Interview with Yuriy Savko, Executive Director, Association of Pharmaceutical Research and Development (APRaD)

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What was the vision behind the creation of APRaD back in 2007 and what was lacking in the market at that time that called for such an association?

APRaD originated from a group of general managers of international pharmaceutical companies who felt that the interests of international pharma were not protected appropriately in Ukraine. This was particularly true for research-based companies considering that Ukrainian law only introduced an IPR clause in 2006 under which such companies could have legal protection for their intellectual assets. It was at this point that Ukraine began to honor its international commitments under the TRIPS agreement to protect data exclusivity in the pharmaceutical and agricultural sectors. The problem was that the mechanism for protection was not very well-structured and this led to a number of violations that directly affected some innovative pharmaceutical companies.

The second reason behind the creation of APRaD was to promote ethical practices of conducting business within the pharmaceutical sector. Such norms are identical to those that you find in the US or in European countries, and we wanted to make sure that the same standards were being used here in Ukraine. Most importantly, we wanted to ensure that there was a transparent and trustworthy regulatory policy of the pharmaceutical sector. In Ukraine, regulations change constantly and at a very fast pace, which is why we need to be certain that all of these processes

are transparent and involve all relevant stakeholders.

As you probably know, Ukraine joined PIC/S in January 2011 and that was a great step forward in committing to the improvement of pharmaceutical regulation and raising current standard to European levels. The next step for Ukrainian authorities is to reach out to other regulatory bodies that are members of PIC/S in order to collaborate and obtain best practices that can truly make a difference. One such example is in the submission of GMP certificates, which in the latest law regarding the registration of pharmaceutical products, there was no mention of the PIC/S agreement and other countries that are a part of it. We raised this issue with the State Inspectorate of Medicines, and expect our European partners to address Ukrainian authorities directly in order to remedy the situation and have PIC/S certificates included in the national legislation.

Throughout the last 4 years of APRaD’s existence, what do you consider have been your main milestones and achievements?

Our main accomplishment has been to become a reliable partner for Ukrainian authorities, by providing them with professional expertise and valuable inputs for regulatory initiatives. There is a lot of work done in the IPR protection sphere, especially if we take numerous legislative and regulatory acts linked with state registration of medicines procedures. Perhaps another good example of a partnership with state bodies and other industry associations was the development of a set of rules for good promotion of pharmaceutical products that was finalized in 2008 . While this was a very positive initiative, its implementation and enforcement proved to be more difficult than expected, particularly in the need to involved local manufacturers and some foreign companies from developing countries. Nevertheless, this is still a work in progress as there are new initiatives that are being put forward by other associations. I expect to see much progress on this front in the near future as we have already seen some positive signs on behalf of the Ukrainian authorities in the past year.

Taking into account the constantly changing regulatory environment of the pharmaceutical sector, what would you list as the main challenges that innovative pharmaceutical companies are experiencing in Ukraine today?

The first major challenge we have already discussed, and that is the need for greater protection of intellectual property. Just last week there was a new law passed that modified the procedures for registering medical and pharmaceutical products under Article 9 of the Medicines Law. This modification was devised to improve the monitoring of pharmaceutical products and it even involved international NGOs in its creation. Nonetheless, international and innovative

pharmaceutical companies were not consulted for the drafting of this new law until it was publicized as Draft Law 7412. Within this law there was a provision that dealt with the terms of data exclusivity stating that a Ukrainian court could annul the period of data exclusivity if it found that the owner of the rights had misused them under monopoly laws. Essentially this means that any regional or local court in the country could rule against a company's data exclusivity rights if a single person brought a case against the company. We were very much against this clause, for obvious reasons. Thus, APRaD was working closely with the Parliamentary Health Care Committee providing the Committee's specialists with information regarding related to this subject international laws and substantiations how a similar protection mechanism works abroad. While working on this issue, APRAD established a fruitful collaboration with PhRMA and our relationship with PhRMA were very helpful in lobbying the Ukrainian authorities to have the clause reviewed. Ultimately we were able to convince them that such a clause was no in the best interest of patients of the country as it would limit the availability of innovative drugs in the country because companies would be afraid to have their drugs copied if they were to commercialize them in Ukraine. Since then, the wording of the law has been changed a couple of times and we are now satisfied with the last version that was released.

