Interview: Illiana Paunova – Executive Director, Bulgarian Medicines Verification Organization (BgMVO), Bulgaria



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Illiana Paunova is the first Executive Director and one of the founders of the Bulgarian Medicines Verification Organization (BgMVO), an organization which has been set up to fight against the counterfeit medicines in the country. She explains the BgMVO's role as well as objectives within the pharmaceutical industry as the second legally incorporated organization of this type in the continent.

You decided to join the BgMVO in June 2016 after more than 23 years working in the industry in top management positions. Can you introduce the organization to our international audience and explain what triggered your decision to join at that time?

Following the 2011 European directive against falsified medicines that will become mandatory as of the 9th of February 2019, the projects of the Bulgarian Medicines Verification Organization are all about patients' safety. Indeed, after several discussions, the European Union felt the need for the industry to take a position to protect patients from falsified medicines and it was decided that all stakeholders in the supply chain should be included in this initiative.

Until 2015, I was on the board of the Bulgarian Association of Research-Based Pharmaceutical Manufacturers (ARPharM) and, as the initiative evolved and we needed to start implementing this directive, the project became more and more important to me so I chose to focus on BgMVO to

ensure the successful implementation of this law in the country. Furthermore, it is also a personal ambition since I believed that it would be great to work for patients and the industry as a whole.

It is also a complex project that requires knowledge in many different areas; from information technology to patients' safety and regulatory work. In addition, my long experience within the pharmaceutical industry both as country manager of GSK and regional director has been key as it really helps establish a strong network in the industry and to know the legislation in place for the sector. Now, it is more about my social responsibility than building my career.

What is your assessment the evolution of the institution during its first year and a half of history?

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During this period, we had to establish everything from scratch. It was very interesting to see the development of the organization. At the beginning, it was just a concept that then developed into a full project.

The main focus of our project is on the legal supply chain, especially the pharmacists and wholesalers. In this regard, our most important action is the creation of the data-matrix code, which should be printed on every single pack of medicines. It was first launched in Germany and we are going to start this pilot project in Bulgaria early 2018. It consists of putting on each pack a data-matrix code with a unique serial number that will be uploaded onto this common cloud European system. Therefore, the pack can be traced from the manufacturer to the distributor and the pharmacy. The most important stage is the pharmacist, who will need to scan the code to verify its existence and deactivate it. As a result, the pack given to the patient is certified to be an authentic medicine.

Our plan is to comply fully and effectively with the European directive. The BgMVO is actually the second organization of this kind to be legally established in Europe and we are aiming to be in the first five or six pilot countries for the project. Of course, not every company will have to participate but it gives time for our players in Bulgaria to prepare – For example, Bulgarian manufacturers like Ecopharm and Sopharma have already started along with other key multinational companies. The project advances quite well compared to our neighbours in the CEE region as we are still building our system, which is more aligned with advanced European countries.

Counterfeit medicines are a global threat, making up 30 percent of the pharmaceutical value in some developing markets; what is the magnitude of this threat in Bulgaria?

Unfortunately, we do not have country-specific data in this area so we rely on European statistics. For Europe, it is between one and four percent and we believe it is approximately the same amount in Bulgaria because our legal supply chain is quite well regulated and harmonized with the EU legislation. Concerning falsified medicines, one of the main risks in Europe is e-commerce. Indeed, only OTC products without prescription are allowed to be sold online and there is a strong regulation for Internet sellers. Therefore, we are organizing specific educational campaigns to educate patients in order for them to know that they should not go online to buy certain medicines but get their treatments from licensed pharmacies.

In May 2017, BgMVO signed an agreement with Solidsoft Reply to implement and operate the Bulgarian Medicine Verification System. Can you expand on the results obtained from this partnership?

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Another strategic decision taken by our stakeholders is to follow the European blueprint model to limit the local variations of the project, making it cheaper and more effective. We had a very heavy selection process between the three European blueprint providers, which have developed the standard tracking systems respecting the European legislation, to ensure that Bulgaria would have an easy and fully harmonised implementation compared to advanced countries like France or Germany who have more country specifics and will need to readapt their system to the directive.

What are the main challenges to successfully implementing this system?

The scope of the project is large so it will be the main challenge. It includes all 32 European countries, 2500 European pharmaceutical manufacturers, hundreds of thousands of pharmacies across Europe and more than ten billion packs per year. Just in Bulgaria, we will have to manage 200 manufacturers, 250 wholesalers, 4 000 pharmacies and 180 million packs per year.

As it gathers all five stakeholders – innovative industry, generics industry, pharmacies, wholesalers and parallel distributors – it is the most important public-private partnership at a European level so far for any industry. Therefore, it is both technically and organisationally complicated as we need various stakeholders to be aligned and work together. Luckily, collaboration is one of the strong points of Bulgaria and all stakeholders were aligned very early in the project. In 2015, all five stakeholders signed the memorandum of understanding and Bulgaria was one of the first countries to have signed an agreement like this. All stakeholders have equal right and we cooperate with the authorities. This alignment was key factor for establishing the organization in early 2016 and for the successful progress of the project. In this regard, a few weeks ago, we presented our

advancements to all members of the Healthcare Committee of the Parliament.

In the same way, we are also often collaborating with our European counterparts to exchange our expertise and key learnings. In fact, we enjoy a well positioning in the European map sharing our experience and participating in all-important European meetings. A clear reflection of such importance is that during the last 18 months we have met representatives of the European community three times in Bulgaria to discuss the project. From this perspective, I believe it is a really beneficial cooperation for the country and we can help other establish their organization as well.

What are the main objectives you would like to accomplish in the upcoming years?

The main objective is to ensure patients' safety by preventing them to buy falsified medicines reducing such risk to zero. Then, we also want to keep and reinforce this important collaboration between each stakeholder in the country – the government and the European community. Finally, I would like for people not to hear negative comments about the system and its establishment. Indeed, our main goal is for patients to understand the directive and our project and have a positive experience with our system.

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