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Anders Blanck, director general of LIF, Sweden's association representing the research-based pharmaceutical industry, breaks down the ins and outs of the country's regionalized healthcare system and the drivers of the Swedish pharmaceutical market. He then delves into the reforms Sweden needs to undertake for its healthcare system to adapt to next-generation cell and gene therapies and regain its position as a testbed for innovative medicines.

Considering its maturity, the Swedish pharmaceutical market is experiencing a healthy growth rate, with IQVIA predicting an estimated four percent average annual growth until 2022. What are the main drivers behind this?

This is what one might expect as the annual growth of the Swedish pharmaceutical market traditionally falls between three and five percent. This growth – which I would refer to as a healthy or sustainable growth – can be partly explained by the mechanisms of the Swedish value-based pricing and reimbursement system which is heavily focused on cost-effectiveness.

In Sweden, generics make up 64 percent of sales volume, while the country has the second lowest pharmacy prices for generic medicines in Europe after Denmark. Prices of generics in most other European countries are far above those of Sweden. As a result, Sweden has one the lowest generics market share by value. In other words, the system pays very little for the large majority of pharmaceuticals on the market. The advantage of this system is that it takes some pressure off

when it comes to financing new medicines as the system will pay extremely low prices later down the products' lifecycle. The national healthcare system is thus in this sense more able to fund new medicines compared to other healthcare expenses.

Total healthcare expenses have grown rapidly over the last decade. While Sweden used to be close to the EU average, the country is now one of the top three highest health spenders as a share of GDP in the EU, along Germany and France. This dramatic rise in healthcare expenses has not been driven by pharmaceuticals. Over the past five years, drug expenditures per capita have actually declined, while overall healthcare expenses per capita have increased by 30 percent.

This being said, although on a macro scale pharmaceutical expenses do not constitute an issue, in Sweden the payers are ultimately the regions (earlier called County Councils). Constitutionally, regions are independent. Each region has its own regional government, levies its own taxes, has its own budget and its own healthcare system. As a consequence, the ability and willingness to finance new medicines varies widely across the country.

In recent years, growth has mainly been driven by the introduction of new hepatitis C treatments and oncology medicines. In order to finance these treatments, the national government has increased the amount of the special state grant for pharmaceutical benefits given to the regions.

As you mentioned, in Sweden the regions have almost all the power when it comes to financing, purchasing and providing healthcare products and services. How do your members go about navigating this complex regionalized system?

In Sweden, it is hard to pinpoint who ultimately decides which medicines are bought and used. At the national level, the Dental and Pharmaceutical Benefits Agency (TLV) only takes a formal decision on whether a pharmaceutical product, medical device or dental care procedure should be subsidized. Every year, the government provides a lump sum of money to the 21 regions to finance pharmaceutical benefits based on a cost forecast made by the National Board of Health and Welfare. However, even though the government gives out this special grant, it has no power to decide which medicines are bought and used. Whether or not a company sells one single pack entirely depends on the regions. As a result, launching a new product in Sweden can prove challenging. This being said, regions have joined hands to create six healthcare regions, with four of these covering more than 60 percent of the population, which makes things a little bit easier.

Companies adapt to this regionalized system by working closely with the key stakeholders in the healthcare and political system at the regional level. The largest ones usually have one person in charge of each healthcare region. The organization of LIF also reflects this regionalization with one antenna in each healthcare region. Not surprisingly, companies would prefer to deal with a centralized healthcare system. Everybody in Sweden agrees that having 21 different healthcare systems is not wise. After all, we are all Swedes. However, this is not very likely to happen anytime soon as it would require a major constitutional change.

As you pointed out, the government provides a special grant for pharmaceutical benefits to the regions. However, an independent pharmaceutical review commissioned by the national government has proposed it be included in the general government grant. What is your opinion on this proposal?

To be clear, this is not an official government proposal, but only a suggestion from an independent review, however, commissioned by the government. At the moment, all healthcare products and services are paid for by regional taxes, expect for reimbursed medicines which are financed through this special annual grant given to the regions. This grant is designed to equalize access to medicines across the country. As previously explained, the amount of the grant is based on a forecast by the National Board of Health and Welfare. However, regions still negotiate the amount with the government every year. If this proposal is implemented, regions would lose their negotiation right, and the amount would be fixed. Not surprisingly, the regions are not fond of this proposal, and neither are industry or patient representatives. The ability of regions to fund innovative therapies would be severely impaired and Swedish patients would have a hard time accessing the next generation of cutting-edge treatments such as cell and gene therapies.

On this point, how is Sweden trying to adapt to the advent of breakthrough cell and gene therapies?

