Interview: Svens Henkuzens – Director, State Agency of Medicines in Latvia (ZVA)

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Svens Henkuzens, director of the State Agency of Medicines in Latvia discusses the key role of the organization in the country and the objectives he has set to further improve the access to innovative treatments for Latvian patients.

Could you introduce the State Agency of Medicines and its mandate?

The agency itself is subordinate to the Ministry of Health. Our operational objective is to implement local and international pharmaceutical legislation in order to ensure that the products used in health care, as well as the involved companies and their activities comply with certain requirements; and in addition to provide objective and analytical information for the purposes of state administration, to the public, health care specialists, cooperation partners, as well as international and EU institutions. In this sense we are quite comparable with peer regulators in other European Member states.

Our remit also partly covers medical devices. Here we share responsibility with the Latvian Health Inspectorate. We are responsible for clinical trials with medical devices and medical device vigilance. The Health Inspectorate is responsible for market surveillance. They visit manufacturers, wholesalers, and other economic operators. Of course, when it comes to vigilance cases, we have to cooperate and coordinate closely with them. As far as locally produced products are concerned,

we possess more information on the products because we issue licenses to the manufacturers themselves. As of this year, we are also issuing free-sale product certificates for medical devices produced in Latvia.

What is the rational between splitting the function of oversight of medical devices?

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There actually used to be a single dedicated medical device and health technology agency. With the financial crisis, the state had to reduce the number of staff and, as a cost-saving measure, it was decided that that particular agency would be abolished and part of its functions absorbed into ours. As it turns out, this has not been a bad move. The medtech industry has, historically been subject to only a light touch regulatory framework. With the development of implantable medical devices, however, there is a need for a much more stringent regulatory code. Moreover, we have been witnessing a breaking down of silos and a convergence between the pharmaceuticals and medtech industries, so it is entirely appropriate that many of the regulatory functions now take place under the same roof.

We also serve as the supervising authority for organizations that handle products of human origin, blood, tissue, and organs. This is another emerging field and should become a much more visible part of the agency in the future.

What would you say are your main priorities right now?

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There are currently three main topics: our mid-term strategy is that we are striving to making Latvia a better place to do business. All public institutions are encouraged to become more customer oriented. We also look for efficiency gains. Brexit is also an important third topic. If we look at the UK’s share of products, it is being redistributed. So we are preparing ourselves to take over some procedures from the UK and seize any emerging opportunities. The other side relates to the national market and ensuring that we don’t experience shortages because of the potential supply chain disruptions brought about by the Brexit process. We are compiling information of products that might be at risk. Let’s not forget that the UK is a reference member state and in certain instances it might be a batch release place or a manufacturing site, so there are other criteria that potentially put products at risk due to Brexit. We want to focus on the products that are really at risk of shortages, and not the ones for which we have alternatives.

How much of a problem are drug shortages? And what are your strategies to minimize this effect?

Shortages are becoming more and more of a problem. As an agency, we of course cannot manufacture ourselves, but we can make sure everyone is informed of any likely supply bottlenecks. On the agency website, we have built a function whereby stakeholders can look up the medicines that are experiencing short-term and long-term shortages and look for alternatives that could replace the products in short supply. Since last year, we have been monitoring availability of vaccines, especially those to do with seasonal flu, and when it comes to shortages that pose a real public health risk, we are communicating actively with marketing authorization holders to ascertain if there are alternatives from other member states that we can secure. We can also trigger shortcuts around issues like foreign packaging so that specific products don't require any translation and can immediately be fast-tracked to market.

More specifically, how much of a risk is parallel trade?

This is a problem that is beginning to snowball and relates to the fact that Latvia is small size market and a middle tier economy where average purchasing power is lower than in many of the other countries in our region. We see that parallel export, especially in the last year, rose by at least 20 percent. Unfortunately, more and more medicines subject to the state reimbursement are being exported because they cost less here than in wealthier markets meaning a lucrative markup for anyone who is exporting. The shortages can be unpredictable. Often it seems to be oncology products where there can be a big price differential.

Though we would very much like to minimize this practice. The parallel trade is regulated by EU legislation that permits free circulation of goods within the Union. Availability of medicines due to shortages is an issue that we and other smaller member states frequently raise at the European level. There are some mechanisms that can be triggered in the event of critical shortages and serious unmet needs. We would ideally like to see more power handed to regulators to mitigate risks to public health. Obviously, we have to be in compliance with the EU's rules at all times, but we are working on identifying better solutions which can then be submitted as proposals for consideration.

Given that Latvia is a very small market, how do you ensure that you are relevant enough for pharma companies to want to come in and do business?

We do have to find ways to increase the appeal of our market so that drug developers consider it worth their while coming in and launching the best products in their portfolios. Otherwise Latvian

patients will be excluded from the therapies that they need. Convincing multinationals to go through the hassle of product launches can be a big issue for small markets like us, because the turnover and profit margins that they stand to make are lower. Our bargaining power is always going to be less than for heavyweight markets with sprawling populations that are too big to be ignored.

Unfortunately, we see many instances of medicines are being authorized simultaneously in a number of member states, but the company deciding not to follow through with a launch here. They tell us that it is a lot of work establishing local partnerships and striking deals with wholesalers and supply chains for not such a favorable return on their investment. Firstly, they launch in big population markets like Poland and Romania and only consider us when they go for a second wave of investment later on.

