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Companies choose to invest in an environment that can ensure stability and predictability and that provides fair public policy

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Iulia Arif-Percă executive director of the Local American Working Group (LAWG), shares her insights on the launched initiatives to finding new funding alternatives that will increase Romanian patient

s' access to innovative medicines. She highlights the constraining environment in which innovative companies operate in, and how LAWG's work contributes to the progress. Furthermore, she reveals the association's outlook for the future while identifying biotechnology as an opportunity for growth.

Could you introduce yourself and share some of the initiatives that you have launched in the last two years?

Local American Working Group (LAWG) is the Romanian association representing the leading American innovative and biopharmaceutical companies or with production facilities in the US, dedicated to promoting public access to innovative medicines. The association was established ten years ago in collaboration with Pharmaceutical Research and Manufacturers of America (PhRMA). We also have good communication with the USA Embassy in Bucharest.

At present, LAWG comprises 14 member companies that represent approximately 40 percent of the Romanian pharmaceutical market.

LAWG covers a large range of topics: innovation, biotechnology, healthcare financing and the modern development of the healthcare system through continuous dialogue with the Romanian authorities and key stakeholders.

In the last few years, we have been an active part in very interesting and strategic projects. We established the first cooperation and dialogue technical platform, “Resources for Healthcare”, in partnership with the Health Commissions of the Romanian Parliament and with the participation of the Romanian Presidency. The platform aims to increase healthcare financing and allocation for medicines in Romania. It joins over 30 stakeholders from patient associations, academia, health and finance authorities, local technical experts, the innovative pharmaceutical industry and private insurers.

Could you explain how the Local American Working Group goes about to ensure the interests of its members are safeguarded?

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Building on these premises, it is important for Romania to work on correcting several market access barriers such as delays in the reimbursement process, a pricing system that is over-regulated and based on the minimum European price, the under-financing of the medicines budget and also limiting the non-predictable clawback tax.

Through LAWG’s most recent collaboration with *The Economist Intelligence Unit* (EIU), we looked at alternatives to enlarge financing for healthcare and medicines, to improve access for patients to innovation in Romania. The EIU assessment of the best-practices from 11 European countries has revealed that Romania should consider all four pillars of the healthcare funding: increased government allocations, compulsory health insurance, voluntary health insurance and out of pocket spending.

How significant are the partnerships between the industry and the Romanian government?

Cooperation and open dialogue between stakeholders has always been the main drivers of progress for the Romanian healthcare sector.

The clawback tax challenge is a clear example of where the industry and public authorities are merging their efforts. The industry is part of an Inter-Ministerial Working Group—collaborating alongside finance and healthcare authorities—focused on the implementation of a capped and differentiated clawback formula, meant to limit the withdrawal of medicines from the Romanian market.

The tax was introduced in 2010 and it refers to the obligation of producers to pay quarterly the excess between the medicines' budget and total expenditure on pharmaceuticals. As the budget has been frozen for several years, with a few minor adjustments, the tax has increased significantly, and this has become a large burden on the pharmaceutical industry. Today, it exceeds 27 per cent of the companies' reimbursed sales, implying that the treatment for one in four patients is covered by the pharma industry.

At the same time, it is important to address the aspect of general financing for healthcare and medicines in Romania, as well as regular access to innovation already approved at the European level.

Now that 2019 has ended and the dust has settled, can you share the highlights for LAWG and its members?

As initiator of the multi-annual platform "Resources for Healthcare", LAWG has been an active contributor, alongside key stakeholders in three technical working groups hosted by the Romanian Parliament. Their conclusions are gathered in a comprehensive White Paper meant as a pillar for public policy development.

The first proposal that received large support was the implementation of an "Innovation Fund for Medicines" – originally in place in other European countries, like France, Italy and the UK – to cover unmet medical needs for patients in the country. This Fund is the missing link of the access to innovation in Romania, as it will be able to provide patients with the latest therapies already approved by the European Medicines Agency, otherwise inaccessible through the current reimbursement system of the country.

Also, the working group focused on finding additional sources for funding medicines and financing the Romanian healthcare system. In Romania, the budget allocated for the healthcare sector is estimated to be 5.2 percent of the country's GDP, compared to an EU average of 9.8 percent. Healthcare has been high on the political agenda in the last years and the Platform revealed an

acknowledgement on the need to update the financing for this strategic system, in order to cover the increasing needs of patients.

The European Commission estimates that the Romanian GDP growth in 2020 will be around 3.6 percent – the largest in the region. This economic development should be aligned with growth in healthcare allocation and expenditure.

Other topics that the Platform's Working Groups have covered include value-based healthcare. Romania is already using value in the decisions regarding reimbursement of new medicines and in contracting some of the therapies. However, on average there is a delay of 850 days from marketing authorization until reimbursement of new medicines in Romania, an important aspect that needs further work such as corrections to the reimbursement system's timelines, the development of Patient Registries and the use of Real-World Data (RWD) in the decision-making process.

What are some of the advantages and challenges of doing business in Romania for pharmaceutical companies?

