Interview: Gergana Semova - GM; Petko Konakchiev

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Gergana Semova and Petko Konakchiev, founders of PharmDedict, share an overview of the Bulgarian regulatory dynamism, the reasons why healthcare companies should continue investing in the country, and explain why PharmDedict is not only a service provider, but also a solutions provider.

After having worked for several years in the pharma industry, what are the needs that you identified in Bulgaria and the points that triggered you to start your entrepreneurial journey with PharmDedict back in 2007?

> *"We became a member of the EuDRAcon in 2010 and this partnership has given us the opportunity to participate in pan-European projects in joint with its network members."*

In 2007 there were not many specialized firms offering regulatory and consultancy services in Bulgaria. On one side, domestic and international pharmaceutical companies already established in Bulgaria were mostly managing their regulatory activities in-house. On the other side, in the same period, foreign pharmaceutical companies that were planning to enter the Bulgarian market mainly relied on their local distributor to manage their regulatory activities in the country.

So, by that time, we had already gained some experience in the regulatory area and we sensed that there was potential to explore on this front. On one side, distributors' core business is distribution and sales while regulatory is out of their main area of expertise and, on the other side, it is not always efficient for pharmaceutical players entering the Bulgarian market to have their own local regulatory team. Hence, the rationale behind our foundation was clear: help our clients to be focused on their core while offering the best regulatory quality services independently from the distribution channel ensuring full compliance with the local regulation – which is crucial in the healthcare industry.

In less than two months PharmDedict is going to celebrate its 10-year anniversary. What is your assessment of the evolution of the company and what have been the main accomplishments since its creation?

Our company already has international recognition, which is an accomplishment in itself. We have long-term local and international clients who have trusted us since the company's inception. Furthermore, we are really proud to confirm that our clients do word of mouth of our quality services, thereby acting as our ambassadors.

From the regulatory perspective, what have been the main trends and dynamics taking place within the healthcare system in Bulgaria over the last few years?

Generally, companies entering the Bulgarian market can expect a regulatory environment fully harmonized with

the EU regulatory framework, which gives them a significant advantage in terms of predictability and ease of access. On one side, there is a constant push from the Union to achieve better harmonization between the Member States. But, on the other side, there are some areas fully reserved for the national authorities such as pricing and reimbursement.

Therefore, these two existing mainstreams, which are the EU regulations and national policies, define the regulatory environment in Bulgaria. Concretely, the Bulgarian regulatory environment is highly dynamic and, just as an example of such dynamism, the current Bulgarian Drug Law adopted in 2007 has had 23 amendments published thereafter and the Bulgarian Health Law has had 68 amendments since 2004.

Furthermore, the legislative dynamism is even more visible when looking at the national pricing institutions, whose administrative setup has changed several times since 2000. The latest add-on to the reimbursement system is the introduction of the Health Technology Assessment (HTA), which became mandatory for new INNs entering the positive drug list.

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However, there is still a lot to be done. The out-of-pocket expenditure in Bulgaria is the highest in Europe and the government has been imposing administrative measures to keep down the drugs' prices through an external reference-pricing model. This measure is intended to reduce patients' price burden without affecting the budget but there are several side effects due to this approach – it encourages parallel export and it discourages some pharma companies to place certain products on the national market. Luckily, the government acknowledged that and some measures have been taken over the last years but there is still a lot to be done.

In a nutshell, Bulgaria has a complicated system under constant development and improvement without even mentioning other areas of self-regulation such as the national verification organization in which compliance is also needed. Hence, the role of the local regulatory partners such as PharmDedict is very important to ensure smooth market entry, accurate procedure planning, lifecycle management and compliance.

PharmDedict has a broad spectrum of solutions such as business development, Regulatory Affairs, and Pharmacovigilance. What are your most demanded services and why?

Regulatory Affairs and Pharmacovigilance are the most demanded services since they are continuously ongoing activities throughout the product's lifecycle. Then, business development and market entry services are more project based but, at the same time, they are very challenging.

Considering Bulgaria's renewed attractiveness what are the key rationales that would motivate PharmaDedict's current and potential clients to further strengthen their footprint as well as investments in the country?

Firstly, the geographical location of Bulgaria is quite attractive due to its closeness to the European but also Asian, Russian and other neighbouring markets. Secondly, it is important to mention that there is political and

business stability working for predictable and increasingly harmonized with the EU regulatory framework. Thirdly, there is an attractive access to good logistic infrastructure (five pan-European corridors pass through the country), qualified and experienced healthcare personnel and, on top of that, attractive labour cost as well as taxation. Expanding on the latter, corporate income tax rate is 10 percent (the lowest in the EU), personal income tax is a flat rate of 10 percent, five percent withholding tax on dividends and liquidation quotas (zero percent for EU tax residents), and others.

Nevertheless, there are certain challenges as well. The BDA does not have yet enough capacity to act as a referent member state in DCPs/MRPs and to perform GMP inspections in third countries on a larger scale. Such type of points somehow bottlenecks the process but the Bulgarian Healthcare Institutions are making huge progresses in this respect – It certainly deserves recognition.

One of your main objectives is to drive the internationalization of the company. Indeed, PharmDedict already has some business presence in Romania. Could you expand on the advancements in the internationalization process of the company?

We became a member of the EuDRAcon in 2010 and this partnership has given us the opportunity to participate in pan-European projects in joint with its network members. At the beginning of such collaboration, PharmDedict mainly acted as subcontractor for Bulgaria and Romania under joint projects requested by our network partners. Later on, we became active initiating and managing projects on behalf of our clients by involving the support of our network partners for their domestic markets.

Expanding on our operations in Romania, we became active on this market back in 2011 with the rationale that both countries were often managed together by the Area Managers and we had to support our clients in this approach. Nonetheless, the volume of services requested in Romania started to gain weight and they have even become independent from the activities in Bulgaria. This encouraged us to upgrade our operational capacity in that market.

Looking ahead, we are targeting non-EU neighbouring Balkan markets and we have already paved our first steps in this front. From the regulatory standpoint these territories are challenging because they have several local specifics but we believe that we can overcome such challenge. It is too early to say now but, in case our initial projects in those markets are successful, we will definitely consider expanding our activities there.

What are the key competitive advantages that positions PharmDedict as the preferred partner for the industry versus any multinational consulting firm?

There is an increasing global and local competition. In the past two years, we have identified at least two multinational regulatory companies opening their offices in Bulgaria to serve not only local but also international projects.

“Conventional” competitive strengths such as quality of service are always considered by our clients but they are not always effective when competing with the multinational service providers. We believe that being part of the bigger network called EuDRAcon is a strategic pillar that enables us to compete face to face to such bigger regulatory players. We are particularly really proud of EuDRAcon since it enabled us to offer quality, flexibility, and cost-effectiveness across the different markets utilizing the transparent network-based approach.

What are your main priorities to continue driving the success of the company moving forward?

We have been successfully running this company for 10 years now. Our clients’ portfolio ranges from multinational originator and orphan companies to well-established generic manufacturers in Europe and Asia. The diversity of clients, with different type of products and business strategies, forces us to offer the best solution and this requires rich as well as diversified regulatory expertise.

Our main priority is to offer not only services but more solutions approaching our projects from many different perspectives such as regulatory, pharmacovigilance, quality, marketing. Such business approach requires good coordination with our clients letting them have all the information and analyses at hand for taking the best

decision. Our objective is to position PharmDedict at the forefront of this integral business model.