The current system is simply not adapted to the adoption of novel therapies such as cell and gene therapies. Individual regions simply do not have the capacity to adapt to this medical revolution. Fortunately, the government understands the need and is rolling-out nationwide initiatives, in collaboration with the regions. For instance, Genomic Medicine Sweden aims to create a national infrastructure for molecular diagnostics and introduce precision medicine to healthcare by using powerful sequencing technology. Moreover, within the framework of Biobank Sweden, regions and

higher education institutions are cooperating to build up an integrated healthcare infrastructure for biobanks.

However, much still needs to be done to adapt the legal framework and supply chain. Cell and gene therapies are not your ordinary pill. It will not be possible to buy them from a pharmacy. Instead, cell and gene therapies will necessitate a direct link between hospitals and pharmaceutical companies. However, in Sweden, by law, all dispensing of medicines to patients must be done by the hospital or retail pharmacies. Moreover, genetic material might need to be sent abroad for manipulation. At this moment, it is unclear if this is even legal. Hospitals will also need to be certified to handle these new processes in a system where 21 regions administrate their own hospitals and follow their own healthcare agenda. Realistically, in a small country of ten million people, it will not be possible to provide these next-generation therapies in each region. Instead, it will have to be done in a handful of highly specialized hospitals in large cities. In this regard, the national government, in particular through the National Board of Health and Welfare, is trying to concentrate highly specialized care in fewer hospitals.

In order to implement cell and gene therapies, regions realize they must work together and will have to negotiate with the national government through the Swedish Association of Local Authorities and Regions (SALAR).

Regarding SALAR, since 2014 this body plays an increasingly crucial role in cost-control and early access of new medicines through Managed Entry Agreements (MEAs). How has this new tool affected the uptake of innovative pharmaceuticals?

MEAs are a double-edged sword. They were originally created for hospital medicines in which regions are responsible for financing with taxpayer money. Before the introduction of this tool, each individual region negotiated the price of hospital medicines separately which put smaller regions at a disadvantage. As a result, they turned to SALAR to devise a system where regions could join hands and pool their negotiation power together. Because there were no mandatory HTA process for hospital medicines, SALAR commissioned the HTA from the TLV.

This system developed into so-called three-party agreements which now also include reimbursed medicines. The advantage of this system is that it allows standardized access to innovative medicines. It was necessary to have one single process instead of 21. However, it is not possible for companies to apply for an MEA. Instead, the regions pick and choose for which medicines they wish to negotiate such agreements, and resources are only available for a handful of products each

year. Not surprisingly, regions choose to negotiate MEAs for “tricky” medicines such as orphan drugs and oncology therapies. Obviously, the industry would prefer to be able to apply within a transparent selection process. Nonetheless, while in the beginning, this process slowed access down, especially in larger regions such as the Stockholm region, nowadays it promotes faster and more equal access across the country.

One of the main missions of LIF is to promote industry-funded pharmaceutical R&D. However, the number of company-initiated clinical trials has been steadily decreasing in Sweden for the past decade. How can Sweden curb this trend and position itself as a testbed of innovative clinical trials?

I wish I had the answer to this question. Back in 2005-2006, Sweden was a world leader in the number of industry-sponsored clinical trials as well as in the number of patients enrolled in clinical trials relative to its population. The situation has drastically changed since then. The number of clinical trials has more than halved in the last ten years and 2018 saw another decrease.

While everybody agrees that Sweden should be a testbed for innovative ideas, no one has the magic formula. Sweden will never be the largest or most interesting market, but it could be the smartest. In practice, it is not the case today, not for pharmaceuticals or medical technologies. It is hard to pinpoint exactly one reason to explain why Sweden has lost its attractiveness. It is certainly not due to a lack of patients, or a lack of interest from patients.

One reason has to do with the fact that healthcare staff lack the time and the incentives to conduct clinical trials. Moreover, companies must fulfil preconditions that do not exist in other countries. For instance, as mentioned, in Sweden all medicines must be dispensed in pharmacies making it impossible to distribute medicines directly to the clinical site. In addition, while Sweden used to be a frontrunner in developing biobanks, they are now outdated. Finally, while neighbours such as Denmark are getting rid of the fees for initiating Phase I clinical trials, the Swedish MPA has proposed to raise the fees. All in all, Sweden seems to have drifted out of tune compared to other countries.

The government should set a clear goal to increase clinical trials by a certain percentage during a given period of time and incentivize regions to reach this objective.

As a conclusion, where do you see the future of Swedish life sciences?

Nowadays, life science is the talk of the town in Sweden, which was simply not the case five years ago. Things are definitely going in the right direction. This enthusiasm for life science started after AstraZeneca closed down its research facility in Södertälje in 2012. This event was the straw that broke the camel’s back. It was a wake-up call. Before, everybody took the life sciences industry for granted. Today, life science is the only sector for which an official government office has been created. The sector is high on the government agenda and substantial investments are being made in infrastructure. This trend makes me optimistic that in five years’ time we will be in a better position than the one we are in now.

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