Interview: Rūta Pumputienė – Head, Local American Working Group (LAWG), Lithuania

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Rūta Pumputienė, head of the Local American Working Group (LAWG), explains the main dynamics impacting the pharmaceutical sector in general as well as the key role of the LAWG in supporting the better access to innovative treatments.

Can you please introduce yourself to our international audience as well as the main activities and responsibilities of LAWG?

LAWG was founded back in 2013 and, since its creation, I have been heading the institution. In parallel, I am also practicing as attorney-at-law more than 13 years specializing in the pharmaceutical and life sciences fields. LAWG is a committee under the American Chamber of Commerce in Lithuania and it currently unites four innovative US pharmaceutical companies: Janssen, Amgen, Pfizer, and Abbvie.

We act as any other industry association in Lithuania through being the active voice of our members' interests. Expanding on LAWG's mission, it is divided in three main pillars: protection of patients' interests with a special focus on access to innovative medicines, promotion of foreign direct investments, and change of opinion on innovation – investment, not expenses. LAWG strategic directions are also three: first, transparency, publicity and objectivity of pharmaceutical policy and the process of medicinal products reimbursement; second – effective use & gradual

increase of country's financial resources for medicinal products with focus on innovative medicines; and third – improving the access to innovative and value-based pharmaceuticals.

After a big crisis in Lithuania back in 2009, the pharmaceutical sector has been steadily recovering; it grew around 5.5 percent in 2017 and it is expected to grow by 6.6 percent in 2018. How satisfied is the industry with this fast recovery?

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Despite the positive performance, we are not still satisfied with the overall evolution of the pharmaceutical sector in general and especially regarding access to innovative medicine in Lithuania. Indeed, it is worth mentioning that Lithuania is one of the slowest countries in Europe in terms of access to innovative drugs.

It is a fact that the government health budget has been increasing over recent years at a higher rate than GDP growth but, at the same time, lower than the pace needed due to the increasing footprint of chronic diseases and an ageing population. However, I would like to stress that this health deficit is not only a consequence of the lack of financial resources, which is a global threat, but also of the inefficient allocation of those financial resources. Besides this, there is also a huge lack of effective health budget planning (i.e. that would take into account both the needs of the patient and the situation in the market). Instead, the Ministry each year is planning to treat patients the same as the last year, meaning that without any strategic thinking, without thinking how to reallocate saved, relaxed funds in the best possible way.

The absence of a well defined state medicine policy and the lack of innovative medicines in Lithuania are common topics amongst the research-based companies in Lithuania. What are your conclusions in this regard?

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Yes, until now access to innovative medicines in Lithuania has been among the worst, whilst generic and out-of-patent medicines were among the most expensive in Europe. Moreover, in 2016 almost 50 percent of the entire healthcare budget was spent on these medicines alone. As Lithuania's population, among many others in the West, continues to decrease and age, fostering innovation in the Lithuanian healthcare system becomes a must, not a luxury. It's estimated that in 40 years' time, healthcare will cost at least two percent of average GDP, therefore policy makers need to focus on innovative treatment methods, which bring better treatment results, shorter treatment durations and greater medicine safety which later helps save funds and reduce

expenditure.

The lack of a national medicines policy has also been one of our main concerns since the Lithuanian policy makers did not have any clear vision and strategy of the pharmaceutical system in the country. Nonetheless, I am delighted to share that our Ministry of Health prepared Medicine Policy Guidelines that were approved on August 2017 – which is still a very general document with few clear objectives and tasks rather than simply declarations, but it is certainly a progress that deserves recognition.

What have been the most significant market and regulatory changes affecting the pharmaceutical industry in general over the last few years?

The Ministry of Health's declared objectives are targeted towards the sustainability of the public health fund, a decrease in the use of generics and off-patent medicines, the reduction of co-payment for reimbursable medicines rates, among other urgent subjects. Hence, all the regulatory changes have been in this direction.

