Interview: Assena Stoimenova – Member of the Management Board, EMA; Executive Director, BDA

"Looking to the BDA's next steps, we are aiming to further expand our capabilities in conducting GMP inspections in Asia by 2017/2018."

21.09.2017

Tags: Bulgaria, BDA, EMA, Regulator, Regulatory Reform, Pricing, Europe

Assena Stoimenova, member of the management board of the European Medicines Agency (EMA) and executive director of the Bulgarian Drug Agency (BDA), explains the

Agency's evolution under her tenure as well as her commitment to ensuring that the BDA remains predictable, transparent and fair, being fully focused on safeguarding patients and society's interests.

Ms. Stoimenova, you were appointed as Executive Director of the Bulgarian Drug Agency (BDA) in July 2014. How would you assess the evolution of the institution under your tenure?

For the last three years, we have made significant progresses in establishing Bulgaria as an active partner in marketing authorizations for medicinal products in the EU as well as GMP inspections in third countries.

It is important to mention that, for quite a long period after the accession of Bulgaria to the EU, the BDA's involvement in decentralized procedures (DCP) was limited to reviewing and assessing the quality of the Bulgarian Product Information text and, in terms of Mutual Recognition Procedure (MRP) and DCP, Bulgaria was mainly concerned only as a member state. However, the BDA gradually started to voluntarily perform linguistic reviews for Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on signals for updating product information (more than 10

“PRAC Voluntary” procedures were reviewed in 2016) and Annex C’s following the outcome of Periodic Safety Update Report (PSUR) procedure and Coordination Group for Mutual Recognition and Decentralised Procedures Human (CMDh) position for non-centrally authorized medicinal products – more than 60 “Periodic Safety Update Single Assessment (PSUSA) voluntary” procedures were reviewed in 2016. Additionally, 12 Advanced Therapy Medicinal Product (ATMP) classification reports were prepared by the BDA; the first report being completed in 2014.

Therefore, our national experts started to gain experience more than three years ago in preparing peer reviews. Indeed, the first procedure set in mutual recognition that Bulgaria was involved in started in 2016 and I am happy to confirm that three more procedures followed later. In fact, for the period 2014-2017, Bulgaria was a member state in six decentralized procedures. In addition, significant efforts were put in conducting GMP inspections in third countries and, since 2014, the BDA has conducted inspections in Serbia, Turkey, Vietnam and Russia.

In a nutshell, the BDA has played a more significant role in legislative processes in recent years while, at the same time, its representatives are included in related working groups.

What are your strategies as well as priorities to build Bulgaria’s reputation as a reference country in Community procedures for Marketing Authorizations?

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The role of Bulgaria as a Reference Member State (RMS) will be further strengthened. In this regard, we have planned to increase the BDA’s capacity for 2018 in order to conduct more community marketing authorization procedures and Good Clinical Practice (GCP) inspections. Furthermore, I strongly believe that collaborating with other countries in Europe, even if they are not state members, is essential to homogenizing the regulatory standards in terms of national procedures for marketing authorization within the region.

In this regard, in 2015, the BDA signed a Memorandum of Cooperation with Medicines and Medical Devices Agency of Serbia (ALIMS) and the Agency for Medicines and Medical Devices of the Republic of Macedonia (MALMED). Such a Memorandum aims to facilitate the integration of Serbia and Macedonia within the EU medicines regulation requirements. This is a clear example that reflects the BDA’s mission to disseminate EU policies in the field of quality, safety and efficacy of medicines.

Through such collaborations, the Agencies exchange scientific and technical information mainly in the areas of market authorization of medicinal products, regulation of medical devices, clinical

trials, counterfeit medicines and quality management and benchmarking.

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Nikolay Petrov, Bulgaria's Minister of Health, explained to us the cornerstones behind the National Health Management Program 2020. As one of the leading governmental healthcare institutions, how is the BDA supporting the government in this regard?

The role of the BDA within the Program is related to the financial sustainability, fairness and effectiveness of the national healthcare system through ensuring access to quality, efficient and safe medicines for the local market. In this regard, the BDA is jointly working with other parties to introduce the Health Technology Assessment (HTA) method – which was initially launched in February 2016 and, since then, approximately 75 new International Non-proprietary Names (INNs) were submitted for HTA and 38 of those medicines received a positive opinion. Expanding on this subject, the BDA will also be involved in defining the procedure of establishing the HTA for medical devices, which is quite unique since it requires new processes for many of the MSs.

In addition, the Agency is involved in promoting the rational use of medicines amongst hospitals and pharmacies through strong engagement programs, medical education initiatives, and specific support for Drug and Therapeutic Committees at hospitals. On top of that, the BDA is actively involved in decreasing the uncontrolled use of antibiotics to target the increasing antimicrobial resistance.

What are the main trends as well as challenges impacting the Bulgarian healthcare market and what part does the BDA play among them?

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Some of the main challenges impacting the Bulgarian healthcare market are low public funding, the emigration of healthcare professionals to other countries, and the lack of a holistic approach amongst all healthcare stakeholders.

I believe that clearer focus on spending effectiveness and results-based payment systems is highly needed in Bulgaria. The country deserves a longer-term healthcare vision, which is a challenge due to frequent changes in the leadership of public administration institutions – building capacity and deploying strategies takes more time than any mandate in Bulgaria.

Having said that, it is a reality that the government health fund is facing budget constraints and, as a consequence, all public and private stakeholders have to adopt a cost-effective approach to healthcare in their operations. In my opinion, it requires proactive stakeholder collaboration, the development of e-healthcare capabilities and compliance controls, and an enhancement the pricing model, among other measures.

The role of the BDA within such a frame is, as aforementioned, about ensuring the rational use of medicines, providing data about medicines' effectiveness, handling shortages of medicines, educating medical professionals, and giving timely feedback to the system in terms of medicines' usage. Therefore, we are establishing key indicators to monitor the proper implementation of the national medicines' policy.

Moving forward, what is your vision of the Bulgarian healthcare system and what specific role will the BDA play within it?

It is a matter of fact that we are living in a continuous and fast-changing legislative environment but, at the same time, the industry needs some stability as well as predictability to grow its operations and offer fairer prices to society. Hence, in this frame of complex healthcare systems, the national regulators play a crucial role.

Referring to Bulgaria, all institutions – including the BDA – have to unify their efforts to collect and analyse accurate data in order to evaluate the cost-effectiveness of their treatments based on evidence-based medicine. This holistic shared approach will help to gain effectiveness and transparency in the system as well as minimize actual healthcare challenges such as medicines shortage and innovation delays.

What are the main objectives set for the BDA to grow its impact in the next five years?

Firstly, one of my main priorities is to build up Bulgarian expertise around the assessment of centralized products through participating in multinational teams. Gradually, I am quite convinced that the BDA will play a more active part in the community procedures related to Marketing Authorizations (MA) and inspections. Secondly, from a national perspective, I intend to expand the inspectorate's capabilities through investing in new resources and optimizing the existing ones. Thirdly, as executive director, I have the duty to ensure that the BDA will continue being a predictable, transparent and fair regulator, always fully focused on safeguarding the interest of the patients and society.

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