Interview: Leonas KalÄ?tinas â?? Executive Director, Lithuanian Innovative Pharmaceutical Industry Association (IFPA)

â??The market of clinical research is quite small in Lithuania, but the research-based players are being quite active in this front with clinical trial investments at approximately EUR 35 million.â?•

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Leonas KalÄ?tinas, executive director at the Lithuanian Innovative Pharmaceutical Industry Association (IFPA), explains the main dynamics impacting the innovative pharmaceutical industry in the country as well as some initiatives developed in collaboration with the national government to continue driving the Lithuanian pharmaceutical sector moving forward.

In 2014, the industry signed a â??stability agreementâ?• with authorities for the period running 2014-2017. What has been the most important result of this agreement?

This agreement was signed under a common vision between the Ministry of Health and the pharmaceutical industry about what the healthcare system in general and the innovative segment in particular should be. It was based on the best practices from Scandinavian and Western Europe countries. Indeed, in 2014, the access to innovative medicines in Lithuania was one of the worst amongst all European countries. Within this framework, we made an accurate assessment of the current situation and we defined the next steps to advance towards the European standards based on stronger commitment from both the government and the industry. Our goal is to move towards a healthcare system where the patient and their needs are the main focus.

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I would like to highlight that, as in many other countries, the main hurdle was, and still is, financial resources. Hence, we defined several industry-payers accords in which both partsâ?? priorities were respected and, subsequently, companies start to close managed entry agreements with the National Health Insurance Fund (NHIF) to market their innovative solutions in Lithuania. I am proud to confirm that we have currently more than 100 of such type of agreements and practically all of them were signed over the course of the last four years. So, the access to innovative treatments in Lithuania has been improved but I want to stress that there is still a lot to be done in this direction.

Is the current pharmacoeconomic model in Lithuania fostering the availability of innovative treatments in the market?

In my opinion, the current pharmacoeconomic model needs to be further developed, moving from purely cost criteria to an outcome-based system. Indeed, the IFPA is firmly focused on the implementation of an outcome-based system that will ensure that the innovative medicines reimbursed are certainly creating the expected value in terms of better patientsâ?? quality of life and lower cost of treatment. I strongly believe that this new approach will help the government to achieve the national healthcare goals in a sustainable but also effective way.

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On one side, the Lithuanian government is quite aligned with the development of such type of reimbursement model. But, on the other side, the country is currently lacking in health data, infrastructure and the methodology needed to implement a value-based system. The IFPA, through its members, is already collaborating with the government to help Lithuania to advance in this regard, sharing our membersâ?? expertise developed in other European and non-European countries.

How would you assess the openness of the Lithuanian government to cooperate with the industry in health matters?

I am quite satisfied with the existing collaboration between government and industry and, in this sense, the IFPA is periodically meeting with the Minister of Health in order to address all these aforementioned issues.

Indeed, we have created a working group in joint with the Ministry of Health but also other Ministries such as Education and Economy to identify and develop the best ways to attract investments for the pharmaceutical industry in general and the biotech segment in particular. In this sense, last year, we signed a resolution among stakeholders that aims to position Lithuania as a biotech center in Europe by 2020. Nevertheless, it is still just a plan because the capabilities needed are not in place yet.

Can you please share with our international readers an overview of the pharmaceutical sector in Lithuania in terms of growth and dynamics?

After the economic crisis back in 2009, the healthcare sector was as negatively affected as any other economic area in the country; in fact, the healthcare expenditure for 2008 was only matched again as recently as 2016. However, I am happy to confirm that the national healthcare budget is growing at a stronger pace than the Lithuanian GDP and the projection is that it will grow at 6.9 percent in 2018.

Additionally, from the regulatory standpoint, I am delighted to share that our Minister of Health prepared the National Medicine Guidelines that were approved on August 2017. These national guidelines are highly needed since Lithuania has not had any National Medicines Policy over the last 20 years. This guideline aims to achieve the sustainability of the public health fund, the decrease of

genericsâ?? price â?? Lithuania has higher prices for generic medicines than the European average according to a benchmark study carried out by a third party -, the reduction of co-payment rates, among other urgent subjects. Hence, the Lithuanian Ministry of Health has done several good steps in this front in order to upgrade the national healthcare system and more changes are expected in the mid term.

What are going to be the growth drivers for the pharmaceutical industry?

The growth of the pharmaceutical value is going to be mainly driven by increasing funds of the National Health Insurance Fund (NHIF) and higher access of innovative medicines in the market to target key national health burdens such as oncology.

Clinical research is one of the main areas of investment of the innovative industry. Can you expand on the footprint of your company members in this front and how much innovative players are investing in conducting clinical trials in Lithuania?

The market of clinical research is quite small in Lithuania, but the research-based players are being quite active in this front with clinical trial investments at approximately EUR 35 million. The factors that positions Lithuania at the forefront of the Baltic region in this arena are the existing capacity of clinics as well as academia and the highly trained researchersâ?? pool.

Nevertheless, I would like to highlight that the contribution of research-based players within the research and development Lithuanian frame is not only in terms of economic value but also in terms of patientsâ?? access to innovative treatments that, otherwise, they will not have access as well as the opportunity given to Lithuanian researches to participate in global projects.

What is the final message that you would like to share with our audience?

I believe that the pharmaceutical sector will innovate the way it works at all levels from government to industry and associations; not only in terms of bringing innovative solutions but also in terms of gaining transparency and effectiveness in its operations. As I mentioned, our main goal is to achieve that in Lithuania the patient would become the center of the healthcare system, to strengthen the focus on patientsâ?? needs and improve access to innovative medicines.

The IFPA and its members are fully open to collaborate with the government to help the Lithuanian pharmaceutical sector in such modernization through sharing our expertise in key areas such as outcome-based reimbursement models and other subjects.

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