Interview: Denis Shevchenko – Founder, PharmVarta, Ukraine



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Denis Shevchenko, founder of the NGO and charitable foundation PharmVarta, provides insights into the main initiatives of this independent, non-profit organization that has freely supplied Ukrainian patients with more than 1.5 million packs over the past 18 months, while he also highlights some critical regulatory updates that could further improve health outcomes in the country.

PharmVarta actually encompasses two different organizations under the same name: first, an NGO that operates as a policy institute, and, second, an independent charitable foundation which freely supplies highly-needed medicines to Ukrainian patients. Why did you decide to set up this organization?

I was working in Spain when tensions between Ukraine and Russia flared, at the beginning of 2014. At first, I thought that this military conflict would only last for a few weeks – but after several months, I decided to come back to my home country and to put my experience to the service of Ukrainian patients. Despite the recent economic recovery that our country has been experiencing over the past twelve months, at least half of Ukraine's 42 million inhabitants still do not have the financial means to access life-changing pharmaceutical products, while Ukraine unfortunately stands as the only country in Europe without a national health insurance program.

In 2015, a German pharmaceutical company generously provided PharmVarta with a substantial quantity of high quality medicines aimed to Ukrainian soldiers fighting in the East of the country. At that time, I thought this donation would be the first and the last that PharmVarta would ever receive. Since then, other pharmaceutical companies have however followed the way paved by the first partner and offered to freely supply our recently founded foundation with highly needed treatments.

As I just mentioned, PharmVarta initially concentrated its efforts on providing free medicines to soldiers fighting in the Donbass, but we have been rapidly expanding our scope of action. In 2017, public hospitals – mostly located in small cities where widespread poverty renders the access to high-quality medicines even more difficult – make up the largest share of our beneficiaries. As a matter of fact, we are now covering more than 100 Ukrainian cities and 23 regions throughout the country, and we count as our generous partners many local affiliates of international pharmaceutical companies implanted in Ukraine, which have all accepted to comply with PharmVarta's unique condition: medicines must be provided freely to patients. We are now covering seven therapeutic areas, including oncology, stroke, diabetes, but also medicines to treat winter viral infections. For cancer drugs for example, we are supplying regional oncology institutions, as well as Ukraine's National Cancer Institute, which takes care of patients originating from the entire country.

With less than two years in activity, we have already distributed free medicines that are worth more than UAH300 million [USD 11.4 million], amounting to more than 1.5 million packs overall. In 2016, PharmVarta moreover received the national "Charitable Ukraine-2016" award, which proves that – although we remain an independent charity – the Ukrainian government acknowledges the efficiency of our action.

What are the main challenges you face as part of the humanitarian activities of PharmVarta?

One of Ukraine's main problems still relates to the country's bureaucracy, its rigidity, and the inertia it generates – and unfortunately the situation hasn't changed much over the past years. Let me give you an example: a UK-based pharmaceutical company made to PharmVarta a substantial donation of around 115.000 packs, for which we received approval from the Ministry of Social Policy of Ukraine. Nevertheless, a very unfortunate, anecdotal administrative mistake prevented these products from completing custom clearance, and I had to struggle for three weeks before being able to correct it, whereas hundreds of Ukrainians are dying everyday of cancer. We are now waiting for a donation from AstraZeneca – 30 packs of very innovative oncology medicines aimed

to the National Cancer Institute. Again, archaic administrative processes have tremendously delayed the import of these products, which we ultimately delivered on May 16.

[Featured_in]

The Ukrainian government has recently implemented reforms to ease the import of foreign drugs. I however feel these reforms have yet to become a reality and more time will be needed for these regulatory updates to trickle down from the Ministries' offices to the operational level. In small cities, regulatory deregulation remains something that public servants have vaguely heard off, and most old procedures are still in effect. Furthermore, corruption remains a critical problem in Ukraine, and the pharmaceutical and healthcare fields have not been spared by this plague.

On the other hand, we unfortunately feel that Ukraine's Ministry of Healthcare is not particularly eager to support all organizations that strive to improve the health of our population, and the Minister's cabinet has so far essentially favored the help of international NGOs – to the detriment of local organizations such as PharmVarta.

Regarding Ukraine's regulatory framework and its improvement, what is the main area of focus of PharmaVarta's policy focused entity?

We are focused on drafting regulatory updates that we submit to Ukraine's key regulators and government officials. In this regard, we are particularly active in the distribution part of the value chain, an area that I know well as former executive director of PharmUkraine, the association gathering together Ukraine's main distributors and wholesalers.

In Ukraine, we regularly boast about our country's capacity in terms of quality control for medicines, which is supposedly aligned with the best EU standards, while we joined PIC/S inspection scheme in 2011. I however still identify significant potholes across our control procedures. In this regard, Pharmvarta recently suggested five regulatory updates to Dr. Nataliia Gudz, the head of Ukraine's State Administration on Medicines and Drugs Control (SMDC), with the idea to further refine the regulations framing pharmaceutical manufacturers, wholesalers, and importers, as well as pharmacists.