Second to IPR issues, another major challenge we have been experiencing recently are the attempts to implement import substitution initiatives. The idea emerged from a number of closed-door meetings between local producers and the government, and it specifically targeted all foreign companies operating in the country. Initially the discussions involved a proposal to eliminate data exclusivity, however, the main objective was to create barriers for the registration of pharmaceutical products that were produced abroad. This included the exclusion of foreign medicines from government treatment protocols and automatically substituting foreign medicines with ones that were produced locally. As with the IPR issues, APRaD was very active in lobbying the local authorities through our American and European counterparts to have this proposal terminated. In the end the proposal simply disappeared, but there was no clear statement on behalf of the authorities acknowledging their retraction of import substitution initiatives. However, we expect to see this idea emerge once again since this is one of the easiest ways to earn political credits before the electorate.

Despite some challenges still needing to be addressed, one of the main opportunities for growth in the market is the possibility of consolidating the much fragmented sector through M&A and collaboration with local producers. How do you assess such prospects?

There is no doubt that the Ukrainian pharma market has great potential for growth and already is expanding. One has to admit that the local producers are a strong presence in the country and are in fact amongst the leaders of the local industry. This is why we have previously seen some cooperation schemes between foreign and national companies, as was the case with Lillly's decision to have Pharmak produce one of its products. Sanofi has also devised a similar cooperation scheme with a local producer and I see great potential for much such collaboration in the future. It is at this stage that full cooperation with leading international manufacturers will lead to quick development of modern production of quality products in Ukraine.

A key component for successful transfer of knowledge and technology processes is the recognition of intellectual property rights. Here I want to stress – the availability of effective mechanisms for protection of intellectual property rights is in the interests of all market participants, regardless of their "residence".

Another great opportunity for Ukraine is to increase the number of clinical trials that are conducted in the country. Ukraine has a great patient pool for clinical research mainly because patients have similar profiles to those of European patients and are generally willing to participate in such studies. This would be a great way to introduce innovative treatments to the population and to educate patients and doctors alike on the benefits that these treatments could provide. APRaD is actively communicating to relevant stakeholders the need to invest in attracting further clinical research to the country, and we hope that soon our efforts will pay off.

Amongst the many current changes that are taking place, are discussions of restructuring the way in which healthcare is provided and the possible introduction of a reimbursement system. While these ideas have been discussed for over 15 years, some believe that finally they will occur. Do you agree?

At the end of the day it all comes down to political will. They have begun the implementation of pilot projects in four national regions, including Kiev, which will hopefully lead to the full reform on a national level by 2014. I am looking forward to positive results from these projects and as APRaD we have participated throughout this process by providing expertise and recommendations to the authorities. We believe the reforms will follow through and we see the momentum heading in this direction, and this is precisely why we are investing so much time and effort to assist them. One recent example of our collaboration was in organizing a roundtable to discuss reimbursement issues and possible models that could be applied in Ukraine. The roundtable was attended by members of the Parliament and experts from other countries, such as Germany, Sweden, Poland and Canada. Overall it was a very fruitful discussion that led to some concrete recommendations

for the authorities to consider. I think at this point it is too early to evaluate whether the current efforts will be successful or not, but we commend the steps that have been taken so far.

One such step has been the recent move to implement a mandatory registration of prices for pharmaceutical products. Such an initiative would normally be welcome by APRaD's member, however, price registration is still under question as it is not clear what the exact procedures to be followed are. As it stands, it is not specified which price is the one that needs to be registered, because the Ministry of Health has only stated that they would like to benchmark local prices on prices that are charged in other countries. The problem is that in European countries there are several prices registered for the same product, including the price with VAT, without VAT, wholesale and retail prices. The involvement of the Minister of Economy has only made the process more complicated as it means that we are dealing with a greater number of stakeholders and conflicting views on the details necessary for registration.

What are you aspirations for the future of the Ukrainian pharmaceutical market and the role that APRaD will play in shaping it?

APRaD is becoming a very important member of this industrial sector and we hope to expand our influence in the future. We are already recognized as a valuable partner by healthcare authorities and I hope that through our efforts we will soon see a reform of the national healthcare system for the benefit of the Ukrainian population. Being Ukrainian myself, I strongly believe that every citizen deserves a healthcare system that is effective and affordable to extend and improve the quality of life.

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