# Interview: Jason Smith, Managing Director, Novartis Australia

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*After just six months in the country, Novartis Australiaâ??s new Managing Director offers his perspectives on the Australian pharmaceutical market and healthcare system, his companyâ??s commitment to R&D, and Australiaâ??s competitiveness for clinical trials in the Asian context.*

**You arrived in July 2012 after working in different positions for Novartis in Europe, most recently as Country Manager in Portugal. Starting with first impressions, what were the good and bad surprises for you about the Australian market?**

The major difference is that the global financial crisis is affecting Europe much more deeply, and Portugal is one of the countries that unfortunately is affected significantly. This is spilling over to all aspects of life, including health.

As an industry this meant we were focusing fundamentally on getting our bills paid and ensuring the basics of access to new medicines. Cuts in medicine expenditure, pricing, and delays in access became the norm. We also saw some portions of the health budget growing ahead of the economy, leading to a perception of unsustainable healthcare spend.

Coming to Australia I see the opposite. The economy is not, of course, completely sheltered from the global economic crisis. Nonetheless, the International Monetary Fund (IMF) reports indicate growth expectations for Australia of around three percent next year. Australia remains a top performer among developed markets in the world.

Looking at the healthcare system I see tremendous positives, first and foremost a very high bar for innovation. Medicines are is subject to a rigorous registration process administered by the Therapeutic Goods Administration (TGA) and independent value for money assessment by the Pharmaceutical Benefits Advisory Committee (PBAC). These processes provide certainty about what medicine companies need to prove to have therapies reimbursed.

Once approved and reimbursed, medicines are prescribed and used effectively and the pharmaceutical industry plays a vital role in educating physicians in the appropriate use of approved medicines.

Furthermore at the tail end of the product cycle, we see good utilization of generics when a patent expires â?? Novartis, through its Sandoz affiliate, is the number two generic company in the world. At Novartis, we fully support the important role of generic medicines. We believe that generics should be of a high quality and utilised after legitimate expiration of a patent. Generics are essential to ensuring that the reimbursement system is sustainable, and in Australia we see a better achievement of that cycle than in any country that I have worked in.

The best evidence for it is to look at the growth of expenditure through the Pharmaceutical Benefits Scheme (PBS): about one percent in an economy growing three to four percent. That stands in stark contrast with the situation in some European countries, where medicines expenditures are growing in a flat growth economy.

**Bringing more acceptable and additional evidence that supports reimbursement is one of the key challenges for multi-national companies (MNCs) in developed markets. How do you see this challenge and is Novartis Australia able to meet increased demands?**

Novartis has a highly diversified portfolio and the company has made a conscious and public decision to be a research company for now and ever. Except Toyota, no other company worldwide invests more money in R&D than Novartis. We were ranked second in the â??Global Innovation 1000â??, an annual survey by Booz & Co, investing 9.6 billion USD in 2011. This commitment allows us to focus more and more on unmet medical needs in the therapeutic areas in which we have experience and ensures the longevity of our robust pipeline.

That means that as we bring newer products to market, they should be more likely to meet the bar for approval and reimbursement in a country like Australia. Novartis is also developing many products with companion diagnostics which are used in the clinical development process. This helps us personalise treatment, identifying those who respond well to treatment, and those who donâ??t. This means discovering better patient outcomes at the outset.

Going forward we trust that the medicine reimbursement system will continue to provide certainty about the value we need to prove, but also be able to respond more flexibly to the wider ways we can deliver value. To achieve this flexibility the reimbursement assessment criteria would need to be broadened. It would be a shame for medicines that meet the bar in other countries not to be able to meet the bar in Australia. We are actively engaging with the Department of Health and Ageing and Pharmaceutical Benefits Advisory Committee (PBAC) to discuss where and how the system could be more flexible.

The bigger issue that Australia faces is the additional government review which looks at spending on health and further determines whether a product should be reimbursed and brought into the market. We believe that the quality of the independent PBAC process provides a high level of assurance about the value for money to be gained from expenditure on new medicines, and whilst we understand that any government has a responsibility to consider affordability and other priorities for any claim on public monies, the deferral process can see a delay for patients in accessing new medicines and can contribute to more expensive and intensive health services including hospital admissions.

The PBAC is looking at exactly those factors in its review and recommendations â?? it ensures an appropriate price and that the submission meets a health economic hurdle, not just a clinical hurdle â?? over time for the healthcare system in Australia. Medicine funded by the PBS has been found to return more to Australia in terms of health and economic benefit than it costs. No other area of the health system in Australia has such an in-built guarantee of sustainability.

We do appreciate that the deferral process has been pushed back by another year on products that have less than a ten million turnover, but not all. We do not believe that deferrals have a place in this independent, sustainable system, and it naturally is one of the key discussion points in our interaction with the government.

**In 2014 the much-praised Memorandum of Understanding between Medicines Australia and the government expires. Do you believe that post-MoU cooperation with the government will be as sustainable and mutually satisfactory as it has been under the MoU?**

One of Australiaâ??s biggest strengths from the point of view of the innovative industry is the transparency and predictability of the market for investment, not only in employment but also in matters such as clinical research or investment to market new products. Mechanisms like the MoU are great ways to solidify that transparency in an industry agreement.

It is expiring in 2014, and I believe the focus should be on continuing the sustainability of the system. It should continue to ensure access to proven innovation, and we have a great process for ensuring that the innovation is real: a high bar for clinical evidence and a high bar for health economic evidence in the PBAC process. As long as a medicine meets those criteria it should be approved and available quickly. A new MoU should focus on maintaining that and ensuring that the growth of the PBS is sustainable, which will probably mean below the growth of the economy overall.

