

Interview: Dr. Volodymyr Redko - Executive Director, Association of Pharmaceutical Research and Development (APRaD), Ukraine



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Dr. Volodymyr Redko, executive director of Ukraine's Association of Pharmaceutical Research and Development (APRaD), which gathers together 15 international R&D-driven companies, provides insights into the perspective of international innovators vis-à-vis the numerous regulatory and structural reforms that are set to transform the country's health system, while highlighting the importance that innovation

should hold in the building of a heightened health capacity in the country.

When you became the executive director of APRaD in October 2014, the country's economy was facing strong headwinds and Ukraine's real GDP actually fell by 6.6 percent this year, according to the State Statistics Service of Ukraine. How did this specific context impact APRaD's activities and the operations of its members?

As part of APRaD's activities, we have been essentially concentrating our efforts on regulatory hurdles that were not provoked by the negative trends affecting our country's economy in 2014 and 2015. In this regard, some of our key areas of focus include product registration, import taxes and VAT, as well as the enhancement of the IP framework in Ukraine.

In the meantime, APRaD members indeed had to cope with contextual issues directly related to the difficult economic context hitting the country at the time, while some of these negative factors still

persist despite Ukraine's recent recovery. Currency devaluation, for example, has been strongly affecting the financial results of local affiliates [*the exchange rate of the Ukrainian hryvnia versus the US dollar decreased more than threefold between the beginning of 2014 and mid-May 2017, ed.*], while rendering innovative, foreign pharmaceutical products particularly expensive to most Ukrainians, in a country where out-of-pocket expenses make up 85 percent of all medicine spending. These difficulties led some international companies to reorganize their presence in the country and to sometimes streamline their affiliates, while economic and political instability made it extremely difficult for our members to forecast market evolution, establish realistic sales targets, and reach the sales objectives set by their regional or global headquarters.

In 2017, Ukraine's economic context has however greatly improved, as the country's economy has been back to steady growth since Q1 2016. To what extent have international innovators been benefitting from this positive trend?

In 2016, indicators clearly showed that Ukraine's economy was back to growth for the first time since 2013 while purchasing power has indeed been increasing since then. Nevertheless, the slight growth currently propelling our economy [*Ukraine's GDP is set to grow 2.5 percent in 2017 and 3.5 percent in 2018, according to the latest projections of the World Bank, ed.*] is not substantial enough to offset the deep recession that our economy experienced in 2014 and 2105 [*Ukraine's GDP dropped by 9.9 percent in 2015 after declining by 6.6 percent in 2014, ed.*]. In this regard, it is still too early to truly feel the positive impact that such modest economic growth could generate – although our economy is undoubtedly moving toward the right direction.

In the meantime, the entry into force of the Ukraine-EU Deep and Comprehensive Free Trade Agreement (DCFTA) has so far had a positive but rather limited impact, as it did not significantly contribute to easing medicine imports for international pharmaceutical companies implanted in Ukraine.

Positive trends that I would also highlight relate to the recent regulatory reforms that were announced and implemented over the past two years, aimed both at further deregulating Ukraine's pharmaceutical market and building a more satisfactory health system. In this regard, APRaD and its members acknowledge the heightened efforts of the government to tackle some of the country's main regulatory issues – although some strategic areas still need to be critically enhanced, such as IP protection, which remains a major hindrance to the development of international innovators in Ukraine.

Various regulatory reforms were indeed implemented in 2016 to further deregulate Ukraine's pharmaceutical markets and ease the registration of foreign medicines in Ukraine. What is your assessment of the impact of these recent reforms?

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In Ukraine, it always takes time for new reforms to “trickle down” from the Ministries’ offices to the experts and inspectors handling daily operations on the ground, while ambitious reforms are sometimes implemented before legal and regulatory processes are fully adapted to cope with these changes. This problem also applies to the recently implemented simplified registration procedure for foreign medicines, which stipulates that the decision of the Ministry of Healthcare now has to be issued within 17 business days for products already approved by the competent authorities in the US, the EU, Switzerland, Japan, Australia, or Canada. Conceptually speaking, this reform undoubtedly stands as a great step forward; on the ground, APRaD members however feel it has not yet become a reality. As APRaD, we are now working with relevant local and international stakeholders to further strengthen and enhance Ukraine’s processes in this regard, while the State Expert Control agency *[which performs most of the regulatory controls for the pharmaceutical industry, ed.]* still struggles to attract qualified experts because of wages that remain substantially lower than in the private sector.

Nevertheless, from a registration standpoint, it is not particularly difficult to bring innovative treatments onto the Ukrainian market – the most challenging aspect indisputably concerns these products’ sales. As mentioned earlier, 85 percent of medicine spending comes as out-of-pocket expenses. Looking at the governmental programs, pharmaceutical companies have to deal with a vast array of different procurement schemes, as the management of these products’ tenders are handled either at the regional or national level. Furthermore, as a result of regulations implemented in 2015, approximately half of the Ministry of Healthcare’s UAH 4 billion *[around USD 151 million, ed.]* drug procurement budget was transferred to the United Nations Children’s Fund (UNICEF), the United Nations Development Program (UNDP), and UK-based procurement expert Crown Agents, in an attempt to tackle corruption and rationalize public procurements.

Although this new procurement scheme has undoubtedly reduced corruption, it still displays significant technical frailties, while its implementation has also increased public tenders’ red tape tremendously. Overall, we are still rather skeptical about the positive outcomes that this outsourced, fragmented procurement system can bring. As a matter of fact, our European partners in Brussels were particularly surprised to see that our government did not choose to immediately set up an independent national procurement agency instead of transferring a large share of its

procurement budget to these NGOs and further delaying the set up of a highly-needed centralized procurement authority in Ukraine.

