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EU markets have an adoption rate of 50 to 90 per cent for biosimilars, and they are supported by EMA. Romania must follow suit if it wants to improve access and optimize its budget.

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Valentina BÄ?icuianu and Adrian Grecu of the APMGR, share their insights on the deteriorating environment for generics in Romania, with unfavourable pricing methodology and a rising and an unpredictable clawback tax. They reveal the solutions that the generics industry has proposed to authorities and outline their continued endeavours to convince the government to become a strategic partner in helping to amend the current situation

What major trends are currently shaping the pharmaceutical industry in Romania?

Valentina BÄ?icuianu (VB): The market is affected by the unfavourable operating environment, the lack of a strategic approach, and the continuity of authoritiesâ?? mandates. This leads to a patching behaviour rather than building an entire policy from scratch in a sustainable and transparent way. This would ensure all political parties contribute to a single health strategy, benefitting all stakeholders with predictability and visibility.

The favourable operating environment has been deteriorating over the last five years ever since the healthcare budget has been frozen. Only in the last two years was it adjusted for inflation yet, it remains still insufficient to cover the increase in consumption from new molecules. Medicines are highly regulated in terms of price, availability, purchase use and cannot transfer overproduction/internal cost rises, unlike consumer goods industries. Hence, rising operating costs and wages, inflation, in addition to a clawback tax of nearly 30 per cent, creates a hostile environment for producers. Inadvertently, they are forced to withdraw products from the market leaving patients with no alternatives. Romanian patients lose availability and access to medicines as they are either withdrawn from the market or tenders are not performed in a timely manner to ensure budget optimization.

This creates a tremendous barrier to entry for competitors and makes it increasingly difficult for our members to prioritize Romania; forcing them to decrease their investments, affecting all stakeholders in the country. It is a lost opportunity for the economy. In a favourable operating environment, investors continuously capitalize their business while the country attracts more foreign investment.

The high turnover in the administration at a state level is an issue that exacerbates these factors. The policies implemented are reactive and mostly dichotomous to the previous mandate which translates into a lack of a healthcare vision.

In 2009, the clawback tax was introduced by the government and agreed upon by the industry as a temporary measure to overcome the passing financial difficulties of the country. In time clawback has become a regular source of revenue for governments and despite economic growth, it has not been decreased or removed. This is specific to Romania and governments put generic medicines producers and production facilities under great pressure and risk.

Adrian Grecu (AG): Romania has the lowest price for medicines in the twelve referenced countries and this policy is a contradiction within the EU market. Drugs are treated like common goods that can move freely within the European Union, but at the local level, there is an imposed pricing policy specific to each country. This allows the practice of parallel trade, completely legal within the EU and even encouraged in some countries. However, the combination of the two â?? free movement with the lowest price â?? undermines the availability of medicines for Romanian patients.

The clawback tax is the deficit between the allocated drug budget and the actual consumption, which is entirely covered by the industry. Since 2015 the tax rose from 12 per cent to 26 per cent and implicitly, this means that during this period on average the net price for the producers has decreased by an additional 14 per cent.

The cost of manufacturing, salary and utilities inflation, clawback, and pan-European guidelines such as serialization are the main source of cost increase for producers. In other industries where free-market principles apply these surges are translated into price rises, but in Romania, for drugs, they are frozen. Instead, significant price erosion takes hold and generics disappear from the market.

What are the hurdles to finding and implementing solutions to these issues?

VB: There are no precedents regarding clawback in the EU. Currently, the medicines budget deficit is over 2.2 billion RON. The yearly increase in need of medicines from patients is not captured by a fixed budget, which widens the gap between real consumption and the allocated drug budget.

The clawback tax has been a good and stable source of revenue to mitigate a lack of budget management and responsibility. There is a reluctance to abandon this policy, as in the last 4 years it

has increased from 12.35 to 26.49 per cent.

AG: Currently, there is a working groupâ??comprised of industry and authority stakeholdersâ??discussing a fairer clawback policy for the entire industry, with emphasis on generic producers. One of the challenges faced by the authorities and passed financially to the industry is the backlog of innovative drugs not approved for several years. Suddenly, close to 100 new molecules are introduced without ensuring proper financing for them, causing the clawback increase.

The lack of continuity in policies is a major hurdle, combined with high turnover at government level. It leaves the industry without a long-term strategy in place and the continuous uncertainty hinders them to implement effective microeconomic policies.

What are some of the solutions that the association recommends?

VB: The main issue is the unpredictability of the clawback tax. One of the propositions would be to put a 3-year strategy in place, with a cap and gradual decrease, basically demanding the authorities to take responsibility for the drug budget management. The aim would be to reach a 10 per cent flat clawback tax for generics, while for longer-term a complete elimination.

