Made in Russia

By the end of 2012, the Government of the Russian Federation is to approve the State Program "Development of the Pharmaceutical and Medical Industries" for 2013–2020, which includes the current Federal Target-Oriented Program "Pharma-2020." One of the objectives within the State Program prepared by the Ministry of Industry and Trade is to "increase the share of domestically produced drugs and medicinal products in overall consumption by the public healthcare services of the Russian Federation by 48%." However, the term "domestically produced drug" still remains to be legislatively defined. According to the draft resolution issued by the Ministry of Industry and Trade in May 2012, a "domestic drug" should mean a drug whose production cycle in the territory of the Russian Federation starts from a substance or a ready-to-consume formulation. Until 2014, the Ministry was ready to regard even those drugs whose packaging was made in Russia as Russian ones. However, no further steps followed. Therefore, the question pertaining to which drugs and which produced by which pharmaceutical companies should be regarded as domestic drugs remains open. Actors of the Russian pharmaceutical industry share their opinions.

Andrey Ivashchenko, Chairman of the Board of Directors of the Chem-Rar High-Tech Center.

In your opinion, to what extent are the pharmacological production facilities to be localized in Russia so that a company could be regarded as a Russian manufacturer?

There are two aspects in localization of production facilities. What does the Russian government want? When buying pills for the public healthcare system costing 1billion USD, it wants a possibly higher share of this amount to be in rubles. In this case, the budget risks to the state are lower. Let us say that 30 billion rubles are to be spent to buy pills. If the drugs are imported and the rate of the US dollar to the Russian ruble moves by 10%, the state will have to look for an additional 3 billion rubles. Let us assume that a drug is being sold in Russia. What share of its total cost is in USD? If

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it has been completely produced in Russia, its entire cost will be in rubles. If the substance was imported from China, 20–30% of the drug's cost will be in USD. Finally, if a drug has simply been bought from a distributor, 90% of its cost will be in USD.

The second aspect consists in the technologies used in our country. This aspect is important in terms of drug safety. If only pelletizing and bottle-filling are located within the country, the technology is very simple. It is better if chemical substances are synthesized in the country. Finally, if Russian manufacturers can produce both synthetic and biotechnological substances, this means that there is a complete set of technologies in the country.

Therefore, various combinations of these two aspects are possible. For instance, in the case where the patent is foreign but the drug is produced in Russia, the biggest share of the drug's cost will be in USD, but there will be production facilities in our country. The opposite case is when the patent is Russian but the drug is produced in China: the biggest share of the drug cost is in rubles, but we do not have the technology for its production. An ideal variant is when both technology and production facilities are Russian. A poor variant (which is nowadays most commonly observed in Russia) is when drugs are simply imported. Hence, the state policy is oriented towards proceeding from the worse alternative to the best one.

Another aspect of state policy is the protection of its industry under conditions of elimination of state boundaries (e.g., after joining the World Trade Organization, WTO). There is such a protection method as technical regulations. Let us assume that most pharmaceutical manufacturing companies in Russia today can only produce drugs in their finished dosage form (FDF). The Government, hence, decides that a manufacturer producing FDF in the country will be regarded as a domestic producer. When most pharmaceutical companies learn how to produce substances, those who produce them within the country will be regarded as Russian producers. I deem the situation will develop in this very direction. Until recently, a company could have been regarded as a Russian manufacturer by simply packaging the ready-to-consume drugs into boxes. Now the situation is different: the company has to be able to bottle and pelletize drugs under sterile conditions, etc. I am positive that with such a policy, in five years, when most manufacturers will start to produce substances, they will lobby for preferences.

One should see the interests of the State in the term "domestically produced drug"; in this case, the situation becomes clearer. It is a rather flexible system. It has been specified in the Federal Target-Oriented Program "Pharma–2020" that drugs produced in Russia should make up 50% of the pharmaceutical market by 2020. Let us assume that Russian companies open plants in China, where the cost of production is low. The largest share of the pharmaceutical market will be in rubles. However, where will we produce vaccines and pills in case of war? Some technologies need to be localized in Russia. This is exactly what the Government is doing right now. There is a list of 57 strategic medications that are to be fully produced in the territory of Russia. It is clear from this list that production of these medications requires one to master the major pharmaceutical technologies.

I deem the Ministry of Industry and Trade holds a rather reasonable position. It is a different matter that it runs counter to the position held by the Ministry of Healthcare and Social Development and doctors. It does not matter for the doctors who

produces the pills. Moreover, they consider imported medications to be of better quality (and they are often right). A compromise, which is not subject to market regulation, has to be reached. There should be a system of interdepartmental regulations. Instead, the Ministry of Industry and Trade is now slamming on the gas pedal, whereas the Ministry of Healthcare and Social Development does not actually care. It steps on the brake, which eventually can damage the entire engine.

There have not been interdepartmental mechanisms for balancing between different interests thus far. However, the number of companies investing funds into import substitutive production is on the increase. Hence, the issue is on the agenda, and some solution is needed. Some kind of mechanism will emerge, but it is unclear yet whether it will be an interdepartmental committee or a self-regulatory organization.

The question pertaining to production localization deals with the same issue. The Government makes foreign companies localize production facilities without giving any guarantees that procurement will be made. Foreign companies have been looking attentively at the situation and eventually have started building facilities. But it is obvious that if rivals invested funds into the construction, they will ask the State for preferences. Russian manufacturers will do so as well. Hence, falling behind is inadmissible. The avalanche-like process has started. The first to construct their facilities were those who had something to lose – various East European players who are being driven out of the market. They produce branded generics, and Russia is the last reserve where these products can be sold. Therefore, such companies as Polpharma, Stada, Gedeon Richter were the first ones to localize their production facilities in Russia. Next were the European innovative firms: Novartis and Sanofi-Aventis. They are followed by American companies falling behind by a year or two. Japanese firms are at the very tail.

