Interview with Vladimir Shipkov, Executive Director, Association of International Pharmaceutical Manufactures (AIPM)

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When Focus Reports prepared a report on the French pharmaceutical industry in 2009/10, we found that the head of the main multinational pharmaceutical association had taken a career path quite similar to yours: he had been an administrator and head of the regulatory authority; he subsequently left the administration and became involved with the industryâ??and this was something that his old colleagues considered â??moving to the dark side.â?• Why, as a former administrator, did you make this move yourself? Is there as much antagonism between the Russian administration and the main multinational association as there is in France?

I joined the AIPM four years ago in 2007 and I have my own understanding regarding why I was asked to join. Before I took the post, I occupied the position of the deputy head of the Russian patent office for some time. Before that I was the head of the pharmaceutical inspectorate of the MOH and I of course had some experience communicating with the international pharma industryâ??including the AIPM and its member companies. My experience with them was very positive because at that time we were absolutely in the same boat in terms of , for example, ensuring quality control and awareness of best practices, combating counterfeiting, and etc. Before my time at the MOH, I had had some experience in the state Duma and before that, I had some experience in state customs.

I am the first Russian citizen that has occupied the position of the executive director of the AIPM since the association was created in 1994. For me, this means that the association itself is evolving in a sincere mannerâ??because before, only foreigners held the position. I believe that, based on my previous experience as a high-ranking official in various governmental bodies, I was invited to carry out bridge and trust-building missions between the authorities and the industry; I was invited to build constructive dialogue. Before my joining the AIPM, there were many contradictions between the activities of the authorities and the actions of the associationâ??there was much antagonism! There was much criticism from both ends and much friction. Even when I was the head of the pharmaceutical inspectorate of the MOH, I eye-witnessed that the main focus of the activities of the AIPM and its member companies was criticism of the authorities.

That is why I think that the decision on the part of the board of directors to invite me was a confirmation of an internal evaluation within AIPM, and a conclusion that image change and productive dialogue were necessary. That is why I am here.

How has the role of the association evolved from one that mainly criticized the government, to one that has a more constructive approach?

Based on my personal understanding the AIPM has, step by step, come to be recognized as a reliable partner of the Russian state in the sphere of healthcare and medical supply. For example, some elements of the DLO state reimbursement program were initiated by utilizing the opportunities of the so-called â??good creditsâ?? of our member companies. Our members were a driving force in the development and achievements of Russian national distributors and some other stakeholders in this field. This mutual understanding of the role of the multinational pharma community in Russia, I believe, is our key achievement.

Now, the AIPM is definitely recognized as a key industry association on the market. To give a concrete illustration: by the end of this month, we will have our usual general meeting and we have received five new applications for joining the AIPM. That, for me, shows a real recognition of our role in the Russian environment. During recent times, we have had some achievements, as an industry, that we have never before hadâ??and I believe that, in these achievements, one can see quite significant contributions from the AIPM.

During my four-year mandate, our member companies twice decided to increase membership fees. This signifies, again, recognition of our role, and is a credit to our activities and the services we provide to members.

While the role of the AIPM has clearly developed in a positive direction, there must still be some points of contention between the association and the authorities. Which, do you feel are the disagreements that have disappeared over the last years, and which are those that endure?

Partnership building and dialogue building are a process. Unfortunately, the key specificity of the Russian pharmaceutical marketâ??indeed, not only the pharmaceutical market, but the Russian market at largeâ??is a lack of transparency; a lack of predictability; and a lack of communication with the business community, especially with the foreign faction of that community.

Step by step we are trying to transform challenges that exist in the Russian pharmaceutical market into opportunities for our member companies. And we do this not mainly for our members, but, first of all, for the Russian patient. Our primary mission is: to promote economic and legal policies that result in the growth of an organized open market for pharmaceuticals in Russiaâ??to the benefit of the population, through the improvement of the quality of healthcare and the choices of medicines available.

I believe that this is our goal and at the same time, it should be the goal of our government. That is why we are in the same boat and why we consider ourselves principal partners of the government. That is why we decided to propose that the Russian regulatory body sign a cooperation agreement with AIPMâ??and this was done in April of 2007, after short period of my taking this office. The agreement was signed with Roszdravnadzor, which was at that time the main regulatory body in the Russian federationâ??and not only with Roszdravnadzor, but with other stakeholders from the government. I would call that agreement a â??civilizedâ?? approach based on formal written frameworks. Gradually, we decided to build our relationship and activities based on this framework. The agreement between the authorities and the AIPM has helped a lotâ??despite some changes in the leadership of the regulators.

