Interview: Tetyana Dumenko â?? Director, State Expert Center, Ministry of Health, Ukraine

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Tetyana Dumenko, director of the State Expert Center (SEC) of the Ministry of Health of Ukraine, the regulatory agency responsible for product registration, pre-clinical studies and clinical trials approval and pharmacovigilance, provides insights into some of her initial achievements since taking the position and her main strategic priorities to further enhance Ukraineâ??s healthcare ecosystem.

As an introduction, could you please define the main responsibilities of the SEC and elaborate on its role within the Ukrainian health ecosystem?

The SEC is responsible for expertise, registration, pharmacovigilance, preclinical studies, and clinical trials. In addition to these historical responsibilities, new departments have recently been formed, in conjunction with the Minister of Health, to handle the demanding task of overlooking price monitoring and the introduction of pricing and reimbursement mechanisms. In this regard, the SEC proudly stands as a key pillar of our countryâ??s healthcare ecosystem, while October 2017 will mark 25 years for our institution, providing us with a great opportunity to assess our recent achievements and clearly establish future goals.

What would you highlight as the main achievements of the SEC since your appointment in October 2016?

SECâ??s processes and activities were recently evaluated by two benchmark international organizations, the United States Agency for International Development (USAID) and the World Health Organization (WHO) and were recognized as appropriate. In this vein, being regularly audited by reputed authorities such as the European Medicine Agency (EMA) also is of the utmost importance to us, as it allows the SEC to pursue a stronger connection with the international regulatory community. Overall, the implementation of the best standards has been a key priority of our organization for several years already, and we remain committed to further harmonize our processes and practices with those of our European and international counterparts. Through the past years we have moreover been following the recommendations and perspective of the International Conference of Harmonization (ICH) â?? despite not being a member â?? and we are now preparing our own application to join.

Looking at pharmacovigilance specifically, Ukraine now proudly stands as one of the most advanced post-Soviet countries. In January 2017, we implemented guidelines that are perfectly aligned with the Module IX of Guideline on good pharmacovigilance practices (GVP). This important regulatory update notably encompasses the set up of a digital web system, which allows doctors, pharmacies, patients and even manufacturers to report adverse drug reactions on a 24/7/365 basis. The implementation of this reform has been helped by the recent appointment of 30 new experts in our pharmacovigilance department, taking the overall number to 100. The SEC now holds 475 personal in Kiev and 70 employees operating at the local level, who all collaborate with our 250 outsourced specialists focused on drug registration and clinical trial approval. Importantly, the wages of our staff, experts and other collaborators have also been increased as part of the governmentâ??s recent decision to double the minimal wages in the country.

Another critical aspect relates to the simplification of medicine registration in Ukraine. On August 08 2016, the Ukrainian Parliament approved a new law to ease the registration of pharmaceutical products already approved by competent authorities in the US, Switzerland, Japan, Australia, Canada, and the European Union. While tremendously reducing regulatory requirements and documents needed for registering these products, it also stipulates that the final decision of the Ministry of Health will be issued within only 17 business days, including a 10-business day timeline for the State Expert Center to review registration dossiers. In 2015, Ukraineâ??s Government and Parliament also approved the set up of a simplified market access for medicines that are critical for public health (cancer, orphan diseases, HIV/AIDS, tuberculosis and others).

We are convinced that the introduction of this critical regulatory update will ensure Ukrainian patients can more swiftly access a greater number of innovative medicines. As a matter of fact, 28 new medicines have already received State Expert Centerâ??s recommendations for medical use between the implementation of this reform and May 17 2017.

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What are some of your strategic priorities for 2017?

The SEC became in 2015 the first regulatory agency in Ukraine to receive ISO 9001 certification for quality management (under the 2009 standards), which was a great achievement for our organization. In June 2017, we will look to consolidate this status and gain recertification under ISOâ??s 2015 standards.

