Interview: Darius Sinkevičius – Chairman of the Board, Lithuanian Association of Generic Pharmaceuticals Manufacturers (VGA)

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Darius Sinkevičius, chairman of the board at the Lithuanian Association of Generic Pharmaceuticals Manufacturers (VGA),

explains the main trends impacting the generic pharmaceutical industry in the country as well as the role of off-patent medicines in creating savings for the Lithuanian healthcare system.

Can you give to our international audience an idea of the importance of the Lithuanian Association of Generic Pharmaceuticals Manufacturers (VGA)?

The VGA is the leading association of generic manufacturers in Lithuania and it acts as the active voice of its nearly 20 members in the country, which are the leading generic players in the market.

The Lithuanian pharmaceutical sector has been passing through several regulatory changes over the last years and our main priority as an association is to ensure that the final regulations implemented that affect off-patent drugs are in favour of the Lithuanian patients as well as our members. Having said that, one of our main current concerns is to find the right balance in which pharmaceutical generic producers can sustainably market their solutions in Lithuania and the government can afford them.

Can you expand on the role of generic medicines in the Lithuanian healthcare system and their market penetration?

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Despite the fact that the National Health Insurance Fund (NHIF) has been steadily growing over recent years, it is a reality that innovative treatments are coming to the Lithuanian market and that situation creates a high pressure on prices of generic products. In such a frame, the savings generated by off-patent drugs are one of the key sources of economic power that enable the government to allocate more resources on the entrance of new molecules in the reimbursement list. Therefore, the importance of generics producers for the government is quite relevant since they are not just giving access to high quality treatments but also driving the savings of the government to re-invest in either reimbursing new molecules or reducing co-payment for the patient. Government has to be aware about price erosion of generic medicines as to high price erosion might create growth of prices in the future due to decreasing number of players on the market.

Presently, the penetration of generics in Lithuania is quite high in comparison to the rest of European countries; representing approximately 70 percent of the volume and 30 percent of the value.

After the big crisis in Lithuania back in 2009, the pharmaceutical sector has been steadily recovering; growing by around 5.5 percent in 2017 and expected to grow by 6.6 percent in 2018. Concretely, can you share an overview of how the generics' segment has performed over recent years?

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As you pinpoint, the overall performance of the pharmaceutical sector has been positive over the course of the last few years, being one of the best performing areas amongst the Lithuanian economy. Nevertheless, the performance of the generic industry in terms of value has not been that great as a consequence of the high-pressure on off-patent drugs prices to reduce the cost of the government as well as the patients' co payment.

In fact, by law, generic prices have to be at least 50 percent lower than the originator's ones in order to enter the market. Furthermore, in July 2017, the government approved a law for off patent drugs in which these medicines are not able to have a price 10 percent higher than average of the lowest one in 8 reference countries.

This situation creates a challenging context in which VGA's members have to navigate in Lithuania and, therefore, generics have not been performing as satisfactorily as the innovative side of the pharmaceutical industry in terms of sales. Additionally, the high regulatory dynamism for generic medicines' pricing has posed an added challenge in terms of uncertainty because companies are not able to conduct accurate business forecasting.

What is your assessment of patients' access to high quality treatments in Lithuania?

It bears mentioning that Lithuania has good level of inclusion of new chemical entities into the reimbursement list and, indeed, around 50 new products have been recently included over the last years. However, the inclusion of new molecules in the Positive Drugs List (PDL) has also increased the healthcare government costs creating a bigger gap that, and it is a reality, is mainly covered by generics' efforts through squeezing prices regulations.

Hence, the aforementioned defying regulatory for generics can negatively impact the availability of some off-patent drugs in the market due to the unsustainability for companies to market such medicines in a small market like Lithuania. The VGA, as the leading association for generic manufacturers, defends that reducing patients' co-payment is as much important as the availability of medicines in the market.

What discussions has the industry engaged with local authorities on these issues, and what solutions is the VGA proposing?

We are already collaborating with the Lithuanian Ministry of Health to develop some regulatory projects that will take place next year and will homogenize the regulatory standards for all industry both innovators and generics. This dialog aims to improve the overall pharmaceutical regulatory system reducing the co-payment of the patient, enhancing the transparency amongst all the pharmaceutical processes, and ensuring the sustainability of the companies in Lithuania as well as the National Health Insurance Fund (NHIF).

Expanding on one of the aforementioned goals, I would like to stress that the VGA is aligned with the government's ambition to reduce the co-payment rate for patients but this effort should be also combined with stronger commitment from other stakeholders such as the ministry of health and the innovative players. In fact, generics' efforts are proven to be not enough because, despite the savings created through off patent drugs, the co-payment is still really high in Lithuania. I believe that the government should reduce the patients' co-payment gap through dedicating more public resources to pharmaceuticals and offering the same level of reimbursement to all diseases since illnesses does not discriminate. Additionally, this should be combined with higher number of

competitors in the reimbursement list to foster companies to lower the prices.

As an example of a key topic in our dialog with the government, we are currently developing the pricing system for fix dose combinations. This type of medicine is the innovation the generic players bring to the market and create interesting breakthroughs in terms of better patients' adherence to the treatment and lower cost of treatment. However, the current pricing system for these drugs does not enable to sustainable market them in Lithuania since the price, by law, has to be the sum of the cheapest price of each ingredient and it does not matter if the producer is using all the cheapest ingredients or not. This dialogue is still in development but I believe that these drugs should have the same regulation as the innovative medicines, meaning only reference pricing, since they are unique in the market.

As a second point that the VGA is advocating, biosimilar prices by law have to be at least 30 percent lower that their originator versus the 50 percent aforementioned for chemical generics. Thus, I am delighted to share that we have already done a proposal for the government in order to use the same biosimilar pricing law for chemical generics and this should be introduced by 2018. This will increase the number of competitors in the market and, as a consequence of the increasing number of competitors, the price will be subsequently lowered.

What will be the association's goals in the coming years?

Firstly, my main objective is to develop the regulations that will allow having as much competitors as possible on the reimbursement list, which will enlarge the availability of off-patent drugs in the market and will subsequently reduce the cost of medicines for the government. Secondly, the VGA aims to drive such savings coming from off patent drugs to patients' benefit in terms of reducing co-payment, which needs to be combined with stronger efforts from both government and innovative players. And, finally, one of the main priorities as chairman of the association is to advance towards a solid pricing regulation for the so-called fixed dose combinations.

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