Anders Blanck – Director General, Lif Sweden



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Anders Blanck of Lif Sweden discusses the Swedish healthcare system, why it's contributing to the plunging profit margins in the pharma market, and the Swedish government's heavy emphasis on cost-effectiveness.

Giving a brief overview of the state of the Swedish market today, what, if any, have been the major shifts in trends that can be seen happening within the market?

Sweden is a very mature market. It used to be a market where products were launched early. Sweden has traditionally been a country with a large number of clinical trials, at least in comparison to both sales and population.

I just looked at the latest sales statistics of IMS, which were quite interesting. The market for originator products has decreased by almost five percent in 2012. The total market has also decreased by almost three percent, while the volumes grew with seven percent in the same period. It is a huge shift as the generics share grew with 7-8 percent, while parallel imports grew with almost 30 percent.

This severely affects the companies in this region. You can have a separate discussion on how to deal with parallel imports internally and the income from that, but the fact is that this is happening, first and foremost due to the very strong Swedish Krone. Today, parallel imports represent close to 20 percent of the entire market, and generics another 20 percent. That is a landmark shift

compared to just five years back.

A very efficient generics substitution system was introduced in Sweden a decade ago. We have supported that reform because we believe it creates headroom for innovation—after the patent expires, generic competition sets in, and the money that is being saved can be transferred into new products.

We have had a very stable system for the last ten years, with annual market growth of 1-2 percent, which we believe represents sustainable growth. But suddenly, this has dropped and the market has gone down. In 2012, 32 new products were launched in Sweden. They have had hardly any sales: 16 million SEK for the 32 products in total. And this group included several very strong products. Why? Because Sweden is supposed to have one of the best healthcare systems in the world, so the focus is fully on cost effectiveness.

Do you feel that government is not striking the right balance between serving patient interest and containing cost?

Industry will always tell you that there is not enough focus on innovation, but if you look at the yearly sales figures of new innovative products, industry has actually delivered strong new products, but they do not sell in Sweden. Generics grow at 7-8 percent and many old products are going off patent. There is nothing wrong with those indicators in itself, but there is something wrong with the absolute lack of uptake of new medicines.

Debate on this topic is growing in Sweden as different stakeholders realize that there is something wrong here. The focus on cost-effectiveness is good, and we fully agree on testing new products' cost-effectiveness and health economics, which Sweden has been doing for the past ten years. These things need to happen, but it is almost put in opposition to innovation. We feel that the balance has been too heavily tilted towards cost-effectiveness in the past two years.

The innovative industry faces an added struggle in Sweden. We have a national-based reimbursement system and a national agency, TLV, that makes value-based pricing assessments based on health economics. That means that you go to TLV with your dossier, and they will give you a price. That price goes for all of Sweden, at least in theory.

Unfortunately, Sweden has 21 regions or counties, and each county has its own recommendation or formulary committee. The counties are the ones that actually run the healthcare system and decide which products to use. The fact that your drug is included in the national reimbursement

system does not mean that the different counties will actually use your drug. The national system is becoming more like a needle's eye—when you have passed it, you still need to negotiate with each separate county. With political power being so dispersed, I am often surprised that the country still functions and the busses still run every day.

Technically we have 21 different healthcare systems in our country, and they all have their own political bodies, run their elections, and levy their own taxes. When my new board members ask me "Who is in charge in Sweden?" I cannot answer the question. This is a super-advanced, high-tech country. Nobody is in charge, nobody is responsible for anything and everyone is responsible for everything. It is a strange country in that sense. Government believes that everything has to be done according to the Swedish model. They believe there is a system.

How would you then rate the quality of the dialogue with government?

It is very good. And it has to be, and that is the problem. We have no conflicts in Sweden. We hardly have any political conflicts at all; people do not like conflict. Even if you disagree, you still make it sound as if you agree. That means that there is no political discussion on where the healthcare system is going, because it is consensus-based.

As an industry we have a very good dialogue and are invited everywhere. When in 2010 the process was set up to develop a new national pharmaceutical strategy, we were part of the process all along the way. We are invited to be part of the discussions that matter; we are invited to the parliament and in consultations regarding all important healthcare issues; Lif, as an industry association, is consistently invited to say what we think and contribute with thoughts and ideas.