Another important goal for 2017 is to further simplify our registration processes, as we notably hold the ambitious goal to follow the example of the European Medicine Agency (EMA) and fully implement a one-off registration procedure, in place of Ukraineâ??s historical model which implied to re-register products every five years. In terms of next step, we also want to implement an electronic application form, which has already been tested, in line with our upcoming objective of having a full electronic dossier to minimize human factors that could delay the registration review.

Finally, it is paramount we can guarantee our decision process remains utterly transparent. In this regard, we can already build on the opportunity offered to applicants to obtain all information through our online database, where they can follow their dossierâ??s advancement through the use of a free of charge access key.

Ukraine undoubtedly holds a promising but relatively untapped potential for clinical trials. As director of the SEC, what do you see as the future for this critical area of Ukraineâ??s healthcare system?

Given that I initially joined the SEC as a clinical trials expert, further developing these activities in Ukraine and providing a greater number of patients with access to pioneering medical care undoubtedly stands as one of my key priorities. Our country holds undisputable advantages when it comes to clinical trials, including a large population of modern-treatment-naÃ¯ve patients, recruitment rates that are lower than those of most EU countries, as well as a very competitive cost structure and efficient clinical trialsâ?? approval procedures. Furthermore, Ukraineâ??s healthcare system boasts more than twenty years of experience in overseeing and running international clinical trials, while international sponsors can rely on our countryâ??s well-educated clinical community trained to Good Clinical Practices (GCP). In this regard, we believe we can double the number of trials currently conducted in our country, which has been steadily rising over the past years to amount to 300 ongoing trials as of May 2017.

In this endeavor, we however still need to overcome some structural hurdles. For example, we still do not hold a comprehensive clinical trial database open to both participants and investigators â?? although it would greatly contribute to raise awareness around Ukraineâ??s opportunities in this regard. We have already started working on the construct of this digital database in partnership with the European Business Association (EBA), which also helps us to better incorporate the budgeting of the building blocks for clinical trials development within SECâ??s budget. Finally, Ukraineâ??s legislative procedures prompt us to work in closer collaboration with our countryâ??s legislators to ensure Ukrainian patients can soon be part of these clinical trials.

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What are the main objectives that you want to reach under your tenure?

This stands as a very interesting question because the current situation only allows myself to have one-year contracts. This is an incredibly short period to create change and stamp my footprint in such a powerful organization such as the SEC. Having worked here for twelve years at many different positions, I however holds a deep understanding of the SECâ??s internal workings and believe this puts me in more favorable position to foster changes across the organization. In this

regard, I hope that my successor will not ruin SECâ??s achievements and rather seeks continual improvement, while tirelessly building on the critical milestones already reached by the SEC. In the grand scheme of things, I consider only a technical team should head the State Expert Center, rather than one with a political based agenda â?? although heading such an important organization can incline its director towards a certain political side.

When I commenced my journey here 12 years ago the organization was run by great management and I grew professionally learning their effective style. Unfortunately, in the past several years there have been many changes in the director position, driving many leading experts to leave the SEC or Ukraine all together. As a result, our fundamental objective is now to continuously strengthen our staff and SECâ??s technical capacity, which will be critical to ensure our organizationâ??s processes and practices remain aligned with the best international standards. Finally, I would like to stress that State Expert Center is an expert body that provides high-quality, timely and transparent assessment which ensures the quality, safe and effective medicines enter Ukrainian market.

It is crucial to highlight the eye-catching specificities of Ukraineâ??s pharmaceutical environment. For the past 15 years, the countryâ??s market has changed drastically thanks to a huge increase in demands. We hold a substantial number of domestic manufacturers that have already started dealing internationally with countries under WHO regulations while exporting their products to the most advanced pharmaceutical markets worldwide. Looking forward, the SEC will remain committed to design and implement simplified registration procedures without compromising our safety requirements, which will help in turn the Ukrainian industry and further enhance the effectiveness of our countryâ??s pharmaceutical market.

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