

Interview with Derek Haynes, Managing Director, Astellas Pharma Ltd. South Africa

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The South African affiliate was established in June 2003. Could you come back on the main milestones in the company's development from 2003 onwards?

Yamanouchi as an entity was an agency in South Africa under Pharmaplan from 1996. In 1997 I joined Pharmaplan as the Managing Director and ran the Yamanouchi agency. Yamanouchi parted ways with Pharmaplan in June 2003, and in May 2006 we became Astellas after the merger between Yamanouchi and Fujisawa.

The development of the company has been mainly based on our category leadership, in particularly urology, dermatology and transplant areas. We are fortunate that these therapeutic areas are relatively concentrated and we have been able to service them with a relatively small sales team. The "category leadership" has given Astellas a competitive edge in these specialized areas. We have had growth in excess of 20% compounded over the last five years. These results can be attributed to a collaboration of value added pharmaceuticals and a dedicated team of employees.

How is the company organized in terms of its management structure and geographical reach?

Astellas South Africa falls under the umbrella of the European operations. I report directly to Europe, which reports to Japan, therefore my relationship to Tokyo is limited.

So far, the focus of this affiliate has been on South Africa and the other English speaking SADC countries. We see new opportunities further north east, that is to say Uganda, Tanzania, Kenya. We have been a little inwardly focused on South Africa over the last years, and that is probably one of the reasons we are looking at new growth possibilities.

Astellas is very strong in Europe. Is the competitiveness and market positioning of the South African subsidiary in line with the kind of performance we can see in Europe?

My key gauge has been ensuring our market shares have been comparable with Astellas' market shares in Europe. The answer is that we are doing at least as good as European operations. We certainly reflect the group's European performance, although we are more in a growth phase than Europe, partly because of the fact that we only became an affiliate a lot later than most of the European affiliates, and because Europe is an established market and secondly due to our long delays for product registrations.

Mr Fagan of Sanofi South Africa told us that he enjoys his position as being part of the change as opposed to reading about the change, as most of your colleagues probably do every morning in Europe. Do your colleagues envy you? What can we expect from South Africa?

At the moment, we are pretty much in a state of flux, but I think the Department of Health (DOH) must be given credit for the great things they are doing. Issues at the Medicines Control Council (MCC) aside, but one has to acknowledge that the National Health Insurance is a great initiative. Although funding is going to be a problem, the DoH has given themselves a 14 year timeline, which should be sufficient.

Minister Motsoaledi is really dedicated to this project; it is an exciting initiative and let us hope that everybody can get on board.

As far as the NHI is concerned, the private market has about 8 million individuals. All of a sudden, we are going to have 50 million individuals in the health scheme. The market is going to grow drastically and will create tremendous opportunities for pharmaceutical companies and more importantly all citizens of South Africa will be provided with essential healthcare, regardless of their employment and wealth status.

The question is whether we will be able to grasp those opportunities. The business philosophy of Astellas describes our corporate raison d'être as that of contributing toward improving the health of people around the world through provision of innovative and reliable pharmaceuticals. Our competitive edge will have to be within the areas of our category leadership where there is a high degree of unmet needs. Just like the European austerity measures we will be confronted with budgetary issues of our own. It is going to take some time and a mind shift for us but opportunities

are there.

As we just closed the year, what is your assessment of 2011 and what have been the main growth factors for the SA affiliate?

Internationally 2011 has been a tough year economically and rumours of a 1930's type slump everywhere. Transplant, Urology and Dermatology continue to be our main growth areas. Solid organ transplants in South Africa look to be significantly down over 2010 so competition via pricing and market share continue. In the Urology market Vesicare(Over Active Bladder) continues to increase its market leadership and Flomax(BPH) maintains market share even after three years of generics. We have also seen a resurgence in our Dermatology franchise with major focus on Protopic for atopic dermatitis.

Although Japanese companies are exporting more and more in the pharmaceutical sector and are increasingly active in terms of M&A operations, South Africa seems to have been out of scope for Astellas with regards to utilizing the generic space in the country. Do you agree?

The impact that some of the Japanese Pharmaceutical companies have had in this country is significant. One just has a look at the alliance formed between Ranbaxy and Daiichi Sankyo, Takeda and the acquisition of Nycomed. Generics are essential in a market such as ours however there should always be a place for a company that provides innovative and reliable pharmaceutical products. I believe there are tremendous opportunities if a company has access to good quality generics but this is only sustainable if R&D companies like Astellas continue to innovate.

Nevertheless we will continue establishing our presence as a leader in specialized fields by supplying high-value-added pharmaceuticals in transplant, urology and dermatology. As for our growth strategy, we have a number of oncology products that are either awaiting registration or are about to be submitted to MCC. Oncology could well be another category leader field for Astellas South Africa in the near future.

Do you ever see this country chosen to develop a research or manufacturing centre?

As far as research is concerned, we are very involved in clinical studies in South Africa. Production is another issue. In a bid to remain competitive a company could pursue any number of strategies. At this stage we have only briefly looked at local manufacturing. However having said this circumstances change often.

In the global company's Vision 2015, Astellas wants to be the employer of choice in pharma. What is your strategy to achieve this in South Africa? And today, how do you attract industry professionals?

The fact that we are small company is the major attraction. We can effectively employ the top people in the industry, we offer relatively competitive packages, and we are simply a really good company to work for.

I firmly believe our staff are our greatest asset. They perform as well as we perform for them; it has been a symbiotic relationship over the years. Our staff has been here for a long time, probably with an average employment in excess of 8 years.