That is not the problem. But Sweden has such a good healthcare system that we are not really focusing on the future but rather on the present; and it is here and now we have a problem with demographics. Look around Europe; the economic situation is disastrous, so they decide to introduce international referring pricing. And what is happening in Sweden? International reference pricing is proposed too. Why? Do we have a problem? The cost of pharmaceutical products is going down under the current pricing system and we have a very strong currency. Thinking in government goes along the lines of, 'Well, we can have even lower prices, and everybody is introducing international referring pricing, so why can't we?'

So how, as an industry organization, do you make sure that the voice of the industry is better heard in government?

The Swedish government has put a strong focus on the life sciences industry, among other things through a bill introduced in 2012 under which the government will invest a huge amount of money in academia and in medical research, which is very positive.

But the focus is solely on the push-part of the business. The government wants to build the infrastructure for a well-functioning life-science sector in Sweden, but does not want to talk about markets, about the pull-aspects of research and innovation, about using new products and paying for them.

And for a lot of our members, Sweden is actually a market. They are running a business. Some of them indeed do not intend to build up research capabilities but rather are here to sell innovative products and make sure that Swedish patients have access to them.

As governments implement measures to restrict healthcare expenditure and stricter regulatory approval procedures of new products, should big pharma accept that major growth will no longer come from mature markets? Or are there other ways to generate significant growth in a market like Sweden?

From a market perspective, the Swedish market will become even less interesting. Our market represents some 0.5 percent of the global pharmaceutical market. I see no other route. Companies in Sweden and worldwide have problems with their research models, because costs have risen.

In a country like Sweden, where everything is consensus-based and taxes are high, public opinion does not approve of companies making too much profit, even though AstraZeneca –with its still very heavy presence in Sweden – is probably the company that pays most taxes of any company in the country. This makes them good citizens. The industry-card is basically the only card that is interesting in Sweden.

What is the pitch then to international pharmaceutical companies in order to persuade them to invest in Sweden?

Innovation, research, investment, and potentially one of the best samples of registries in the world. A strong research foundation is the attraction of Sweden.

Even though numbers are declining, Sweden is still overrepresented in clinical trials. While AstraZeneca and SOBI are the only substantial players running basic research in Sweden, companies like Pfizer, MSD, and Novartis are still conducting lots of clinical trials here.

We have very strong academic research centers and a government that really invests in these strong academic research centers and not only in the Karolinska Institute, which is one of the best known medical research institutions in Europe. Government spending on academic research has increased significantly even throughout the economic crisis, which is impressive, even more so when comparing it to levels of spending in other EU-countries.

What does the future hold for the industry in Sweden?

Sweden is particularly well suited for post-marketing studies that look at the entire population of a country. In other countries that can be a challenge, but in Sweden, we have all nine million Swedes ready as an unselected population to do research with.

This is the future. We wish to discuss how we can link all the actions that are taking place in the research field, the push side, with interesting projects to assess or evaluate new medicines. That is more interesting than to tell Swedes, ‘You have to buy our new products because we have made them available for you.’

Again, the government is giving a strong push for the life science industry when it comes to infrastructure, seed-capital for small companies, etc. We have been and still are interesting as a destination for clinical trials because of the research quality and the availability of strong registries. Everyone in Sweden has a personal identification number, which is unique and makes certain that you can be followed. Is it good or bad? It actually means that in Sweden, when I am supposed to file my taxes, I do not even have to fill out a form—they know everything about me already. I get a ready-to-sign paper in my mailbox.

Regardless of the privacy aspects, it certainly gives massive opportunities from a research point of view. But it also means that, if you have all these opportunities in your country and are ranked first on the Economist’s global innovation ranking, are you really interested in talking about new medicines? Well, perhaps if they are produced and exported from Sweden. Otherwise we focus on paying lower prices, and perhaps we will use these new medicines later on. Let’s have other countries use them first so we know if they are really effective. This approach has to change.

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