Interview with Naira Adamyan, Janssen

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Janssen recently signed memorandums of understanding with both the Skolkovo Foundation and ChemRar. Can you describe the strategic parameters and intended outcomes of these agreements? How do they factor into what seems to be an invigorated approach by this company to bring R&D to Russia?

The idea to bring R&D to Russia came from the call of government and the Pharma 2020 initiative for the establishment of a local innovative industry. Many companies responded to this initiative in a rather bold fashion, but the majority took the production route. We preferred to contribute to the emerging Russian healthcare system by focusing on an area where we consider ourselves quite strong.

After we took the decision to explore R&D partnerships in the region, we held a number of meetings with the Ministry of Industry and Trade and his team. Our corporate management visited Russia to participate in the discussion; conversely, the official delegation headed by the Minister visited our European headquarters. After listening attentively to what Russia needs in terms of R&D, we came to the conclusion that Russia is very strong in fundamental science, and strong in developing chemical and biological compounds at their initial stages. However, moving forward in the development process, there is an unmet need for this market to commercialize research into marketable products. We discussed with the government, and with a number of other stakeholders, the possibility of Janssen to contribute in filling this gap.

Together with an R&D team from our U.S. base, we visited a number of facilities in Russia in order to try to understand their capabilities. We sought to understand how we could enhance or compliment the existing strengths of interesting facilities. This is how we came upon ChemRar as a potential partner. ChemRar can truly contribute as much as we can contribute, and we found the potential for a win-win collaboration.

There are several ways in which we can collaborate with the ChemRar center. One example is venture funding: Together with ChemRar we plan to cooperate with Russian leading R&D centers and academic institutions to identify and select for funding initiatives in the biotechnology, which may be transformed into startup companies with promising commercial prospects. . Venture funding can be supported by other partners, e.g. Skolkovo Foundation. This kind of collaboration is under further negotiations with potential partners.

Another potential direction of our collaboration with our partners is in helping them to build competencies in GLP. Russia is very ambitious, and Pharma 2020 is an impetus for the creation of a local industry meant to cover not only local patient needs, but also to export products abroad. If this country is to export medicines, then from the very beginning—and this is something we stressed during our negotiations—we need to set up capabilities that meet FDA and EMA requirements. The transfer of competency is a secondary work stream we are considering.

We are also discussing collaboration in specific therapeutic areas for asset exchange. In such a scenario, early-stage assets can be transferred to our Russian partners for further development, or perhaps vice-versa. In this situation, the parameters are of course again that the development standards should be very high.

In fact—and this is an intriguing challenge—the standards should conform not only to what Western authorities require today, but what they will require 6, 8, 10 years from now. This is quite important, and pertains to a broad challenge for pharmaceutical development: 10, 15 years ago, we were doing things in a way that was accepted then. Subsequently, governments, driven by budget pressures, raised the bar for data collection, etc. Suddenly, the entire industry was ill prepared. Having had this experience, we already know that we must leapfrog this potential setback and work in a framework that will safeguard us against any future regulatory demands. This is one of the greatest risk areas of modern R&D: how to prepare a product right now, which will meet the requirements of the environment that will exist 10 years from now. For our Russian colleagues, all of this is quite new. Hence, we think we may significantly strengthen their capabilities in this arena, as well.

You mention that the impetus for your collaborations was the government call to bring R&D to Russia. Hence, are these agreements simply Janssen's way of being in line with government mandates via the Pharma 2020 initiative? Or does the company see true added value in Russian-born projects?

That is a good question. At this stage, we cannot be certain about the tangible benefits of our projects. In general, within Pharma 2020, the Russian government clearly communicates what they want to see, and where they want to advance the nation; but they do not clearly communicate what the benefits will be for companies that aid in the advancement process. The general situation is 'what' without a 'how.' If we are to operate in this region, we need to acknowledge and live with this reality.

