Interview: Dr. Natalya Gudz – Head, State Service on Medicines and Drugs Control (SMDC), Ukraine



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Dr. Natalya Gudz, head of the State Service of Ukraine on Medicines and Drugs Control (SMDC), provides her vision for the development of Ukraine's key regulatory authority and the win-win relationship she wants to bolster between the pharmaceutical and healthcare companies operating in Ukraine and SMDC's international counterparts.

You took over the helm of the SMDC in December 2016. What have been your first priorities since your appointment at the head of this key regulatory authority in Ukraine?

Prior to joining SMDC, I honed my industry expertise by working for several domestic healthcare companies operating at various parts of the industry value chain, including pharmaceutical manufacturers, a pharmacy chain, and the association gathering together the largest distribution companies in the country. My appointment as the head of the SMDC actually came as the result of a rigorous open competition procedure, marking the first time in the history of Ukraine's health sector that such a transparent selection process was implemented. As part of this selection pathway, I notably had to present my development vision for Ukraine's pharmaceutical and healthcare sectors in general and for the SMDC in particular. First and foremost, I stressed the critical need to strictly assess SMDC's rooms for improvement and modernize its operational structure and processes.

In this regard, one of my first priorities was to complete a comprehensive, in-depth audit of SMDC's central office in Kiev, which we finalized within the first few weeks of my tenure. Based on this audit's findings, we have been transforming our central office, while my second objective was to build new leadership teams – both at the central and regional levels – that would hold the technical competences and management capacities to supervise the transformation of our State Agency's processes throughout the country. To ensure only the best candidates will be ultimately selected, we implemented open competition procedures for all management positions, which also marked the first time such rigorous recruitment process was implemented across our organization.

Less than six months after my appointment, SMDC now holds talented and experienced team leaders, which have been entrusted with the mission to pursue a deeper audit of our 25 regional offices, in order to ultimately bolster greater synergies and efficiencies between our different departments. Over the last two years, Ukraine has faced serious defense and economic problems, which have drawn a large share of the government's resources – to the detriment of our healthcare sector. This scarcer access to resources has also impacted our agency, especially at the local level, and this on-going audit will help us to identify the margin of maneuver we hold to further improve SMDC's processes. In this vein, I am particularly glad to announce that this nation-wide assessment of our capacities has been progressing very rapidly, as twelve of our 25 regional offices have already been audited.

In 2016, foreign pharmaceutical products made up slightly over 25 percent of the volume of the Ukrainian retail market (in terms of units). How do you plan to further ease imports of products manufactured abroad?

Ensuring Ukrainian patients can access an increasing number of foreign, high quality products without lowering our quality standards stands as a fundamental objective of the SMDC – and we recently released several regulatory amendments that will contribute to the fulfillment of this objective. One of Ukraine's long-standing problems relates to the tricky situation where multiple importers are linked to the same batch of products: when quality problems arise, it is then extremely difficult for us to identify responsibility for these shared imports. We are now in the process to tackle this regulatory frailty, and an upcoming legislative decree will soon ensure imports can no longer be processed without known responsibility.

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After several challenging years for the industry, it now seems Ukraine's pharmaceutical market is back to robust growth. How would you describe the relationship you want to

build with international pharmaceutical companies operating in the country?

According to our projections, we indeed forecast Ukraine's pharmaceutical market will grow around 10 percent (in US dollars) in 2017. After years of instability, pharmaceutical companies are looking for clear, long-lasting rules, requirements, and controls that are acceptable to both sides. Pharmaceutical companies in Ukraine, be they local or multinational businesses, want to operate within a predictable regulatory framework that would allow them to control their operational costs, while – as a regulator – our priority is to guarantee that only high-quality products reach the Ukrainian market.

In the grand scheme of things, we need to acknowledge that the industry and the SMDC share a common interest, while we are ready to closely work with transparent, professional, and efficient companies – without forgetting that building win-win relationships would require that our own people display such attributes too. As head of the SMDC, this is exactly the message I delivered to members of the international healthcare industries at a recent high-level meeting organized by the European Business Association (EBA), Ukraine's largest industry association. Our openness to embrace an inclusive approach toward the industry has undoubtedly been warmly welcomed by EBA's healthcare committee, as – a few days after our meeting – they sent us an official letter to express their gratitude and highlight their eagerness to more closely collaborate with the SMDC.

How could a stronger SMDC foster the growth of local pharmaceutical manufacturers?

Our country can be proud of the level of development that its domestic pharmaceutical industry has already reached. Ukraine holds 117 pharmaceutical manufacturers, which is absolutely remarkable from a European standpoint. More than 30 percent these companies are GMP-certified and have been inspected by Ukrainian and international regulators, notably from very advanced European markets. Ukrainian products are already exported to more than 50 countries, while, on average, SMDC draws up around ten new export certificates a week.

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When it comes to ensure that our local industry can produce and export more high-quality products to the world, it – again – trickles down to the necessity to strengthen the stability of our institution. Let me give you an example: the SMDC was set to become PIC/S Participating Authority in 2008, but actually joined this international network only in 2011 – because of internal and political problems affecting our country. SMDC's management, structure, scope of action, and even our organization's name have significantly changed over the past two years! In order to build thriving relationships with our domestic companies and external and international partners, we need to

ensure these stakeholders work with the same interlocutors over the upcoming years, and to sign a number of bilateral documents on this occasion. A recent legislative decree has fixed SMDC's overarching structure and scope of action for the next five years, which should provide our partners with more guarantees and give us the time needed to fully deliver on our promises.

Finally, fostering international collaboration and further harmonizing our standards with other regulators is also one of our priorities. Actually, Ukraine's first steps toward this objective go back to the early 2000s: we for example implemented international inspections of GMP compliance in 2004, which now provides the SMDC with a substantial experience in this field. In terms of next steps, we recently triggered the process that should lead us to the signing of an Agreement on Conformity Assessment and Acceptance of Industrial Products (ACAA) with the European Commission within the upcoming years. In the meantime, we want to develop bilateral agreements with other countries and have already entered into such negotiations with South Korea's regulatory agency. On the other hand, Israel signed a similar ACAA with the European Commission a few years ago, and we now plan to work closely with this country's regulator to leverage the experience they hold in this process and accelerate our own development. Finally, we do not forget either the opportunity to help other countries' regulators and SMDC is particularly open to foster knowledge sharing with international partners.

What would be your final message to our international readers?

My overarching mission is to ensure SMDC becomes an evermore reliable, efficient regulatory agency, whose decision making process is evidence-backed and transparent. We have to ensure we hold the scientific and inspection capacities to provide Ukrainian patients with a greater access to safe, high-quality pharmaceutical and healthcare products. We however will not be able to reach this fundamental objective without the clear commitment of Ukraine's overall health ecosystem. In this regard, some recent industry trends are particularly promising: for example, we see that Ukrainian retailers and pharmacists are progressively heightening their quality requirements when it comes to evaluating and selecting their commercial partners and suppliers. As head of the SMDC, I welcome the wider development of this kind of industry approaches, which will automatically contribute to ramp up the qualitative improvement of Ukraine's pharmaceutical market.

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