In the meantime, a great first step toward the introduction of a reimbursement mechanism has been recently reached: since April 1 2017, 21 International Nonproprietary Names (INNs) in three therapeutic areas (diabetes, cardiovascular diseases, and asthma) are now reimbursed. As Executive Director of APRaD, what is the association's position regarding this crucial milestone, which could soon lead to the gradual reimbursement of a greater number of products?

At first, Ukraine's Acting Minister of Healthcare Ulana Suprun and her cabinet had ruled almost all international innovators out of this program; nevertheless, after intense negotiations, we finally managed to ensure innovators' products would also be included. Overall, APRaD members do not hold a very substantial number of products covered by these 21 INNs, but we are nonetheless monitoring the advancement of this reimbursement mechanism very closely as it could stand as the basis of a more ambitious reimbursement program.

In this regard, we are closely supporting Ukraine's Ministry of Healthcare in the implementation of this new mechanism and the design of its next steps, and APRaD members are deeply committed to bringing international expertise and resources to the table, whether through our members' corporate capacities or the European Federation of Pharmaceutical Industries and Associations (EFPIA), to which APRaD has been affiliated since 2012.

Nevertheless, the current government has not been particularly eager to leverage this industry expertise, while it has so far constantly favored the contribution of international organizations such as the WHO. In this regard, we also regret that the selection process through which advisors to the government are picked remains particularly opaque. We hold similar reservations regarding the recently updated governmental list of essential medicines, which was directly inspired by WHO's Essential List of Medicines. When building this list, the government solely took into consideration the absolute cost of medicines, therefore ruling out all APRaD members' products from this list.

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How do you explain that the economic advantages procured by innovative medicines, which can reduce hospital dependence and/or palliative care for example, were not considered?

First, Ukraine doesn't hold the Health Technology Assessment (HTA) capacity to evaluate the social, economic, organizational, and ethical issues of innovative technologies.

Actually, our products' dismissal was based on the false assumption that innovative products are *inherently* expensive – without any further economic assessment of this unfortunate bias.

Nevertheless, the situation has positively evolved since this initial mistake, and the Ministry has now provided APRaD members with the opportunity to showcase the added value of our products, based on additional documentation and studies we have to produce.

In the grand scheme of things, we unfortunately see that Ukraine's population does not hold appropriate access to innovative, life-changing products. When will this situation favorably evolve? Short-term prospects are negative, and we do not know yet what to expect in the mid or long term. In the meantime, Ukraine still doesn't hold any patient registers, and the set up of these crucial tools also stands as one of the priorities of Acting Minister of Healthcare Mrs. Suprun.

At the moment many substantial reforms are under legislative review, do you feel that public stakeholders truly acknowledge the value that innovative products could bring to Ukraine's reformed health system?

As an association, we strive to be particularly active in this building process, but we unfortunately encounter substantial difficulties in conveying the critical importance of innovative products in the strengthening of our country's health capacity. As a result, APRaD is currently assembling a targeted program for key government stakeholders and KOLs which will aim to place innovation at the center of the debates. Nevertheless, such an endeavor becomes even more challenging in a country that does not hold the financial resources to fulfill basic health needs.

Nevertheless, the recent example of Gilead Sciences, which agreed to decrease the price of its product for hepatitis C treatment by twentyfold in comparison to its average price in the EU after negotiations with the government, shows that the Ministry of Healthcare is ready to engage with international innovators – and the further consolidation of such openness would clearly stand as great news. Leveraging EFPIA's expertise, APRaD has already prepared a framework agreement for negotiations between the innovative industry and the government – following the way paved by countries like Romania, Lithuania, and (through a more advanced form) Ireland. For the past two years, we have been unsuccessfully trying to reach an agreement with the successive Ministers of Healthcare about this negotiations framework. We are now closely liaising with Acting Minister Mrs. Suprun, who was appointed in July 2017, but she seems to be essentially focused on the implementation of other programs, such as enhancing drug affordability.

Looking forward, what makes you optimistic regarding both the future of innovative products in Ukraine and the development of the country's health system?

Regarding the short and mid term prospects of innovative pharmaceutical products in Ukraine, I am not optimistic at all. Nevertheless, when it comes to the upgrading of our country's healthcare standards, I am more positive: promising steps have already been taken and some important reforms have been implemented, including crucial areas such as healthcare financing and optimized resources allocation. We also see very positive reforms when it comes to the optimization of government procurement, and we can hope the overall process will become even smoother with the set up of a State agency for medicine purchasing, which is planned for 2019.

Overall, many positive trends make me believe that health levels in Ukraine will improve over the upcoming years. We however still do not know at which pace this situation will improve and if the government will ultimately hold the resources needed to complete a truly ambitious health reform, as it will highly depend on our country's capacity to renew with strong economic growth.

What would be your final message for our international readers?

In the coming years, Ukraine will definitely stand as an extremely appealing investment destination for international pharmaceutical companies, while the value of our people, the really high level of education and expertise of our physicians and industry professionals will undoubtedly contribute to further bolster our country's attractiveness. In Ukraine, international innovators are well implanted and will do their best to bring expertise, resources, investment to the country, without forgetting education-oriented and charity programs. In this regard, we see that APRaD are already bringing innovative products to Ukraine whereas these products' sales prospects are almost nonexistent at the moment – but we believe that in the mid and long-term more Ukrainian patients will be able to access these life-changing medicines.

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