For example, SMDC experts are not authorized to inspect Ukraine's bonded warehouses *[which are customs-controlled warehouses for the retention of imported goods until the duty owed is paid, e.d.]*, as the latter is under the exclusive control of the customs. This means there is no way to guarantee medicines are stored under the right conditions, whereas current regulations allow all imported goods to be stored in these bonded warehouses for up to three years! As part of these

five proposals, we also recommended to ease the imports of pharmaceutical products that are part of humanitarian aid. Another update we highlighted relates to the opportunity to conduct laboratory analysis in the countries of origin of imported products, rather than having to put them in quarantine in Ukraine while inspectors conduct these analyses. Furthermore, we also stressed the importance to authorize the purchasing of pharmaceutical products on Internet and to combine it with a delivery system based on parcel post, as many Ukrainian villages do not hold pharmacies, rendering access to life-changing treatments particularly difficult to some patients.

Finally, PharmVarta is also advocating for the tightening of licensing conditions for wholesalers, a position I have been defending since my time at PharmUkraine. In 2014, we counted more than 600 certified wholesalers operating in the country. Nevertheless, less than ten distribution companies make up more than 90 percent of the market, which casts doubts on the real activities of the other 590 registered players. In my views, this fragmentation doesn't fit within our country's ambitions to be aligned with the most advanced markets in the world, where their distribution sectors moreover are more consolidated than in Ukraine.

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In November 2016, Ukraine's government released an ambitious four-year health reform plan that aims to transform the country's health system. Leveraging your industry expertise and the field experience you have been honing with PharmVarta, what would you consider as a priority in order to increase health outcomes in the country?

Several reforms are currently reviewed by Ukraine's Parliament. The first one aims to implement a patient-centric financing system, where the money follows the patient and not the way around. The second aims to urgently increase the wages of healthcare professionals in the public sector, including physicians. Nevertheless, after the implementation of this reform, doctors' wages would only culminate at USD 220 a month, which seems particularly low to truly tackle the rampant corruption affecting our health system. Finally, the current administrative reform that aims to build regional hospital districts is also – in my views – highly needed. From 52 million inhabitants at the time of Ukraine's independence, our country now only holds around 40 million inhabitants, which means we critically need to rationalize the size of our health infrastructure.

Without any doubt, the main issue at stake however relates to the absence of a national health insurance program in Ukraine. The government has recently allocated around USD 19 million to the set up of a reimbursement mechanism covering a certain number of medicines in three therapeutic areas (diabetes, asthma, and cardiovascular diseases). This new initiative, which has been

effective as from April 2017, stands as a promising first step toward the overarching objective to gradually implement a broader reimbursement scheme over the upcoming years.

In 2017, the State's overall budget for medicine purchasing amounts to around USD227 million overall, although these resources are spread out throughout various regional and national procurement agencies. When adding up these two budgets, I however think we should be able to ensure our citizens can benefit from a relatively satisfactory access to medicines… In reality, Ukrainian patients have to pay for almost everything, in a country where 90 percent of all medicine spending comes as out-of-pocket expenses. For inpatient care, the State allocates a substantial amount of resources to medicines purchasing but hospitals' shelves remain desperately empty. Widespread corruption deprives Ukrainian people from accessing the medical resources that the State is paying for.

In this regard, I am convinced that a reformed health system should not exclusively rely on the public sector. Private health insurers, for example, would be able to implement a more stringent level of control than our administration. At the moment the government strives to design a new health system for our country, we should seriously consider the great opportunity to allow the public system and private health insurers to coexist and to offer more health options to our citizens than solely Ukraine's public sector. Nevertheless, this hybrid option seems politically unpalatable, because the government is fully committed to design a single-payer social insurance system, while the Ukrainian Constitution stipulates that in Ukraine "healthcare is free", which – in reality – is far from being true.

Looking forward, how do you plan to develop PharmVarta's charitable activities?

We want to start recycling "obsolete" medical equipment: in some advanced European countries, medical devices and similar equipment are contractually replaced every ten years. As a result, they are still more modern than what we find in a significant number of Ukrainian health centers, hospitals and clinics – especially in the countryside. We are already liaising with hospitals in Austria, France, Italy, Denmark, Spain, and Germany to freely access replaced medical equipment, while this program will provide these devices' manufacturers with a great visibility in the Ukrainian market, which could become extremely beneficial to them once our economy will have fully recovered.

What would be your final message to our international readers?

From a business perspective, Ukraine's competitive landscape in the healthcare field is extremely appealing to ambitious international companies. Many healthcare services and products have still

to be developed and introduced onto the local market, in a country where health outcomes moreover have to be critically heightened. Furthermore, our country now offers bountiful opportunities in terms of pharmaceutical manufacturing by leveraging production costs that can withstand the comparison with these of countries such as China and India.

In the meantime, Ukraine has been moving toward the building of a new health system, which stands as crucial milestone in our country’s modern history. This historical aspect moreover provides international healthcare providers and stakeholders with the opportunity to be largely involved in the design process of our new health system. In this regard, Ukraine undoubtedly stands as a country where ambitious entrants can hope to rapidly establish themselves as market leaders. Finally, we see that the Ukrainian government is particularly eager to attract new foreign direct investments, which should ensure international companies can benefit from a particularly favorable investment environment.

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