Moreover, to optimize the budget the association has put forward various proposals and solutions to the government, inspired by other EU member states, yet they have not acted upon.

AG: In my view, it is a simple management of generic penetration versus entry of innovation combined with a minimum budget adjustment based on the realities of 2020. The association is advocating for the government to take responsibility for what is being overspent and for bringing the budget on balance through sound management and proper funding. Biosimilars and generics offer a way to optimize the budget while allowing investments to flow into the country. If the Romanian government were to unfreeze prices, even allowing small incremental raises of RON 1 -4 (USD 0.2 â?? 0.8) this would attract more competition in the generic field. The presence of more players, even at slightly higher prices, will trigger a natural price competition amongst them without increasing the cost for the authorities, while improving drug availability for the Romanian patients.

What is the current situation of generics in Romania?

VB: The discussion about affordability and accessibility has taken the stage in EU. Romania is slowly aligning to these highly important subjects with the endemic ageing of the population and the increase of cardiovascular, diabetic or oncological incidence. The most effective way to increase access is to allow generic and biosimilars medicines to enter quickly the market and speed up their uptake. This is not understood by politicians and unfortunately, there are more barriers for biosimilars than for generics. EU markets have an adoption rate of 50 to 90 per cent for biosimilars, and they are supported by EMA. Romania must follow suit if it wants to improve access and optimize its budget.

Due to the clawback tax and price erosions, more than 2,500 medicines were withdrawn from the market, some without any remaining alternative. Recently the National Agency for Medicine and Medical Devices of Romania (NAMMDR) announced an additional 700 drugs to be withdrawn.

AG: It is well known that Romania is the seventh-largest country in the European Union with almost 20 million people, hence it is relevant for any producers. Furthermore, with an ageing population and

with more informed patients caring about their health, the needs of medicine and access to treatments will only increase in the future. With the onset of social media and growing access to information, patients are increasingly raising the pressure on the government and regulatory agencies to facilitate access to innovation. Additionally, the economy is growing at one of the fastest rates within European countries. The environment is fertile for generics and biosimilars, but they need to be enabled and viewed as a strategic investment/partner by the national authorities.

How is the association supporting its members when faced with these challenges?

VB: The association has a high level of engagements with the parliament and ministries, where it puts forward its recommendations and solutions on a myriad of topics. The aim is to educate and communicate the challenges that our members are facing and use all the media outlets at our disposal to raise awareness around these issues. Our members rely on the association to be their mouthpiece on various topics with high-level healthcare stakeholders.

Some companies have the benefit of intra-community exports and outside EU, but the bulk cannot move to a different operating environment. Hence advocacy and education, remain our strongest tools to fight for a better environment.

From the perspective of the government, APMGR plays a role both as partner and investor. In Romania, 20 productions facilities some of them belong to the generic manufacturers, and ipso facto members of the association. However, the association is not considered a strategic partner despite its footprint and its ability to mitigate medicine shortages in times of crises.

How do the association and its members adapt to such an environment?

AG: It is a matter of expectation management: its members are mentally prepared that the clawback will evolve in a certain way and hence they implement optimization measures on their business. This entails either taking unsuccessful drugs off the market or reducing their investment in the country, by reducing their footprint. When the budget has been increased, there are mixed feelings as it is a far cry from what needs to be done, yet it is an incremental improvement.

What are the strategic priorities and objectives of APMGR in the foreseeable future?

VB: The ideal situation would be that the government increases its focus on attracting new investors, absorbing more EU funds, to ensure sustainable economic growth and resolving health economics. In the current situation, the aim would be to reach and engage more stakeholders on a European level through international media outlets.

AG: One of the objectives would be to convince the government that the association is a trusted and reliable partner. We understand the constraints and are willing to take a balanced, and fair, approach as APMGR would like to add their contributions. Furthermore, AMPGR wants to help in creating a more favourable environment for generic manufacturer and biosimilars. This would not only benefit the industry, the country but will ultimately cascade to the patients. However, the current government is navigating a ship through a storm without any bearings, making it impossible to have a 5-year strategy. Regardless of what happens, we must be adaptable and flexible.

Valentina, you had exposure to various industries, how has this shaped your expertise and helped with your current role?

VB: My entire career has been spent in difficult environments and highly regulated industries, and always in public affairs and communications even though I have a background in law. However, I am proud to say that in each position, I managed to make a difference which I attribute to my curiosity and my sense of drive. These elements are well suited for this position, as I am fighting for fairer treatment for the members of APMGR despite an unfavourable environment.

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