Interview: Kristina Garuoliene – Vice Minister of Health, Lithuania

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Kristina Garuoliene, vice minister at the Ministry of Health of the Republic of Lithuania, explains the cornerstones behind the new National Drug Policy approved in August 2017, the commitment of the Ministry to ensuring Lithuanian patients have

access to the latest high-quality medicines regardless of their location or spending power.

What were your initial goals, aspirations and priorities upon assuming your current position as vice minister of health last year?

My responsibilities are focused on the pharmaceutical area. It is important to mention that Lithuania was lacking a National Drug Policy in the past and, therefore, my main priority was the elaboration of a new one fully aligned with European standards. In this sense, I am delighted to share that a National Drug Policy was recently approved by our minister of health in August 2017 and should stay in place for the next decade, which will give all stakeholders a long-term view of the pharmaceutical sector in Lithuania.

One of the main objectives of this new National Drug Policy is to reduce the price ofpharmaceuticals in Lithuania since our cost of drugs is higher than the existing ones in our neighbouring countries. I believe that it will drastically improve the patients' access to medicines through not only giving savings to the National Health Insurance Fund (NHIF) but also reducing the patients' co-payment, which is one of our main priorities in the Ministry of Health.

Can you tell us a bit more on the major priorities and ambitions behind this National Drug Policy?

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The main cornerstone behind this National Drug Policy is to sustainable offer universal healthcare coverage to all Lithuanians ensuring their access to the latest as well as highest quality medicines regardless the location and the economic power.

Firstly, as aforementioned, reducing the patients' co-payments through pushing down drug prices is one of the main strategic goals behind this new policy in order to increase the patients' access to the needed medicines.

Secondly, improving the rational use as well as prescription of medicines is a key topic in this plan. There is a consumption trend in Lithuania in which pharmacists give prescription medicines to patients without an actual prescription. This can be dangerous for those patients who are purchasing a drug without a healthcare professional's support. In this sense, since 1st of November 2017, the law allows the Ministry to send mystery shoppers to the pharmacies to ensure the correct commercialization of drugs. This measure has been unpopular because now patients need to get prescriptions to be able to take the drug that they were taking without prescription in the past; nevertheless, I believe that this is needed to be in accordance with European regulation as well as to ensure that patients take the right drug.

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Thirdly, we aim to foster the use of generics in the country since some healthcare professionals and patients in the country do not believe that generic molecules are as effective as originators. In this area, we are collaborating with the industry to educate doctors and patients about the effectiveness of generic drugs; this will help the government to achieve a better sustainability of the public health funds.

How has this new National Drug Policy been perceived by healthcare stakeholders in Lithuania?

The elaboration process of this new policy was based on active roundtables with all the different healthcare stakeholders from government institutions to patients and industry associations. Obviously, it was really challenging to find common ground and there was not a full consensus in certain topics; but, overall, I am delighted to confirm that we count on the support of all the healthcare actors in the country.

The high co-payment rate of medicines by patients and the limited funds of the NHIF are common topics in the Lithuanian healthcare sector. Having said that, how would you assess patients' access to drugs?

On one side, Lithuania is one of the countries in Europe with the highest number of pharmacies per capita, which means that medicines are quite near to our patients.

However, on the other side, patients' access to medicines is somewhat limited by financial circumstances; some patients with limited economic resources do not always have access to the treatment needed. On top of that, it is important to remember that Lithuania has limited financial strength and, therefore, we are not always able to introduce the latest innovative medicines in the market. That being said, this situation has drastically improved over the course of the years since 2012 but I believe that we still have a long way to go in this regard and this topic is at the center of our National Drug Policy.

What specific actions are you putting in place in order to reverse the situation?

In Lithuania, we have the so-called "waiting list" in which there are medicines that have been already approved to be included in the reimbursement list but they are still waiting for their final inclusion depending on the availabilities of the new budget for the next year. Thus, apart from the benefits coming from the new National Drug Policy, we aim to move as much medicines as possible from the "waiting list" to the reimbursement list enlarging Lithuanian patients' access to the latest treatments.

In parallel, we are developing new reimbursement criteria to certainly choose those medicines that create value in the system in terms of better quality of life for patients and lower cost of treatment.

To develop such outcome-based schemes the country needs e-Health capabilities. What are your conclusions of the advancements of Lithuania on this front?

We have been trying to implement e-Health capabilities since 2005 but it is still far from being fully in place. However, I would like to highlight that we have made really interesting advancements in this front through e-Prescription, which already represents more than 45 percent of all the reimbursed prescription medicines.

Having said that, hospitals in Lithuania started to develop their own database of patients' registries long years ago but they are not interconnected and therefore, they represent only a limited sample of the country. Our challenge is to find the right way to create a centralized database that will interconnect all the different hospitals' e-Systems. Unfortunately, we are quite far away from

achieving this ambition due to several barriers.

The integration of pharmacoeconomic criteria in the pricing decision-making process and risk sharing models are increasingly popular as many new and very effective but also innovative treatments are being brought to market. How much importance are you giving to these trends?

We are already developing some “risk sharing” agreements with the industry in some key therapeutic areas such as oncology and hepatitis C in which we evaluate the reimbursement of the medicines according to their therapeutic value. Indeed, we are building up some patient registries to assess the real effectiveness of such medicines. However, these “risk sharing” agreements are still very limited and we invite the industry to develop such type of schemes in other more spread therapeutic areas.

What have been the latest regulatory changes in terms of pricing?

Last 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 ones in eight reference countries; it has helped us to reduce the prices of off patent drugs by 20 percent.

Looking ahead, we are discussing a new reimbursement system for innovative medicines in which our reimbursement prices will be calculated using all European countries as reference markets. Then, the final price of each patented medicine will have to be less that the average of the three countries with the lowest price; this is expected to be in place by the second quarter of 2018.

Furthermore, we are currently assessing the implementation of the so-called “generic substitution” in order to enforce patients to be treated with the cheapest generic in the market. This law will be backed up with some Key Performance Indicators (KPIs) for pharmacies in order to ensure that this measure will be properly deployed.

All the aforementioned pricing regulatory changes will not only enhance the sustainability of the NHIF but, ultimately, drastically reduce patients’ co-payments; making medicines more accessible in Lithuania.

The Lithuanian government aims to position the country as a European center for biotechnology by 2020. Why do you believe that Lithuania could hold this role and what actions is the government implementing to achieve this goal?

Lithuania has an historical legacy of biotechnology manufacturing through Biotechna, which was acquired by Teva in 2004. Due to this legacy, Lithuania has the skilled talent pool to serve the industry in this arena. Hence, I strongly believe that Lithuania has the base as well as infrastructure needed to be positioned as an attractive location for the biotech industry and the government is implementing several regulations to make the country even more attractive.

In a nutshell, what are the main objectives that you would like to accomplish in the next two years?

One of the main objectives of any governmental institution is to arrive to a system in which resources are effectively managed for the sake of the Lithuanian population in a sustainable way. From a Ministry of Health standpoint, our foremost goal is to *ensure Lithuanian patients have access to the latest as well as highest quality treatment regardless of their location or spending power. This is my main priority and I want this to be my legacy.*

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