Interview: Dr. LÃvia Ilku â?? Director, MAGYOSZ, Hungary

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04.07.2016

Tags:

Pharma, Pharmaceuticals, MAGYOSZ, Hungary, Innovation, Regulation, regulatory Reform, Manufacturing, CMO, Interview, Insight, Exclusive, Executive, Free

Dr. LÃvia Ilku, director of Hungaryâ??s main domestic pharmaceutical manufacturersâ?? association (MAGYOSZ), describes the current priorities of its member companies and the key factors for success in Hungary; specifically innovation and complying with regulatory standards.

Given its more than 100-year legacy in the country, how has the pharmaceutical industry supported Hungaryâ??s evolution over the years in the terms of economic growth and development?

Currently, the pharmaceutical industry employs more than 14,000 people in Hungary and produces approximately five percent of the nationâ??s GDP, with our members exporting roughly HUF 900 (USD 3.26) billion worth of products each year.

From an investment standpoint, pharmaceutical companies are investing approximately HUF 80 billion (USD 290 million) on an annual basis, on top of the HUF 70 billion (USD 250 million) thatâ??s being invested in R&D.

These figures alone demonstrate the impact and significance that the pharma industry has on the countryâ??s socioeconomic evolution. Our priorities at MAGYOSZ center first and foremost on advocating for an environment that maintains or even grows these contributions to ultimately extend the industryâ??s longstanding history within Hungary. The other priority focuses on educating government and community stakeholders on the value of innovation, specifically with respect to R&Dâ??in turn encouraging the widespread introduction and adoption of more added-value

medicines.

How can the government better recognize the value of these contributions?

The role of supporting authorities can definitely be strengthened.

But, I believe we are certainly heading in the right direction. Weâ??re about to establish a strategic agreement with the government, and if successful, it will indicate the governmentâ??s commitment to the development of this industry.

Under this agreement, decision makers will cooperate more strongly, particularly on a legal level, with all the strategic partners involved. This will entail, for example, invoking industry participation through more public tenders. This collaborative effort will also extend to a more transparent and stakeholder-inclusive determination of the drug budget, which in recent years has experienced consistent declines.

There have already been two negotiations. The attitude from the governmentâ??s side and the associationâ??s side is very positive, and weâ??re now in the final stages of confirming the details.

We see that the industry has undergone several structural reforms recently, including the cost-containment measures introduced under the SzÃ©ll KÃ¡lmÃ¡n Plan in 2011. How have these changes translated into some of the primary challenges that your member companies are facing today?

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This plan of course had widespread repercussions on the pharmaceutical industry here in Hungary. Approximately HUF 60 billion (USD 220 million) was cut from the drug budget, which corresponded to a 30 percent cut in pharmaceutical spending, materially limiting the industryâ??s growth prospects. Additionally, several new taxes specifically targeted at pharmaceutical companies were introduced including a surge in sales representative fees to USD 50,000 and an increase in sales tax on reimbursed products from 12 to 20 percentâ??coupled with a clawback after budget overspending.

What was also particularly detrimental was the implementation of the blind bidding system for new products entering the market, which effectively created downward spiral on the average prices of generics. Many companies had to implement cost-cutting initiatives to stay competitive and truly come to terms with a new reality. Only those companies who turned to innovation are the ones who have come out the other side in a stronger position.

These circumstances were compounded by two other externalities. This first was the Russia-Ukraine conflictâ??two major export markets for domestic manufacturers, which negatively impacted the industryâ??s revenue prospects. The other externality was the result of increased administrative requirementsâ??pharmacovigilance in particularâ??in line with EU standards and adequately managing the added compliance burden for companies.

It seems the level of uncertainty is perhaps the only constant in this market. How does MAGYOSZ help its member companies cope with this uncertainty?

Weâ??ve actually been living with this environment since 2007.

