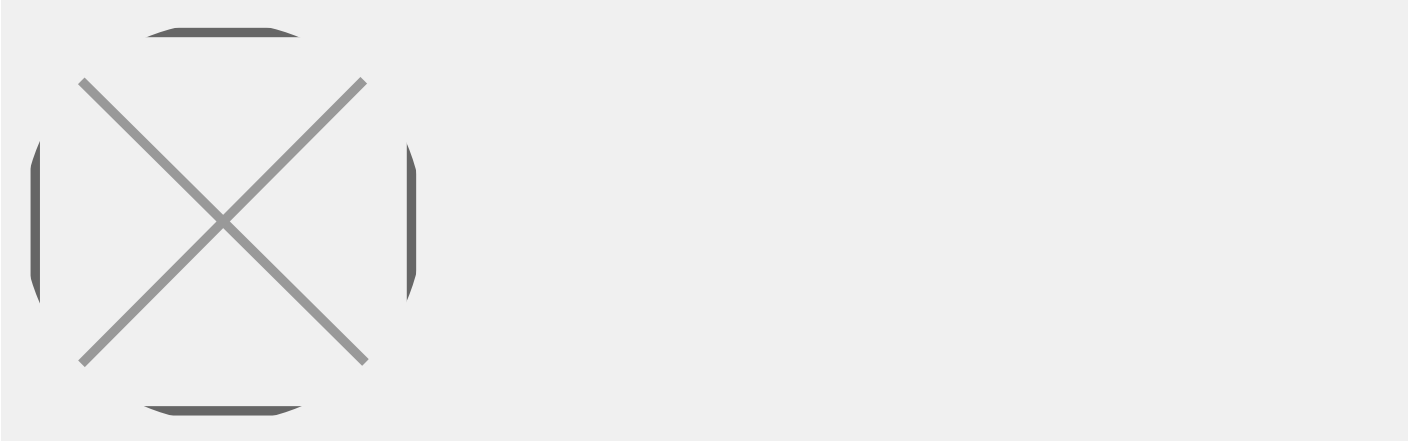
Interview with Peter Soelberg, Managing Director, Novo Nordisk – Australia



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Can you start by commenting on the state of diabetes in Australia at present?

According to 2011 statistics nearly one million Australians have diabetes and about half of those are not aware that they have the condition. Australia is ranked 7th in the world in terms of prevalence of type I diabetes. Like type II, type I is growing quite fast: 17-18 percent, making it a very significant disease for Australia. With the current growth rate we expect the number to reach 3 to 3.5 million by 2025, and the disease presents a big and growing problem for the individual, for families, and for society.

We have a project which we worked on for a while – the Changing Diabetes map, for which we gathered data all the way down to a postcode level to show the level of control on blood glucose. It shows that little more than half of people with diabetes has good control, which means the other half are at risk of complications as a result. The key thing with diabetes is that the patient needs to be in control of his blood glucose, otherwise the risk of complications increases manifold. This means Australia already has and is facing a massive increase in avoidable health costs as a direct consequence.

The cost burden of diabetes for Australia measured some years back is estimated to be around six billion dollars annually in direct and indirect costs. These do not include productivity loss, and these costs will grow dramatically as the population grows and ages.

How do you establish good control, how challenging is it in Australia and how does Novo Nordisk help?

Diabetes is a difficult and chronic, progressive disease. The Australian healthcare system, like others around the world already struggles to cope with the costs of patients who cannot keep their blood glucose under control and with the growth in number of people with diabetes.

At Novo Nordisk, we are operating under what we call Triple Bottom Line business principle, which means focusing on sustainable business development. We are about much more than delivering products and services: we want to be involved in solving the problem of diabetes as a company which takes its social responsibilities very seriously. We engage with stakeholders throughout the world in prevention programmes and education which aims to be a game-changer in helping stop and prevent the spread of diabetes. Regrettably, Australia does not have an current National Diabetes Action plan and has not had one since 2007. We do not have a coherent strategy for tackling diabetes in Australia, and that is an unsustainable situation. In April 2012 Denmark hosted the European Diabetes Leadership Forum between the Danish presidency of the EU at the time, the Danish Diabetes Association and the OECD countries including Australia. The OECD strongly advocates that member countries need to have a diabetes action plan in place because it is not only a health challenge – it is also a significant economic and growth challenge. It is a multi-sectoral issue that needs to be tackled. Novo Nordisk has been deeply involved because it is regarded as having long experience and knowledge of best practices in both primary and secondary prevention.