**Novartis is known to have a strong diversified portfolio. Which therapeutic areas and products are key growth drivers in Australia?**

Novartis just celebrated an important anniversary with the treatment of macular degeneration. Before this medicine entered the market, the best many macular degeneration patient could hope for was that the disease would not progress. A study by Access Economics in 2011 showed that every $1 spent on treating wet macular degeneration provided $2 in social and economic benefit and that our treatment has had a very positive impact for patients.

Novartis is very proud of the number of patients whose lives we have been able to touch in Australia.

It has been a great collaboration with the government.

Another key Novartis innovation is the launch a little over a year ago for a new treatment option for people with multiple sclerosis.

Novartis has a tremendous number of products in its pipeline, and sometimes the diversity of our great pipeline is actually the hardest part of working for Novartis!

**Novartis is a large R&D investor in Australia with close to 25 million AUD annually. Can you talk about some of the projects youâ??re undertaking? you detail the activities?**

In 2011 alone the number is close to 30 million AUD. We conduct over a 100 trials at 100 centers with about 1000 patients. Clinical research is critically important both to patients and to our future. Novartis has actually been a key part of the Clinical Trials Advisory Group, which put forward a number of recommendations for which new measures could be implemented to make Australia even more attractive as a clinical research hub.

A great example of such measures is the recent launch of a new website, a portal for clinical trial participation. It is a great site and raises awareness of all the studies that are out there. A patient with a particular disease can see what studies there are today and might be in the future; healthcare professionals have access to it as well as the industry. It is a great way to continue to drive

participation in these studies and a great example of the industry-wide commitment to further improving the environment for clinical trials.

**Do you believe there is room for improving the speed of clinical trials â?? for instance in ethics approval and corporate governance issues?**

I believe there is always room for improvement. The bureaucracy that is critical to ensure that the right administrative work happens in getting a trial up and running can be improved. The Clinical Trial Advisory Group made a number of recommendations to create a linked database of all patients in the study. Already there are measures to create a single, national ethics approval as opposed to a center by center for these studies.

**The attention of the global pharmaceutical industry is gravitating towards other countries in Asia-Pacific. Why is Australia still a competitive place to invest?**

The quality and the ability to do work that other countries cannot do is key. Novartis has announced our collaboration with the Brain & Mind Research Institute which is set to become a leading centre for studies in neuroscience. We are supporting the first multi-country analysis of MRI work in its kind in the Southern Hemisphere. Novartis has been instrumental in putting the case together. This has only been done in the US and in Switzerland, and now Australia is the third country to have this capability.

At the center level and at the government level there is a strong awareness of the need to continue to attract research, not just because it helps drive Australiaâ??s reputation but also because such studies provide great education for researchers directly or indirectly.

Novartis has a great story with its treatment for Chronic Myeloid Leukemia (CML). Early research for the drug was done by Australian researcher Professor Tim Hughes. The new methodology that he created to help monitor how patients respond to CML therapy became the international standard.

It is an Australian methodology that has become embedded in all our and other companiesâ?? studies on how patients respond to CML therapy. It is discoveries like these that are tremendous first and foremost for patients around the globe, but also for Australiaâ??s reputation â?? and it all began with Novartis conducting clinical research in Australia.

**What is the importance of Novartis Australia in the countryâ??s global operations?**

It is one of our strategic markets. We designate our strategic markets very specifically and have sponsorship of one of the executive committees of Novartis members. Australia sits within the AMAC region â?? Asia, Middle East & African countries, and that positioning helps us. We share some similarities particularly with countries like Taiwan and Korea in terms of the market access model, but we can actually learn a lot from the countries that we donâ??t have direct similarities to, the countries that are higher growth and have different health systems, just because they do things in such different ways it helps sparks different thinking in us.

We enjoy those interactions â?? I have had the opportunity in one of my past jobs for Novartis to work directly in the Middle East and in Africa, and I was pleasantly surprised by the high levels of pragmatism and the desire to get thin
s done in those markets.

Also from an investment standpoint it is an advantage to be in a high-growth region as opposed to being part of other regions that for a variety of reasons are experiencing less growth and as a consequence lower levels of investment.

**What is your vision for Novartis in Australia over the coming years â?? where do you want to take the business during your tenure?**

We are in a very good position. Novartis is a company to keep your eye on. We are showing one of the highest growth percentages among the top MNCs.

Our vision is very simple: we want to be the most successful healthcare company in Australia; we want to be a leading innovator and a trusted partner to physicians, government, and the various agencies we work with. We want to be the best place to work for our employees, and we will do that be being commercially successful. It seems an easy thing to say â?? that we want to be the number one healthcare company â?? but we believe that each of the points is achieveable.

We have the research success and the pipeline to make us number one commercially. Through our focus on our people and our investment in growing them as leaders, I believe we will be the number one place to work. In becoming number one in terms of reputation with our partners, it is critical that we engage in partnership. We work closely with Medicines Australia, and I am looking forward to engaging further as a new member of the board.

Collaboration is increasingly important in developing innovative treatments that improve the quality of life of patients and enabling them to live longer and pursue their goals. We will strive for more meaningful dialogues and partnerships with governments, industry, patients and physicians to ensure patients have access to the best care possible.

**What would be your final message to Pharmaceutical Executive readers?**

Look at Novartis, look at what Australia has achieved economically, look at what we have achieved in the health system. Australia has created an incredible system in value of medicines and in ensuring that medicines are used in the right way, as well as in ensuring that the overall system is sustainable. Globally, Australia is under-recognized for how well the system operates to support and treat patients here. If you have to be a patient somewhere, this is a wonderful country to access to the health system.

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