We want to make sure that this changes and that in-country product launches are not perceived as a burden. We are talking with the industry how we can make the system more attractive and streamlined. We are committed to reducing national barriers and complexities to launching products and to making our regulatory processes as user friendly as possible without cutting corners or becoming a ‘light touch’ regulator. In short, we want to make Latvia an easy place to do business if you are a pharma company. The hand that we have been dealt when negotiating with best-in-class pharma MNCs is not the strongest so we have to go on a charm offensive, respond to their needs and offer them a really attractive operating environment.

When you speak of becoming business friendly, what practical steps are you taking to increase Latvia’s appeal as a pharma market were there is good business to be done?

We want to simplify the application processes and dossier compilation by eliminating any unnecessary complexity or bureaucracy. Current regulations governing the placement of languages on drug packaging could be considered too cumbersome, time consuming and onerous to comply with. We shouldn’t be trying to place 14 different languages and translations on a single package. We want to make this as small of an issue as possible. Even the three Baltic member states do not constitute a large market. So we have issued waivers of translations, you can enter the Latvian market with a sticker in the Latvian language.

Then, when it comes to fees, we want to make sure there are not too many administrative fees that are very fragmented. We understand that time is money so are transitioning towards single annual fee system. As of this year or next year, we are planning to move to an annual fee that would include all variation costs and all costs related to marketing authorization. We are also thinking

about how to notify price more easily. As a marketing authorization holder in Latvia, you have to announce the price prior the launch in the Latvian market and then you have to update it every half-year.

How do you compare to the other Baltic states in terms of the time it takes to process approvals and costs?

When it comes to time, we are quite harmonized and we prioritize decentralized procedures and make sure there are no lags due to internal issues. 98 percent of the time we are in compliance with the time limits that are set on our side. We make sure the process is as smooth as possible. The costs are also similar. Costs are lower in the Baltics compared to large member states. There are some annual costs but they are comparable.

What about regulatory convergence?

There has been a lot of progress around decentralized authorization procedures. So you apply to one of the agencies and you say this will be a Baltic pack and I'd like you to authorize this in all three Baltic states and that referenced Baltic member state will make sure that it is being harmonized with Latvia, Lithuania and Estonia so you don't have to go to all Baltic states. That has been in effect since 2012. We are also sharing best practice and capacity when it comes to good manufacturing practices. Recently we had a joint inspection in one of the manufacturing companies in Latvia. The final product is being manufactured in Estonia, while the active ingredient is being manufactured in Latvia. We also have Baltic Meetings where we exchange views on topical issues like implementation of new regulations, efficiency gains, GCP inspections, etc. We also compile statistics every three years. Much of this is common sense. There is a great deal of sense in working in concert with our peers in the other Baltic markets so that we are all deploying our resources in the most efficient manner possible.

As the science is moving more towards biologics, regulatory agencies are really being pushed to the limit. How are you dealing with these changes in terms of enhancing your capabilities?

You also have combined products, where the lines are even more blurred. The efficiency gains definitely do not relate to development. We have doubled our budget for personnel skills development. This is a key part of our strategy for the next three years. We are also planning to strengthen our capacity with biological medicinal products in the coming years. We have been cooperating with other member states. I hope to find synergies in the future with medical device clinical trials.

How many people are working at the agency?

We have 138 employees here. We will have to strengthen our capacity because of Brexit, biologic, new regulation for clinical trials and medical devices. . We will also look for more capacity outside the agency. Part of the expertise will have to be sought with external exerts. We are increasing our cooperation with the University of Latvia and they are coming to the agency to see how medical assessments are being done. We are also doing some training exchanges. This sort of strategic outsourcing enables us to achieve more with less. These are the types of ways that we can carry out our functions much smarter.

We've heard that the Baltics have a good base for clinical trials in terms of expertise. You play a big part in that. What are you doing to help nourish that?

With the clinical trials, you're right. We are happy about this. Our clinical trials unit is the best-rated unit by customers. We need to keep it that way.

What do you see as emerging trends in terms of exports, generics and innovative products?

Last year, the market was almost 400m euros, in terms of value, it increased last year by 6 percent and the year before by 11 percent. In 2015 it grew by 5 percent. In terms of volume, the increase is around 1 percent. Basically most increases are due to more medicines on the state reimbursement list. OTC medicines make up around 18-19 percent and the share of generics is pretty large at 75 percent in terms of volume, while in terms of value they represent 43 percent. In medical devices, we do not compile many concrete statistics.

We've been seeing a lot of reform process underway, the latest has been the government's health financing law with a EUR100m injection into public health. How does this impact the agency, if at all?

Yes, the injection will be the largest we have seen until now and it is projected to bring benefits not only to patients in terms of quality, timeliness and completeness of care but also to healthcare professionals in terms of salaries.

As an agency, which tasks do you perform best, and where do you identify that there is still room for progress?

We had a benchmarking of European medicines agencies last year, overall it was better than 3 years ago. What was highlighted as our strength was pharmacovigilance. We have enthusiastic experts that are, inter alia, looking into effects of the strategies that we are pursuing of the effects

of risk minimization measures. Also pharmacovigilance inspections planning is well appreciated. When it comes to procedures we have increased our presence at the EMA comities, especially in the last year. We increased our share of procedures by 20 percent. We have also a very active member in the pediatric working party. In terms of improvements, we need to improve our expertise and become involved in biological medicines at the EMA. I also hope one of strengths could be combined products, but we will see.

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