Interview with Mark Fladrich, Managing Director, Australia & New Zealand, AstraZeneca Australia

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In interview to Australia a year ago after spending eight years in Europe with the company. In your view, what were the key changes in the Australian market?

Looking at the overall market, the biggest changes have been the various reforms to the Pharmaceutical Benefits Scheme (PBS). PBS reform started back in 2004 and culminated with the signing of the Memorandum of Understanding (MoU) between Medicines Australia representing the Industry and the government.

Through these reforms, significant savings have been delivered by the industry to government who have clearly stated that PBS spending must grow only at a controllable rate. The MoU has actually delivered A$2.5 billion in savings, which is significantly above the governments own estimates, which in return was supposed to deliver a stable and predictable reimbursement process with room for new medicines to enter the Australian Market.PBS reform introduced the process of price disclosure which was designed to deliver savings resulting from generic entry of off-patent medicines because the country's generics prices were relatively high. Price disclosure was designed to bring prices down and reduce the cost burden on the PBS.

The government has chosen various mechanisms beyond PBS reform designed to slow PBS growth further such as deferrals and cost-effectiveness reviews. The bar for achieving reimbursement of medicines is arguably at an all time high, resulting in a reduction of new medicines of the PBS for all medicines.

Industry's greatest disappointment is that the predictability and stability that we require has not been delivered and the PBS itself has become increasingly politicised in the quest for savings and an balanced federal budget, which in my view does not achieve the best health outcomes for the Australian public.

And looking at the organisation that you now lead, what have been the key changes?

AstraZeneca has effectively doubled its size since 2003 in terms of sales on the back of our outstanding portfolio of medicines. . With a market share of ten percent, we are one of the highest performing subsidiaries for AstraZeneca globally. This ten percent ranks Australia in the top half of the top ten countries within the company, ahead of Germany, the UK, and Spain in terms of contribution to global revenue, which helps us to punch above our weight globally. We are particularly effective in Australia and historically we have had good access for our medicines. We are a highly competitive company and have managed to deliver very good market share across many of our therapeutic areas.

To what extent do you see the regulatory environment in Australia as a threat to the industry?

The PBS price cuts are having quite an impact on the innovative industry, and AstraZeneca is no exception. Not only do we deliver savings to government, but we're a leading export Industry to Asia. Yet the government's lack of an holistic plan for the sector threaten our collective success, jobs and our enviable reputation as an outstanding country for access to medicines.

As I've mentioned, the unpredictability of the reinbursement process is a real hinderance however, AstraZeneca has been one of the few companies in the past 12 months to have successfully achieved a PBS listing.

This was for our drug Brilinta, probably the most important asset that AstraZeneca has globally. We were successful on the basis of very strong outcomes evidence. Brilinta is a good example of providing the kind of evidence that is needed to secure good pricing and market access. We have a very good clinical study which showed a CV mortality benefit, which was key to achieving reimbursement.

But, let's face it, not all medicines deliver that kind of innovation. That is the dilemma that the industry is facing: the benchmark for innovation continues to increase and obviously the cost of research and development is not decreasing. This balance between bringing incremental innovation versus breakthrough innovation is our biggest challenge as an industry and at AstraZeneca.

The challenge is generating acceptable evidence that will support reimbursement, at least in markets where governments effectively pay for medicine.. AstraZeneca recognized several years

ago that we need to provide extra evidence for payers, beyond what we need to provide to get a product registered. AstraZeneca is building this into our phase III program. Of course, given that it takes quite a long time to flow through, we will only seethis deliver over time – , although Brilinta is an early example of this being put into action. We recognize that payers need additional evidence, and if we ignore their needs we will not get good pricing and access.

Should big pharma companies resolve themselves to accept that growth will not come anymore from such mature market?

Mature markets generally face an ageing population. Australia is no exception, although the percentage of the population over the age of sixty is relatively lower than in Germany or Italy due to high immigration and a relatively high birth rate. This nonetheless means that effectively the pharma market is still growing, including in so-called mature markets.

The big barrier we face is to demonstrate the innovation that someone is willing to pay for. I would not give up on some of the core markets that we operate in – we just need to deliver the right medicines with the right level of evidence.

How would you outline the present and future role of Australia within AstraZeneca?