I will give you an illustration of our work together. Since the 1st of September last year, the new law regulating the circulation of medicine was adopted and entered into force, and in some aspects it was the rather successful result of very intensive discussion among the AIPM, various other stakeholders, and the authorities.

Our first reaction to the law, as previously drafted, was very, very negative and eight different association heads signed a joint letter of concern. We sent the letter to the Russian president, to the

Prime Minister, to the heads of Russian parliament, to the MOH, and to the Ministry of Economic Development. It was a very motivated letter and some of us were even invited to meet with the authorities and requested to clarify our positions. As a result of the cooperation agreement with Roszdravnadzor that the AIPM and the government had previously signed, we had a very pragmatic dialogue, and we were able to harmonize the regulation of pharmaceutical circulation on the Russian market. The harmonization was made possible largely because we, as the AIPM, organized communications between a Roszdravnadzor and the European Department of Quality Control (EDQM) in Strasburg, and the European Pharmacopoeia. It was a very interesting approach and collaboration between a Russian regulatory body and European regulatory bodies, which sought to harmonize legislation, to harmonize enforcement, and to harmonize quality control.

Based on our international experience, we provided additional arguments to the authorities in order to improve the Russian legislation. Some of our key arguments were then included in the final version of the law. This was a positive experience.

What aspects of the law still need work?

Some aspects of the law are highly appreciated by multinationals here, but some aspects are not. For example, price regulation entails an unequal approach for Russian producers and international producers because Russian producers now have the opportunity to factor inflation rates and investments allocated for modernization of production in increasing their pricing. Unfortunately, these opportunities were not extended to multinationals.

This is discriminatory to us, especially because our prices for 2010 and now for 2011, are supposed to be based on average prices calculated over a period of six months in 2009â??something that does not correct for inflation and other market developments. The implication is discrimination in terms of localization, in terms of production, and in terms of promoting the innovation of modern medicine to the Russian population.

But, as I have said, some of our arguments were indeed accepted by the authorities. And despite a lot of challenges during the last year, the Russian pharmaceutical market, in general, grew, and the businesses of our member companies are doing quite wellâ??something that we believe is in large part due to the improvements that we were able to push through.

There seems to be a paradox here. You mention that pricing regulation is hurting multinational companiesâ??but is it not true that in Russia, it is increase in price, rather than increase in volume, that has actually driven the business growth of those same companies? Is that a misconception?

You are right and wrong simultaneously. During previous years the market indeed grew mostly in valueâ??perhaps only in value. This year and last year it grew both in value and in volume. Of course, that is a positive development and we hope that such a development will continue. I mention pricing regulation to highlight a disparity in the law as applied to multinationals versus local companies.

We are trying to be not only reactive, but also proactive. We suggest to the authorities some ideas, based on international experience, which can allow us to further develop the Russian pharmaceutical market. One of the examples is the policy study â??Conceptual approaches for improving the provision of Essential pharmaceutical drugs for out-patient treatment in the Russian Federationâ?• that describes the different reimbursement models and develops economically verified solutions for the organization of the drug provision system, with attainable indicators for the improvement of the longevity and quality of life, enhancement of the demographic situation in the country, and addressing the issues of GDP growth.

What are the prospects of the Russian pharma market?

I believe that the market has huge potential for growthâ??not only domestically, but also in the development of the CIS countriesâ?? markets, and even beyond. These opportunities are very important for our member companies because most of our general managers are responsible not only for the Russian market, but also for CIS markets, and sometimes, other including neighboring Asian markets like Mongolia.

One of the national priorities identified by President Medvedev is the modernization of the manufacturing capacity of the Russian pharma industry. What role will multinational companies play in that modernization?

Four years ago, when I joined the AIPM, the first question posed to me by the former Minister of Health of the Russian Federation was: â??Why are your member companies not building local manufacturing facilities?â?• My answer was that such a question should not be addressed to the industryâ??it should be addressed to the government. The Minister and his superiors should themselves address the question!

But in any case, we made an internal analysis and conducted an additional survey. And two years ago, we declared publically, based on our survey, that on behalf of the AIPM member companiesâ??we were ready to invest between 1Bn USD-1Bn EUR in local production, at the initial stage. Believe me, this was a very big surprise for the authorities.

