

Interview: Deyan Denev - Executive Director, Association of the Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM)



15.09.2017

Tags: [Bulgaria](#), [ARPharM](#), [Association](#), [Pharma](#), [R&D](#), [Clinical Trials](#), [Innovation](#)

Deyan Denev, Executive Director of the Association of the Research-Based Pharmaceutical Manufacturers in Bulgaria (ARPharM), shares a clear overview of the role of innovative pharmaceutical players within Bulgaria, and the association's commitment to working with government to enlarge patients' access to innovative medicines.

How has the overall situation for innovative pharmaceutical companies evolved over your time as head of the Association of the Research-Based Pharmaceutical Manufacturers (ARPharM) in Bulgaria?

Looking back in time, a lot of changes have happened in Bulgaria since it joined the European Union back in 2007 and this has also been reflected in the domestic pharmaceutical sector.

At that time, the Bulgarian nominal expenditure in healthcare was nearly 10 times lower than the European average so research-based pharmaceutical players had a lot of hurdles to successfully navigate here since innovation comes at a cost and Bulgaria was not able to pay for such products in the past.

Having said that, it is also true that the Bulgarian patients' access to innovative medicines has drastically improved over the last decade, which has positively impacted our members' operations

while the off-patent market has remained more or less steady. Even though the Bulgarian public expenditure on drugs per capita has increased from EUR 41 in 2012 to EUR 74 in 2017 (including 20 percent VAT) it is still quite low in comparison to the EU average and most European economies. However, the evolution is certainly worthy of recognition. Just to share a quick figure that demonstrates this, 15 new drugs on average have been listed in the National Health Insurance Fund (NHIF) for reimbursement annually over the last five years.

Expanding on some current market access challenges, the time between the EMA drug authorization and the entrance of such medicine into the Bulgarian reimbursement plan is really high, being up to three years. This situation is not only because of the administrative hurdles, but also because pharmaceutical players delay application or do not apply at all for listing their products on the Bulgarian reimbursement list as a consequence of the Bulgarian drug pricing model. Indeed, the Bulgarian drug pricing system consists of selecting the lowest price for prescription drugs through the reference prices in ten other European countries: France, Greece, Romania, Slovakia, Lithuania, Latvia, Portugal, Italy, Slovenia, and Spain- which ensures the minimum price in the market.

Nevertheless, innovators sometimes decide to launch certain drugs later in Bulgaria due to unattractive pharmacoeconomics, which certainly limits the patients' access to the latest treatments in the market. Fortunately, the government is fully aware of that and has made strong efforts to increase public healthcare expenditure, which has doubled from 2007 to now and is expected to continue growing in the future.

Additionally, it is worth highlighting that out-of-pocket expenditure in Bulgaria is one of the highest in Europe, being almost 50 percent of the total healthcare expenditure; this is partly because of the reimbursement model, which is structured in four different co-payment levels depending on the drug: 25 percent, 50 percent, 75 percent, and 100 percent.

[Featured_in]

Such a reimbursement gap limits patients' access and, consequently, some drug consumption trends that pose a healthcare challenge for the government have arisen. Just to share two examples, firstly, there is an increasing referral from patients to alternative medicines rather than taking the one prescribed by the doctor and, secondly, some patients have undertaken their own decision to reduce the Rx dosage because of not being able to afford such a co-payment gap.

As a consequence of the limited market access and the questionable financial sustainability of the NHIF, the government introduced the so-called clawback system in 2015. This system was a

challenging but highly needed compromise from the industry towards the government that stated that companies will compensate the public fund for a certain amount of total expenditure - This amount is generally 10 percent of the government sales, which will have to be refunded to the NHIF afterwards. As historical data since this commitment was introduced, such compensation was BGN 50 million (USD 30.3 million) in 2015 and it has increased up to BGN 90 million (USD 54.6 million) in 2016 and it is expected to reach BGN 130 million (USD 79 million) in 2017. It showcases the strong commitment of pharmaceutical companies to helping the government minimize the healthcare gap with the European average while already selling their drugs in Bulgaria at the lowest price.

Expanding on that point, what is the main contribution of research-based companies to the Bulgarian healthcare eco-system?