We believe in the next five years we will stay in the top five global markets for AstraZeneca globally, we also we have a privileged position owing to our center of excellence for manufacturing based on blow fill seal technology. This technology is about injecting sterile solutions blown into plastic type vials that are then presented as sterile products either for injection or inhalation.

It is high-end manufacturing which needs to be done in a sterile environment and for which highly trained operators are needed. For twenty years AstraZeneca has built the capability and productivity of the facility, and today we are the sole supplier to the Chinese market for our asthma treatment medicine. The Chinese market for this medicine is projected to grow from 50 million units to 250 million units in the next decade, thus presenting tremendous opportunities for AstraZeneca Australia.

Why has the choice been made to continue production from Australia rather than to invest in facilities in cheaper and booming competitors such as India or Indonesia?

For many lower value added manufacturing processes decisions are made every day to move manufacturing to India as an alternative to producing in Europe or Australia. The opportunity for AstraZeneca here is that technology that is used to support our medicines is complicated. To start up as a green field operation with all the required validation and then get all the machinery functioning and produce products that need to be sterile was not a viable alternative to the great manufacturing environment that Australia offered. AstraZeneca chose to build on the capability and the very high level of productivity of the Australian site.

The Australian Government needs to recognise that we are an Industry worth getting behind. We export more than the cars or the wine sector and as a high skilled, knowledge based indutry we have the ability to become a key driver for the economy beyond the resource dependent industries that the country's economic success is based upon. Government just needs to have the courage to nurture the industry and realise the tremendous added value that we bring as a sector and not just see us through a lens of cost burden in the manifestation of PBS spend.

We have seen a major decline in clinical trials conducted in Australia over the past years, and numbers today are still below those of 2007. How would you rate the attractiveness of Australia as a destination for clinical trials today?

Quality, cost and speed are the three drivers of clinical development and selection criteria for a location.

Australia offers great quality and infrastructure and the ability to collaborate with academic institutions is probably as good as in any advanced economy globally.

A major challenge for the Australian clinical trials sector is connected to the high Australian dollar, which is increasing the relative cost of conducting studies.

We believe that government should try to simplify the speed with which ethics approval can be granted at both a national and a state level within individual institutions. We see inconsistencies within states: in some cases there are two or three ethics committees required to sign off before a trial can start. This makes Australia less competitive than Korea or other countries in Asia that are able to put in a single ethics approval process and start studies faster.

This issue is very important in remaining attractive for clinical research and has been raised with the Pharmaceutical Industry Working Group and thus with Ministers Plibersek and Combet. Nonetheless we do not see a lot of momentum for change yet, which in my view is a weakness of not having a whole-government approach to the sector.

Prior to returning to Australia you were Vice President in the AstraZeneca Global Marketing and Sales Organization. What challenges associated with your new role made you accept this position and come back to Australia?

AstraZeneca has an extensive footprint in Australia. Australia is one of its largest subsidiaries and is an organisation that has a big impact on the overall health of Australians. I was very happy to come back to Australia and lead this successful and important business which touches the lives of so many Australians.

The industry needs a strong position on the big topics such as innovation and investment. Through Medicines Australia we are making steps in the right direction, and I hope that my international

experience combined with my leadership AstraZeneca in Australia will create a bit more influence on government to create a more sustainable framework for the industry.

It is important for our politicians and bureaucrats to hear that the decisions they make actually have a big influence on the level of investment that comes to Australia, and I spend a lot of time fighting for that cause in Australia.

When asked recommendations they would give to their peers when taking the helm of country operations for their company, many CEOs tell us: 'Assess, listen, come with an open mind, and do not have preconceived ideas'. In your case it was probably something difficult being an Australian. How did you manage to keep a clear eye?

I spent the first three months after starting the job travelling over 7,000 kilometres around the country to speak and listen to all different parts of the organisation, including manufacturing and our sales field force. After this I spent considerable time in Canberra getting to know many of government's key decision makers such as Ministers Combet and Plibersek. In these conversations I explained the needs of AstraZeneca and the needs of the pharmaceutical industry, but I also listened carefully to their needs. We know and understand that the government, like us, has challenges to deal with. The only way to overcome the differences is to understand each other's agenda. Furthermore the industry and the country share a bigger agenda: the pharmaceutical industry can add significant value back into the Australian economy as well as providing good health outcomes for Australians.

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