. The other one already discussed is the future of industry development in Australia and the indications from the new government that it wants to develop a strategy to encourage the industry here. With the competitive pressures facing the industry, it will be an important task to encourage the industry to develop further here.

How does Medicines Australia go about showcasing the country's activities to the international community?

Australia is only 1% of the world pharmaceutical market. We recognise that. But I think while we might be small in terms of our size and market share, Australia is actually quite influential in the global market, in terms of a case study of how the industry can interact with government in a proactive sense. We're also active in the international market at an association level through the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Although Australia represents a small part of the global market, its influence on international policy development is far beyond its size, in terms of trends that start here and migrate internationally, such as Health Technology Assessment and cost-effectiveness evaluation. For example, Australia was one of the first countries in the world to introduce HTA, and more countries in Europe and Asia are following suit. Internationally, governments are looking to Australia as a model, as it provides an excellent testing ground and for new ideas. It will be interesting to see if Australia's reforms to reference pricing, through the PBS reforms, are reviewed as a model for reform overseas.

To what do you attribute Australia's success, despite its small size, in being a global reference in exporting its policies and ideas abroad? In the survey you referenced earlier, quality of labour force was the number one factor your members pointed to.The survey of our members we conducted last year identified a range factor conditions important to the industry's development in Australia and how important our members regard them. Our members highlighted Australia's well-educated workforce, that by international standards, at least historically, was fairly cheap with a good base, and in proximity to the Asian region. One of the challenges going forward lies with the fact that this

reality is changing. The advantage Australia had 10 or 20 years ago is changing somewhat, with Singapore, South Korea, and India coming to the fore. As these countries become more competitive, the challenge will be for Australia to finds its niche in the future.

So what should Australia bet on? Is it innovative manufacturing?

If you look at the successful manufacturing operations in Australia across all manufacturing industries, not just pharmaceuticals, they are not based on cheap, mass production and do not rely on a low cost of labour. Australia's successful manufacturers are high skilled, high value, innovative, niche manufacturing operations with quick turnaround times. This applies not only to pharmaceuticals. If a company needs a smart, flexible, manufacturing facility with quick turnaround time, there is no better place to go than Australia. The country has a small highly skilled population, and therefore it makes good economic sense to have a flexible plant here to adjust to different conditions and markets, and the ones that do well have quick turnaround times. This may well be the future of the Australian pharmaceutical industry.Another important area involves excellence in clinical research and innovation, having centres of excellence in a few areas, and a focus on clinical trials which have been growing quite steadily. There has always been pressure from emerging markets like India, which has been mounting a strong case for clinical trials. But certainly over the last five or 10 years clinical trials have been growing in Australia and we are a competitive location for these.With a clear focus, the industry should continue to see more success stories, like CSL, which has grown tremendously. IDT is another company, which although smaller is innovative, research-based, commercially smart, niche. They manufacture in Melbourne for export around the world. Arguably, part of the strategy for Australia is to build more companies like these in addition to courting interest from the big multinationals. The industry to date has done very well with good export growth, but there is some fragility. Export performance is impressive; Australia exports more than wine. Unfortunately, the $4 billion pharmaceutical export base is underpinned by a handful of main manufacturing plants. With this concentration in a handful of players, if one or two of these plants disappear, it could change Australia's pharmaceutical export landscape dramatically. One of the challenges will be to consolidate that and build on it in the future. There's always rationalization going on, but I seriously think the decisions made by government and industry in the next five years in Australia will set the framework for the following 20 years for Australia's pharmaceutical industy.

What is your vision for these next five years?

Existing manufacturers reinvesting in new plants and bringing more work here, utilizing the strong Australian skill base, excellent research and competitive advantages, and growing more indigenous Australian companies. There's a vibrant, burgeoning biotech industry here with many companies starting to grow out of the one or two product laboratory companies and starting to achieve some scale. They are starting to put products in clinical trials, more and more partnering with other

biotechs or larger multinational manufacturers, or even becoming vertically integrated and doing it themselves. It's important to have the right environment for such Australian companies to flourish. Export growth is good, and there is a strong history of innovative R&D, and the key will be to consolidate and adapt to a new environment. The ingredients for building on the success story are there.

What is your final message to the readers of Pharmaceutical Executive?

Australia has a good track record and is a great location to export from, and globally the industry should look at where the country's industry has been and where it's going, and what the opportunities are. Because it is a small market, Australia sometimes undeservedly flies under the radar. My message to readers would be "have a good look at Australia" because there are real opportunities and success stories here that are substantial. For example, a product like Gardasil, which is the most well-known, represents a classic case where an Australian researcher partnered with a local company, CSL, and a multinational, Merck & Co., and came together to work very well. There's a lot of good research that happens in Australia, and it would do companies well to look at Australia because there are many good things going on and a lot of good gems just waiting to be found.

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