What are the obstacles preventing the national policy from being updated?

That is a good question and it is the question that we ask the Australian government. Diabetes was made a national health priority back in 1998. While we have had some successes as a result of previous national diabetes strategies, it is an unfortunate fact that today, we are not getting an answer yet to this question. Australia’s approach today is lacking in coordination, effectiveness and direction.

What kind of relationship do you see the company sharing with the regional and federal authorities in Australia?

We have good relationships which we try to use in terms of having the discussion about the situation and the outlook and solutions with our government and other key stakeholders. In the current political context it appears that most of the focus of the current government comes down to budget management. Australia has a growing and ageing population and with a chronic disease such as diabetes, it requires long term thinking and investment into prevention, early diagnosis and effective intervention when required. The challenge however is that politicians regard long term strategies in three year electoral cycles and Treasury is all about 12 month forward budgets. This

accounts for why we don't have any commitment to the long terms strategies which will stop diabetes. It's all about cost, not savings to the country that can be generated with the right strategies.

Can you outline the significance of the current PBS reforms to the industry and in particular the impact it has on Novo Nordisk?

We have long held a very high regard for the PBAC process in Australia. The PBS as a system and as a principle has been held out as a Gold Standard internationally. The challenge for patients and the industry now is that it has been politicized and we are concerned that it is now focused on cost-to-government instead of its charter of cost-effectiveness. A process known as PBS Reform instituted by the previous government aimed to generate PBS savings, so that the PBS could provide timely access to new, improved medications on a sustainable and affordable basis. The industry entered a Memorandum of Understanding between Medicines Australia and the Australian government, which was supposed to give certainty to the industry while delivering even greater savings, with the intent of affording new medicines.

However, looking at the record of listings in the past year we see that less than a handful of drugs based on cost-effectiveness have been recommended – a significant change in the way PBAC operates and a concern to people who will depend on new medicines rather than cheap generics.

We and the industry had a high regard for the PBAC process as it was. Looking at it a few years back, there was an emphasis on evidence-based medicine. Now it's medicine-based evidence. I see the PBAC process now as more cost-focused. While the scientific discussion is still there, the emphasis is entirely on cost to government. We recognize that we need to show cost-effectiveness to justify pricing, but I wonder whether the pendulum has swung a bit too far toward cost vis-à-vis the economy in the long term.

Politically I would also like to see health featuring much more than it does. Health is inevitably linked with the economy and productivity and I am not sure I am seeing that government sees it that way. Health is looked at as a cost. Medicines like ours that keep people out of hospital are seen as a cost. They are not seen as a benefit. This is a debate that needs to be had and, as an industry, we need to lead that debate.

Which products in the Novo Nordisk portfolio have been the biggest growth drivers and which products are in the pipeline?

At present we are the only company with a full portfolio of insulin analogues in modern pen devices for the treatment of both type 1 and type 2 diabetes. Novo Nordisk has the widest and deepest pipeline in diabetes. We are still working on the listing of our once daily human GLP 1 analog liraglutide for type 2 diabetes, which is still in the PBAC process. Insulin degludec, a fourth

generation ultra-long acting insulin analog, is under regulatory review, as is degludec plus, a soluble formulation of degludec together with fast-acting insulin aspart, which is in the same situation.

Further down the pipeline as a company globally we have a combination of insulin degludec and our human GLP 1 analog liraglutide for type II diabetes. In the same phase III stage we have liraglutide also being investigated for use in both diabetic and non-diabetic obesity treatment.

We are also working on a compound for once-weekly administration of human GLP-1 for type 2 diabetes, and also orally administered insulin and GLP 1. In haemophilia we have a listed product, NovoSeven® RT for the treatment of haemophilia with inhibitors, and we are on the way into general hemophilia with recombinant factor VIII, IX, and XIII products.

It is a very strong pipeline, and the hope is that we can bring it to Australia, which we of course will do our best to do, but the challenges are significant in the context of reimbursement and access as discussed.

Looking at the broader picture, as the head of an innovative company in Australia, how would you rate the government with regard to creating an attractive business environment and encouraging innovation?