I would like to structure this question in three main areas: product availability, market access compromise, and clinical research development.

Firstly, the medicines that research-based companies bring to Bulgaria are the most modern achievements in medical science and create unquestionable breakthroughs in terms of patients' quality of life. Established therapies have a really important role in providing wide access to treatment. However, there are still significant health challenges in a number of areas such as oncology, diabetes, respiratory, rheumatology and so on that need more sophisticated solutions that only innovators can provide.

Secondly, as commented before, the pharmaceutical industry is forced to pay back to the NHIF around 10 percent of their governmental sales in order to help improve the patients' access to medicines - This is translated of a forecasted economic value BGN 130 million (USD 79 million) in 2017.

The out of the pocket expenditure in Bulgaria is really high, mainly due to the aforementioned four levels of public reimbursement that obliges patients to pay certain amounts of their medicines. Therefore, companies are trying to compensate such a gap through different co-payment decrease programs with the patient in order to, again, make the medicine more affordable. These co-payment decrease programs, which are separate from the clawback system, are an extra effort for the industry valued at BGN 60 million (USD 25.2 million) in 2017.

Thirdly, clinical trials are a key area of investment from research-based companies, being valued at USD 350 million of investments in Bulgaria in 2015. Indeed, Bulgaria is ranked as one of the countries with the highest number of clinical trials considering its market size. Nonetheless, and

besides its economic value, such investments contribute to the system in other ways such as medical education, opportunity to physicians to collaborate in global scale projects, patients' access to innovative treatments, and others.

[related_story]

Prices that reflect the value of innovation and quicker market access are the main concerns of associations such as ARPharM. Could you please comment on advancements that have been made in both areas?

Bulgarian public expenditure on pharmaceuticals has been drastically growing over the last years; especially since 2012 it has increased at a pace of 14 percent on an annual basis. It is certainly a positive sign that shows the commitment of the government towards bringing innovative and high-quality medicines to the Bulgarian patients, but there is still a long way to go in terms of market access and reaching EU averages.

However, such public healthcare expenditure growth creates strong concerns about the financial sustainability of the model and it results in tough cost containment measures that make access to innovation more difficult.

Looking at numbers that demonstrate this assumption, around 40 percent of the products that have marketing authorizations issued by EMA get in the Bulgarian reimbursement program. As said at the beginning, this is not only because such drugs are rejected by the Bulgarian public system but rather because the industry does not apply to enter to the NHIF due to its high-pressing cost containment measures such as referral prices and the claw back system for instance.

What kinds of discussions has the industry engaged in with local authorities in order to find a better drug-pricing model?

I believe that the current pricing and reimbursement model for medicines that enter the NHIF needs to be optimised. Hence, we are in constant discussion with our authorities and with our industry members in order to define, develop, and implement a better and more balanced drug-pricing model.

We, as an industry association, fully recognize the affordability challenge that our government is facing in this regard and we are willing to help them to decrease the financial budgeting impact of new molecules in the national health fund. But, I believe that the government has to find other ways, not just putting pressure on the industry, in order to increase public investment in pharmaceutical treatment as well as improve efficiency, for example through implementation of

Ehealth – which is already a governmental focus.

In a nutshell, I am happy to confirm that the collaboration between industry and government is quite fruitful. We have the duty to help the country to achieve the national health goals while, at the same time, the government needs to improve efficiency and commit more healthcare investment to meet the growing patients' needs and achieve better health outcomes.

What are the factors that positions Bulgaria as an attractive place for the pharma research-based' community?

All countries in Eastern Europe share more or less the same healthcare legacy due to historical roots. In fact, you can see a common trend amongst them moving from high generics' penetration to also including innovators to treat the existing unmet medical needs.

There are several challenges in Bulgaria but I feel confident in confirming that the opportunities surpass any hurdle – in fact, this attractiveness has already been identified by pharmaceutical multinationals, both innovators and generic companies, which own 90 percent of the market. The increasing consciousness of the government towards improving access to healthcare and in particular to innovative pharmaceutical treatment, is what has led to the growth of innovators in Bulgaria. The drive to improve not only access, but healthcare outcomes, is both the challenge and the opportunity which lies ahead for the R&D pharmaceutical industry.

[See more interviews](#)