This situation is quite new for our environment and I think we should take into consideration the international experience and adapt best practices of public private partnership which proved successful in other countries. The industry is moving more and more towards partnership and alliance. By the call for partnership within Pharma 2020 Russian Government is catching this global trend. In any case, we may have some R&D value from our Russian initiatives. It is well known that in most large companies in this industry, there are a number of R&D assets on the shelf. Why not use local partnership, for some of our undeveloped assets?

We have high hopes!

When Focus Reports spoke with Mr. Martin Selles at Janssen Spain, he remarked that despite the challenge of weak IP protection in the country, Janssen had gone from 45th in sales to 7th in sales in only 10 years. In your understanding, how is Janssen ranked in Russia?

Janssen is one of the leading companies on the Russian pharmaceutical market. Our ranking was impacted due to the recent reinforcement of protectionist measures to replace innovative products with locally-produced analogues in government tenders. Despite the recent challenges we managed to maintain our position in Top 10 pharmaceutical companies.

I want to qualify this statement: I am now comparing company rankings without considering OTC divisions. Janssen does not offer OTC products—OTC is sold through the consumer products division of our parent company Johnson & Johnson. If we compare apples with apples, and consider Janssen together with the OTC section—as other major players do when measuring their success—we are quite a bit higher in the overall rankings.

Without taking into account OTC, what is Janssen’s strategy to regain its positioning after some loss of ground?

We are certainly not going to live with this challenge! The only option we have is to launch additional, innovative, patent-protected products. Of course we need some time to make it happen but we have strong aspiration for growth.

How strong is your pipeline in this respect?

According to recent experts opinion and publications our pipeline is called one of the very best in the business. Johnson & Johnson was declared prospectively extremely strong.

We had pipeline challenges several years ago, which we faced across Europe and the U.S. However, acknowledging this problem, our leadership team actively moved forward with a number of deals and developments. Here in Russia, we are launching four new products just next year.

One of your key DLO medicines, Velcade (t treatment of multiple myeloma), is on the ‘List of 57 Strategically Important Drugs to be Manufactured in Russia.’ So is Prezista (antiretroviral agent for HIV). What does inclusion on this list entail for the future of these drugs? What options is the company exploring?

The products you mentioned are priorities for us. So expecting this situation, we moved ahead with a partnership for local production with Pharmstandard. Our drive is not towards construction of a Greenfield facility. Nevertheless, in the partnership, we may transfer certain technologies for certain products, in order to help our partner to produce.

This collaboration is specifically for these two products, and we have already completed the first stage: meaning both products are now packaged in Russia. For Velcade, we currently engage in secondary packaging; for Prezista, we engage in primary packaging. Already, for our last tender bid, we supplied locally-packaged Velcade.

Going forward, we are in discussions with partners to deepen our partnership, and bring earlier stages of production to Russia. We are only in the negotiation phase because moving in this direction will require a heavy investment from local partners. If they are willing to make an investment in upgrading their existing facilities, to match our internal requirements then we are quite happy to broaden the scope of our collaboration.

As Russia goes about the modernization of its healthcare system and the education of its doctors, you have been quoted as saying that Janssen employees participate in this mission with a “results-

driven mix of professional commitment, youthful vigor and intense personal interest.” What tangible results have you seen from your efforts to improve physician skills and healthcare paradigms?

This is a favorite topic of mine, because we conduct a number of very interesting educational programs. The outcomes are definitely quite positive, because we see a great response from doctors in terms of demanding the kind of knowledge we offer, and learning within the interesting framework we provide. Doctors are looking for alternative interaction models in addition to the the standard rep visit, and the standard conference.

One example of our initiatives is in the onco-hematology arena. We established a forum for multiple myeloma debates. This is a program that was introduced by our corporate management, which we have translated to the Russian setting. It is a very interesting venue where Russian doctors, opinion leaders, and research scientists have an opportunity to speak and debate with colleagues from around the world. We find that there is a wealth of progress made when we are able to bring together doctors in this way.