Step by step, we are affirming our political statement with concrete decisions. Some of our member companies already have manufacturing facilities here in Russiaâ??for example, Gedeon Richter, KRKA, Sanofi-aventis, and Servier. Some other members, such as Berlin-Chemie, Nycomed, AstraZeneca, or Novo Nordisk, have facilities in the works. If we calculate all the figures, we are rather close to the investment initially promised. I believe that this is a very serious contribution by the international pharma industry, and a very serious argument in favor of the real implementation of our promised mission.

Now we are speaking with the authorities to figure out what it is to be considered a â??localâ?? product, because there are a lot of speculations in this regard. What is â??localization?â?? Because some time ago, we were told that the authorities would consider any stage of local production as a local product, and that those products would be granted the ensuing preferences typically granted to local product. But suddenlyâ??and this is why I speak about lack of predictabilityâ??one day, Ministry of Industry and Trade declared that the Russian authorities will consider as local products only those that have had full-cycle local production, including APIs.

This is something that would not work in any pharma market in the world!

Absolutelyâ??I agree. So there is still a lot of speculation in this regard, and there is a lot of speculation on so-called â??import substitution,â?? or â??import replacementâ??. Such speculation is very dangerous for, first of all, the Russian population and the Russian patient: because such an approach is absolutely wrong. Unfortunately, most Russian local manufacturing facilities have no GMP standards in placeâ??that is why we highly appreciate all government initiatives regarding the development of the Pharma 2020 concept and strategy, which is devoted to the development of modern GMP infrastructure. We declared our own readiness to promote such an approach and we are ready to be involved in real discussions.

What is your view of the role of political goodwill in the national industry?

According to my understanding, much will depend, especially in Russia, on political will. For our industry, and for our local market, it is very important that Russian political decision makers include healthcare and pharmaceuticals in their personal political agenda.

In some cases the implication of this inclusion meant positive development; in other cases, negative. But in general terms, I consider political will to be a good signal for the further development of the Russian pharmaceutical marketâ??it is a key driver, and will provide additional opportunities for the industry.

When the government speaks of import substitution, does it have the means to implement it?

It is a very ambitious declaration of intentions and it means the development of the local pharma industry based on international GMP standards. We would highly appreciate such an approach, because we would welcome real competition. If the international pharma industry would be subject to this competition here in Russia, it would provoke our own internal development, and encourage us to meet new challenges.

In other words, we are looking at a lot of opportunities for the pharmaceutical industry, both local and multinational. First of all, I mean this in terms of the creation of a universal reimbursement system based on international experience. Two years ago, we initiated a special project related to the possible reimbursement model here in Russia, and we provided some ideas to the Russian authorities and other stakeholders. We circulated a lot of information regarding foreign models of reimbursement in various countries around the world, including Japan Australia, the U.S., Canada, Sweden, France, Germany, and so on.

Now, the reimbursement issue is already included in the agenda for various speakers, decision makers, high-ranking officials, and so on. Even the Minister of Health, Tatyana Golikova, and even the current Prime Minister, two years ago, made statements regarding the necessity of implementing a comprehensive program based on accepted world models.

How does the future look for multinational pharmaceutical companies operating in Russia?

I believe that the future for companies that explore the implementation of GMP standards, Intellectual Property Rights (IRP), and marketing ethics, is very good. We, as an association, will try to do our best to improve the general conditions for their operations.

I am absolutely sure that the situation, in this regard, will be improved significantly in five or ten years. We have all necessary opportunities and resources and although at the beginning, the Ministry of Health was one of the most â??closedâ?• ministries in the Russian government, it is gradually opening up. We have developed our partnership with them and now as a representative of the multinational pharma industry, we have working meetings on a regular basis, have a direct dialogue with the people responsible for market access, registration, clinical trials, and other sensitive issues for the multinational industry.

Recently, we had a meeting with Minister Golikova and provided her with further concrete amendments to the law on medicine circulation, which was prepared by our member companies experts, and she accepted these amendments for internal consideration.

To sum up, for a company that is not yet in Russia, and plans to penetrate this market, what would be your advice?

First of all, I would like for any multinational pharmaceutical company to come to Russia and not to be afraid of doing business here on the one of key emerging markets with great growth potential. I also would recommend any company with a real interest in developing business here, to join the

AIPM. I should say that maybe it is necessary for them to find local talentâ??albeit with international experienceâ??to aid in running those operations. Russian people are more and more actively occupying the positions of general managers, and other decision makers, at the Russian subsidiaries of multinationals.

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