In this sense, in July 2017, the government approved an amendment of the legal act for reimbursable generic and off-patent drugs in which these medicines are not able to have a price 10 percent higher than the lowest one in the reference countries. The aim of this measure was not only to reduce the co-payment rate but also to stimulate a price competition among the manufacturers of these generics and off-patent drugs which may, accordingly, reduce costs for such reimbursable drugs of the government.

Looking to future regulatory changes that may impact the innovative players, the Ministry of health is considering expanding the scope of the current eight reference countries to all Europe in order to compare prices that are being declared here in Lithuania with the lowest prices (namely – with 3 lowest) in Europe. Furthermore, the government is planning to introduce maximum patient co-payments for reimbursable medicines. In the near future, and this is only for generic and off-patent drugs, the government is also assessing the possibility of introducing the so-called "cheapest generic substitution" requirement for pharmacies, though only in the amount of 50 percent of their total sales, in which the government will only reimburse the medicines with the lowest price in the market. Other developments include a desire to reduce the preferential VAT tariff on uncompensated non-reimbursable medicines.

All the aforementioned regulatory changes are, as the Ministry declares, for the Lithuanian patients' sake. The government is indeed highly committed to minimize the patients' co-payment rate of pharmaceuticals in order to make drugs more accessible and enhance the Lithuanians' life

quality. And this is worth to admit as a huge plus for our Ministry of Health. Therefore, even though some regulatory initiatives still need further assessment, and, in our opinion, there could be more effective/additional initiatives that may help the government to effectively as well as efficiently manage its healthcare budget, we do hope that the Ministry wouldn't hold back with these plans as the governing units before them have done.

You represent some of the most important innovative players such as Pfizer, Amgen, Abbvie, and Janssen. What is the contribution of your members to the Lithuanian economy?

LAWG members are among the biggest pharma companies in the world and top investors in R&D in the world. In Lithuania, taking into account the 2007-2012 period, LAWG members created approx. 200 working places and overall invested more than 88,913 mln. EUR among which is more than 76,46 mln. EUR into clinical trials. These are indeed the huge numbers, having in mind quite small Lithuanian market.

By nature the pharmaceutical market and industry in Lithuania are and will remain very small, yet why should international companies like your members not overlook the country?

Despite the size of the Lithuanian market versus the rest of Europe, it is the largest market amongst the Baltic States – Lithuania, Latvia, and Estonia, and is usually seen as a 'leader' in all the Baltics. Hence, several multinational pharmaceutical companies use Lithuania as a gateway not only to the domestic market but also to its Baltic neighbors since all these countries are very similar in terms of healthcare regulation, system, and dynamics. Furthermore, Lithuania is globally recognized as the 16^{th} best country in the world in the 'Ease of doing business' ranking due to its progressive tax scheme, high-educated professionals, fully aligned European regulation, and others.

From a personal standpoint, you have a quite unique professional background coming from the legal world. What are the factors that triggered you to stay at the forefront of multinational innovative companies' interests in Lithuania?

My first contact with the healthcare field was by mere chance at the very early stage of my professional career in a law firm. At that time, the expertise about life sciences legal regulation in Lithuania was very under developed and, in fact, pharmaceutical and life sciences law was not even taught in the Lithuanian law universities. Thus, I quickly became really attracted by healthcare and life sciences and I decided to develop my career in this front focusing exclusively on

the life sciences sector (pharmaceuticals and biotechnology, medical devices and technologies, healthcare services), and alongside doing an international law master decree (LL.M) in Intellectual Property Law, which is an integral part of life sciences law, in London university to become a specialist in this field. Now I am an attorney-at-law with over 13 years of legal experience, working in a wide range of both cross-border and local commercial law-related projects. Considered as one of the most experienced life science law experts and leaders in the Baltic States, I have also been recognized as one of Lithuania's top life sciences legal experts by international lawyers' rankings 'Who's Who Legal' and 'Best Lawyers'.

Personally, I believe that there are a lot of things to be done regarding healthcare in general and its regulation in particular; being part of Lithuanian healthcare's progress is certainly fulfilling.

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