Another of our formats is our Kazan Advanced Medical Technology Educational Center. Our colleagues from Johnson & Johnson Medical use the center to educate doctors in the use of novel medical equipment in surgeries. Janssen utilizes the center, as well—for example, we make use of the tele-bridge. Recently, we had a tele-bridge between Moscow, St. Petersburg, and Kazan. Doctors were sitting in Kazan discussing case studies with live patients, with their colleagues in the central cities. Kazan also has very well equipped halls, and we are able to use them for our conference offerings. Finally, a number of Janssen’s advisory boards are in Kazan, and we invite opinion leaders to discuss pressing topics via tele-bridge. We look forward to establishing a tele-bridge with European facilities in the near future—and later, with the U.S. We also have interesting training centers for young specialists who are in the midst of post-graduate education.

The dream is that we may create—at least in the fields where we are active—a very comprehensive curriculum for those interested in enhancing their education. We hope to bring a strong global faculty to this endeavor. We have a number of plans in Russia, and are trying to crystalize what will be possible.

Beyond the management of this company, you were appointed chair of the PhRMA Local Area Working Group in 2008, and became an AIPM board member in 2011. In your work to coordinate the most pressing issues on this market, on a personal level, what would you say are your ultimate ambitions for this industry in Russia?

I would like to first explain the nature of the PhRMA LAWG. It was a working group of a pharma association that is based in Washington D.C., whose membership consists of companies that have a large portion of their business based in the U.S. During my chairing, we fully established the association in Russia—because prior to that, it was, as we said, simply a working group. That was perhaps my ultimate goal with PhRMA! It was clear that you must have some presence and a legal framework in order to be recognized as a valuable partner and be able to voice your position for key stakeholders, I chaired the PhRMA in Russia for two years, and the association is still alive, and quite active—even much more so than before.

The AIPM has close to 50 members comprising both generics and innovative companies. and dealing with common industry issues relevant for all. Still, Russia needed an association to specifically support innovators to advocate some particular issues related to innovations : for example, data exclusivity, patent protection, and the fundamental recognition of the value of innovation. Russia is not a largely innovative pharmaceutical market, and innovation is undervalued. For this reason, we want to promote innovation as the biggest value we bring to patients and government. Moving forward, the PhRMA will only become more important. Yes, data exclusivity and patent protection may come if Russia ascends to the WTO. Nevertheless, the recognition of innovation, and the difference between offering patients innovative medicines and generic products, is still not something that the regulators and legislators fully accept. There is much left to do in the promotion effort. Looking at China and India, innovation is under big pressure. We do not want to share that destiny in Russia! For me, this is an absolutely burning need, and I will channel significant efforts to this effect.

Truly, my ultimate goal is to establish in Russia an understanding that innovation is vital. The pharmaceutical industry is highly knowledge intensive and innovative by nature. We do more than stamp tablets and sell them in pharmacies.

We are open for cooperation and welcome Russian innovators to join the PhRMA association. If we can do so, we can, together with Russian innovative partners, enhance the message of innovation in this country.

What Janssen does is therefore quite consistent: we contribute in R&D, we sell innovative products, and we champion innovation as a concept.

What is your final message to the international readers of Pharmaceutical Executive?

I would again emphasize that Janssen here in Russia was, is, and will continue to be a proponent of innovation. When the first wave of reimbursement came in 2005 innovative products became very

demanded and from perhaps 22 or 23 in the rankings we were in 2005. we jumped to number four. Why? Because our portfolio has very innovative and therefore more costly products to which patients did not have access before. Thanks to increased access to innovations the life expectancy in Russia has been increased by 3.7 years. I believe that we collectively need to further promote the innovation idea, because there are statistics that show that Innovative medicines generated 40% of the gain in life expectancy in 52 countries between 1986 and 2000. My aspiration here in Janssen is to drive this matter further, and I do believe that one day the Russian government will embrace the value of innovation, and will broaden access to it to more people.

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