Australia is a sizable and mature market, and that means that the growth rates are characterized just like a mature, European market. Obviously there are countries just north of us in South East Asia such as Malaysia, Indonesia Thailand and of course India, China – that have big health challenges and very much focused on securing better access to health and medication – big growth drivers for companies such as Novo Nordisk and the industry as such.

At the same time challenges with listing figure more and more prominent in Australia, and priorities will follow that. That is also a proposition that is less well understood by government: if we do not have a resolution on the ability to list in the medium- to short term – as intended with PBS reform, many major pharmaceutical companies will shift their priorities elsewhere, which in turn will impair Australians access to new and innovative medication.

This goes for clinical trials as well. Australia has long been a good and well respected country for clinical trials, and I wonder what the outlook for that might be. If a company cannot list innovative drugs in this country because government refuses to pay a reasonable price, then on the longer term why would it put them to trial in Australia? In this context I note reports on already a marked decline in late stage clinical trials being conducted in Australia.

At some point in time I would expect the pendulum to swing back in a more balanced position. We adhere in hope to the long term view and would like to believe that it is still sustainable to invest in clinical trials in Australia.

How has your management style been influenced by working for Novo Nordisk in such fundamentally different cultures as Denmark, Russia, Japan, and Australia?

I have been almost 17 years with the same company. Novo Nordisk has a very strong value set and management principal, the Novo Nordisk way, and that is the foundation for the company all over the world, and the foundation in all countries. It is very encouraging for me that, no matter which country I go to, the foundation is strong and people treasure and engage with it.

Culturally and business wise there are of course differences in each country, and from a leadership point of view, that aspect is the most interesting. How do you become effective in the particular local culture interwoven with the company's culture? It takes preparation and listening to how things are done locally, and then figuring out how to operate effectively and sustainably within that. I have had a few transitions through the years, and I think I got better and better at it, but it continues to be a very interesting challenge in which there is always more to learn.

The Novo Nordisk Way is very compatible to any culture, because the originally Scandinavian value base is very fundamental; they are sound, basic principles. People around the world recognize this and embrace it once they look at it. The Triple Bottom Line works from the simple business principle that we put patients at the center of everything we do. In a business situation in which it is unclear what to do, a fundamental test is to ask if it makes sense for e.g. a person with diabetes, because if it makes sense for them, then it makes sense for us. You can make very simple but good decisions on that basis, and they are the test for everything.

Seventy-five percent of the Novo Nordisk business is diabetes, and that makes us unique. We work hard on that every day, on making the lives of people with diabetes better.

Where do you want Novo Nordisk in Australia to be at the end of your time at the head of the Australian operations?

I have a long term commitment to Australia. The foundation is to make a difference in diabetes and also in haemophilia. The first focus is on making a difference with our current products, and the second on the broader engagement into the advocacy, first of all by getting a Diabetes National Action plan in place. We are working hard with partners in the national patient associations and through our dialogue with government to achieve this. It is the only way to solve the diabetes challenge in Australia, and it goes hand in hand with what we are as a company.

We will try and continue to bring innovation on the product side to Australia. I hope that the environment will slightly change so that it will open up for a bit more balanced opportunity for reimbursement. While recognising the Budgetary challenges that this and any government has, I do think that effective health spending has to be regarded as a higher priority in terms of government policy.

The cost in type II diabetes is not in drugs –which account for only 6-7 percent. The rest comes from complications, and the drugs are used to make sure that you do not get complications. Logically it is worth investing into proper treatment for people who unfortunately do get the disease. Of course it is also worth investing in primary prevention because type II diabetes can mostly be prevented. Those investments can go hand in hand for the longer term of avoiding complications, and that is important for the individual as well. It is important that we continue to focus and work with stakeholders on that.

What is your final message to our international readers?

I would like to see globally a follow-up of the trend of engaging in the debate and solve the state of a disease on a much broader scale than just delivering products. The pharma industry needs to improve public perceptions of what it really does and is good at- science and research leading to vital new medications. The industry needs to shift its thinking and try to put itself in a position where it is a partnership of working on alleviating the disease burden on societies. In mature markets we see the focus on the cost burden of health increase ever further, and the solution of that is not just cutting medicine expenditures but being able to articulate what the solution is. The dialogue needs to be broader and how the pharma industry can play a big role, similar to the one that Novo Nordisk is playing every day, everywhere in the world.

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