Considering the increased development and availability of new health technologies, the growing prevalence of long-term chronic disease and the ageing population, it is increasingly important for Romania to invest in healthcare.

Nonetheless, corrections still need to be done to the reimbursement process. Currently, Romania has the Health Technology Assessment (HTA) system and two types of Managed Entry Agreements (MEA), but there are still large delays when it comes to launching new medicines into the market. As mentioned, research suggests that it takes 850 days from market authorization to market access in Romania; compared to 100 to 200 days in Northern and Western Europe.

Biotechnology is another area where pharmaceutical companies invest, with half of their pipeline dedicated to the development of biologic medicines. Biological medicines are being produced for over 100 diseases. In Romania, patients' access to biologic and biosimilar medicines is increasing, which is contributing to positive outcomes for patients and the economy, in the long-term.

The clawback tax and pricing issues are big topics in the pharmaceutical industry – ones that have raised a lot of criticism. In terms of the reimbursement, can you explain how

it works here in Romania?

Innovative medicines must pass through the HTA system, and those that have a favourable response will either become part of the reimbursement list or will be negotiated on cost-volume or cost-volume-result contracts. However, there are still many technical delays during this process, such as the publication of prescription protocols, an unpredictable updating of the list of reimbursed medicines.

The development of modern solutions and policies for the healthcare system in Romania is possible with the participation of all the actors involved. There is an open dialogue and a good cooperation between the pharmaceutical industry and the public sector, with the purpose of increased reimbursement and patient access to new life-saving medicines.

How would you compare the market now to the market in 2010 when LAWG was first established in Romania?

The healthcare landscape is much different now compared to ten years ago, when LAWG was established in Romania.

In 2010, Romania was recovering from a difficult economic situation, with the support of the International Monetary Fund (IMF) and the World Bank, which contributed to the country’s economic path and diminished the budget deficit. These economic difficulties had an impact on healthcare as well.

Since then, the Romanian economy has recovered and it has taken important steps towards improving the healthcare system, such as the implementation of a clear reimbursement procedure that includes HTA and MEA. Additionally, in the last few years over 100 medicines were introduced into the Romanian market. Throughout this time, the pharmaceutical industry has been an active and reliable partner to the Romanian authorities, working together to find and implement solutions.

What are the growth drivers in the Romanian economy and which the pharmaceutical sector benefits from?

Romania needs to provide better and more innovative life-saving treatments, that are not yet covered by the reimbursement system, as many other European countries do. This can be achieved by addressing the current delays of access process and, at the same time, by introducing

an Innovation Fund for Medicines to cover the access gap from European approval until local reimbursement.

Overall, Romania is a great place to invest in. There is great untapped medical potential and patients are looking to access new, life-prolonging therapies. Moreover, the business environment in Romania encourages collaboration with Romanian authorities to work on ensuring stability, predictability and transparency.

The new therapeutic discoveries are already helping patients, subsequently reducing costs in the health system and stimulating economic growth through a healthier workforce. Therefore, investment in healthcare creates long-term benefits for the country.

Looking forward, what are LAWG's and its members' expectations with the newly appointed Ministry of Health?

LAWG is part of the Inter-Ministerial working group proposed by the health and financing authorities, that is focused on the clawback tax in the short term, with the perspective of addressing pricing legislation and healthcare financing in the long term. The concerns and hurdles are understood by the newly appointed Minister, as well as many key people in the administration. We hope that collaboration allows us to progress in the right direction by implementing a mutually beneficial agreement.

Equally important is the Parliaments' support in order to limit the clawback burden, which will result in providing increased access to innovation for patients while considering the current budget constraints.

At the same time, we are confident that the Medicines Agency, who is now undergoing an administrative reorganization, will reach a solid structure that will accelerate HTA and clinical studies.

Mrs Percă what are your objectives and priorities for 2020?

2020 is actually a very important milestone for LAWG, as it marks 10 years of partnership and promoting innovation in Romania.

Romanian patients demand access to medical treatments and medical services like their European counterparts. Our priorities for 2020 involve the proposal of a functional framework for the Innovation Fund for Medicines, to support the patients' unmet medical needs and reduce the risks of avoidable deaths in the light of current medical knowledge. The recent Report of the European Commission, State of Health, has highlighted that Romanians live on average 6 years less than the rest of EU citizens, a concerning aspect that must be addressed.

Besides, we want to raise awareness on biotechnology in Romania. LAWG has contributed to including Romania among the 16 European countries that mark the annual "European Biotech Week" by partnering with EuropaBio. Biotechnology is part of the daily medical life, whereas the diverse treatment needs of patients have demonstrated the necessity to increase the availability and variety of biological products. Especially by including in the reimbursement system new biologics, already existing in other European states.

What lasting message would you like to convey to the readers of PharmaBoardroom?

Investment in healthcare has proven to ensure the long-term wellbeing of the population, while benefiting the economic growth of the country, as a result of having a healthier workforce. Therefore, increased healthcare financing has to be a priority for Romania in 2020 and the following years.

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