Many MNCs are having pipeline concerns in the “new era” of post-blockbuster drug development. How is Bayer positioned in this respect?

Bayer Schering Pharma has one of the richest pipelines in the industry. In Australia, the company is launching in the next three years, 18 new products or product line extensions, thus representing six per year being above the industry average. These introductions include a new, innovative oral contraceptive called YAZ, which builds on the success of Yasmin. This oral contraceptive will also be for the use of light to medium acne, water retention, PMDD and is therefore innovative in its therapeutic class. In the area of cancer, Nexavar, will be launched in 2008 with reimbursement on the PBS. In 2009, Xarelto will be introduced to the market for venous blood clot prevention in patients undergoing elective hip and knee surgery followed by Kogenate for the Haemophilia community. This represents four major product launches in the next 10 months, and is in addition to other product launches and line extensions. More importantly is, however, that Bayer will grow with these product launches above the current pharma market growth.

What are the biggest challenges for Bayer in terms of the Australian operating environment?

Right now the biggest challenge, and this is not only a concern in Australia but worldwide, is the tendency towards price reforms and price reductions in the pharma business. Our industry invests heavily into R&D with up to USD1.2 billion upfront investments to bring just one new molecule successfully to the market. And success is not always guaranteed. Therefore, the introduction of the PBS Reforms from August 1 2008, which has resulted in price decrease of up to 25% is certainly carefully observed by our industry. Although many of Bayer's products are positioned outside of the PBS and are available in the private-market, some of our products are also exposed to the 25% price cut. You mention Bayer is exceeding market growth in Australia.

Can you be more specific about the company's evolution since your arrival just under two years ago?

Whichever segment Bayer operates in, we are amongst the top 3 companies and lead market growth. For example in contraceptives, Bayer has a market share of 76% in Australia and clearly drives the growth driver in this segment. Oncology is to a certain extent a new segment for Bayer,

with Nexavar. The company has an existing Oncology range, but has so far been a relatively small player. However, with Nexavar, we intend to invest competitively to ensure that we perform above market growth and increase our market share. Again in Diagnostics Imaging, Bayer is the market leader as well as with Betaferon in Neurology against Multiple Sclerosis with over 40% market share in Australia.

Can you tell us about the importance of clinical trials and R&D for Bayer in Australia?

Only two years ago Australia was not on the global map for clinical trials at Bayer Schering Pharma. Today, we run global trials with around 900 patients, 230 investigators and are spending in excess of \$10 million with partners on local R&D in Australia. Bayer in Australia is now clearly part of a global framework, thus bringing accelerated global trials to a country where investigators are known to be of an extremely high quality.

But research quality has been that way for more than two years – what was it about the timing that made the move into Australia more attractive?

It's important to recognise that for a company like Bayer Australia, as part of a global R&D network, we somehow also compete internally with other countries for R&D resources, however, we are proud to say, that we have established over the last 18 month a professional Medical and Clinical Development team, which can cater to these R&D requirements.

Can you elaborate upon your management style?

It's very simple: I prefer an open, transparent, pre-dominantly performance-driven management style with a high degree of social competence, which is not only for myself but important for Bayer as a whole. This is clearly a cultural heritage, which we carry on a worldwide basis as part of our leadership principles.

What kind of Corporate Social Responsibility commitments has Bayer made in Australia?

Bayer is networking with many organisations, both large and small in size, including organisations such as Mission Australia and the Cancer Council. We tend to undertake a lot of small community projects with strong employee involvement. For example, the "Give Program" within the company; for each community project in which employees become involved, Bayer matches their donations dollar-for-dollar, doubling our employees' efforts. On a larger scale, Bayer has embarked on a Global Climate Change program in which we are investing a staggering 1 billion Euro worldwide. This program translates to very concrete measures that will benefit the global environment. In this respect, Bayer has set clear emission targets for all its three subgroups of CropScience, Material Science and Healthcare in the range of 5% to 25% by 2020. In Australia and New Zealand for example, Bayer supports green cars, by offering employees a choice of hybrid vehicles. There are many proactive steps, which we have been taking in addition to environmental audits at all of our

production sites here in Australia.

Where do you want to take the company in the next five years?

Within the next 5 years, we want to position Bayer as one of the leading healthcare companies in Australia and New Zealand with sales reaching \$600 million AUD with strong platforms in pharma, animal health and consumer care.

This would catapult Bayer into the top 5 healthcare companies in the country. What is your final message to the readers of Pharmaceutical Executive?

As Bayer we have established ourselves since 1925 in this part of the world, and we are proud to carry an extensive history in Australia. Indeed, Australia was the first country worldwide to launch the contraceptive pill, even ahead of Europe and the US. And we will continue to foster and encourage this pioneering spirit amongst our employees. Overall, it is important to remember that our strategies are not embedded in lengthy documents, but rest with the great capabilities of our people, which brings me to my last statement. Truly successful companies do not only have a full product pipeline, but focus also on a great people pipeline.

We are going to have a relatively lean two years, but we are expecting in a third year to have a certain number of registrations. Our oncology products should then come to market, and we should become a significant player in the oncology area. As a result, in the medium term, we are going to look very good.

Despite the frustration from having products sitting at the MCC for five years now, our pipeline is looking good in most of the categories that we have a focus on: oncology, urology, anti-infectives, and definitely transplant. As for personal ambitions, to continue having a good time and to making a difference.

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