As such, weâ??re focusing a lot of our efforts on the changing regulatory environment from a European and Hungarian perspective. There are new safety requirements for prescription drugs

which will be challenging to adhere to, and weâ??re proactively preparing our member companies for these changes. Every box of medicine will require disclosure of these safety features, and there must be a more centralized database to store this type of information for patients to reference. Itâ??s a huge challenge to manage this amount of data, as every player across the pharmaceutical and broader healthcare value chain can both input and access this data.

All of our member companies are required not only to manage the administration side of this process, but comply with these safety features, which can incur costs upwards of HUF 5 billion in the first year. And these are only the known cost elementsâ??there could be many indirect underlying costs.

With respect to budgets, we can conclude that thereâ??s no individualized planning process for the drug budget. Itâ??s always a function of the national budget. There needs to be a separate budgeting procedure that incorporates the needs of the community and industry, while also factoring in future growth and development to truly bring about more stability and predictability. Furthermore, regarding instances where spending exceeds the planned budget, the degree of clawback should be directly calculated as a function of a specific companyâ??s revenues to produce a more equitable tradeoff, as opposed to a flat-rate levy taken across the board.

In line with the governmentâ??s aim to streamline back channels within state-run agencies, the National Health Insurance Fund (OEP) will soon be integrated within the Ministry of Human Capacities. How will this transition conceivably impact that way that companies approach product reimbursement in Hungary?

At this stage, no one is really sure how exactly the decision processes will change. But, speaking on behalf of the industry, companies are most concerned with changes regarding two major tasks: invoicing and financing; the latter of which is more along the lines of our advocacy initiatives at MAGYOSZ.

Until now, OEP has worked as a separate regulatory authority, and now with this impending integration, the organization will work as part of the Ministry. Why the OEP is being solely integrated into the Ministry of Human Capacities is quite unclear, as in terms of financing, the Ministry of National Economy might be a more suitable destination. But these are discussions that we hope to receive more clarity around in the coming months as the integration progresses.

What are some words of advice you would give pharmaceutical companies entering Hungary for the first time looking to generate commercial success?

First and foremost, I would definitely advise them to become members of MAGYOSZ, or any of the other associations, as we offer many services that can help companies effectively set up and run a new business in Hungaryâ??especially considering the level of professional ties that we have within both the government and business community.

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But, even before coming to Hungary, I would advise them to carefully assess the Hungarian market, the demand trends, consumer (or commercial) behavior, and then structure their product offerings accordingly. And this recommendation extends beyond just pharmaceuticals, encompassing the entire healthcare and life sciences sector. Furthermore, itâ??s imperative that businesses understand the complexities and nuances associated with the regulatory environment before formulating merchandising or commercial strategies, as Hungary is quite strict compared to other European countries. An inadequate understanding of regulatory processes can result in hefty fines, delays, or even complete disruptions to operations.

Furthermore, there are many cost elements, which are unique to the Hungarian market, spanning areas such as labor, taxes, back offices, logistics, and infrastructure. Prospective companies need to incorporate these extra cost elements into their revenue forecasts to maintain an accurate depiction of business prospects.

Having led the organization for exactly five years now, what would you highlight as your proudest achievements?

These past five years have been very successful. Weâ??ve managed to create a more sustainable and competitive operating environment for our member companies. Thereâ??s been a lot of background work, especially in further establishing productive working relationships with government stakeholders, as well as our member companies.

The other important aspect is on the educational side. The association conducts comprehensive training sessions with our member companies regarding topics such as pharmacovigilance and safety features. We also partner with universities to provide training sessions with students and prospective industry professionals on an undergraduate and post-graduate level.

Another notable achievement is the unprecedented level of cooperation between the three other main associations in Hungary: Association of Innovative Manufacturers (AIPM), Hungarian Biotechnology Association (HBA), and Generikus EgyesuÌ?let. We have achieved a formidable level of lobbying power and influence when advocating for industry issues and there are currently several platforms where weâ??ve actively working together to improve, and weâ??re looking forward to continuing this unique collaboration moving forward.

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