The contests held by the Ministry of Industry and Trade include two types of events. First-priority events include everything associated with import substitution. There is intense rivalry in all the group 1 contests. There are several players for each lot, which pushes down prices. It means that there are a lot of companies in Russia dealing with import substitutive production. In turn, this fact means that all of them will have their drugs certified in 3–4 years and will compete further during the stage of Government procurement. And all these medications will be manufactured in Russia.

How will it affect the demand for developments made by our scientists?

Of course there is no demand for developments that fall behind, whereas cutting – edge developments are needed. Global competition still exists; there is no way to escape it. Identically to the USA or Europe, Russia will learn to build virtual regulatory barriers to protect industries that are important to us. However, there will be no rigid wall. No one can protect us against competition from foreign manufacturers; hence, we need to reach for cooperation models, incorporate into a high-profit unit of the added value chain, together with the foreign producers (e.g., into research & development). Of course, it is important to make the lives of the local developing companies easier; however, we also should not isolate ourselves from the world market. Balance is required. We are moving towards it; although the imbalance between the State policies hinders this move. But this is presumably a stage that we need to go through.

Aleksandr Bykov, Director of Government and Public Relations, Novo Nordisk.

According to one of the viewpoints, only the pharmaceutical manufacturers that have full-cycle production facilities (from substance to the drug in its finished dosage form) on the territory of Russia should be regarded as domestic manufacturers. Do you think this approach is reasonable?

I think it is not quite reasonable to insist on substance production. The development of the pharmaceutical industry should be guided not by drug safety, but by intensive scientific activity at pharmaceutical production facilities, modernization of the industry, and development of its intellectual potential. The safety thesis is applicable to a very narrow group of medicators only.

On the other hand, let us assume that we start producing substances. It is a very complex chemical production process during which we are bound to encounter a lack of some additional ingredients, catalysts, or equipment. According to this logic, we will have to relocate the production of these ingredients, catalysts, and equipment providing functioning of our chemical production facility to Russia, as well. But this is a way towards North Korea's Juche ideology, which insists on relying on domestic resources only.

In your opinion, what should state policy in this area be?

I think that the investment attractiveness of the market should be developed. Preference should be given to companies that localize their production facilities in Russia, thus contributing to the Russian economy's modernization. Among these companies, there can also be Russian enterprises that reorganize their technological process in accordance with GMP standards or participate in joint cutting-edge developments.

Aleksandr Bykov: The development of the pharmaceutical industry should be guided not by drug safety, but by intensive scientific activity at pharmaceutical production facilities, modernization of the industry, and development of its intellectual potential

Biotechnology and new directions in drug synthesis should come under focus when developing the pharmaceutical industry. If we do not get integrated into the global industry, we can find ourselves left far behind. Of course, we will be supplied with medications. The process of producing mass medications via chemical synthesis is relatively simple. But if foreign manufacturers are forced to produce biodrugs here (while the volume of domestic consumption is small), the costs of production organization will be higher than the potential profits. Hence, investing here will be less attractive, and investments will go into the production facilities of India and China.

Do you mean that the best definition for the term "Russian producer" is "companies producing drugs in their finished dosage form in Russia"?

Exactly! By 2018, the volume of medications produced in Russia (according to the lists of strategically important drugs and vitally essential and most important medicines) is scheduled to increase to 90%. However, joining the WTO assumes that the excessive trade barriers will be eliminated: by then there probably will be no need at all in establishing the nationality of manufacturers or products. The requirements to the products manufactured in Russia and imported ones should be identical. In this case, it will be reasonable to align the principles of price formation for drugs produced in Russia with global ones. Of course, Government procurement in the frame of the WTO is not regulated. However, it is quite possible that in five years Russia will have signed some additional agreements, which will determine this sector of the market, as well. In this case, the competitive advantage will disappear.

What can be the response of foreign manufacturers to the requirement to produce substances in Russia so that a drug is regarded as domestically produced?

There will be no response. The companies that have already localized their production facilities in Russia will not close them down. This measure will stimulate further localization of substance production only for companies whose drugs are consumed in huge amounts. In this case, they may consider substance production in Russia. However, if only a few thousand people need a drug, it is not reasonable at all to build a plant that would operate for only a day or two. Production of small amounts of substances will be economically a nonstarter. India and China are producing substances for the entire world: for their domestic markets, the foreign market, the USA, and Europe. Large multinationals subsequently purify the substances produced in India and China and produce drugs in their finished dosage form. Hence, is it possible to compete with India in substance production? And do we actually need to compete? Substance production is not a highly intellectual process. It is simply the chemical production and is also associated with certain environmental costs.

Which ways of stimulating the development of new drugs in Russia should be used?

I deem it necessary to develop pharmaceutical clusters. They are the link between science and technology and production. The research organizations (institutes, centers, laboratories) do not structurally belong to the pharmaceutical companies working in the pharmaceutical cluster. Meanwhile, these institutions can solve the urgent problems of the industry and be additionally supported via the scheme of public – private partnership. However, they need to cooperate with the international pharmaceutical industry so that their developments can reach markets. There are very few cases when a drug was recognized only in the local market and successfully sold.

Victor Dmitriev: The current Federal Law FZ-94 with price being the major driving force is against both patients and Russian manufacturers

Viktor Dmitriev, General Director, Association of Russian Pharmaceutical Manufacturers

Your organization has recently proposed to elucidate the question pertaining to the definition given to a domestically produced drug. Why is that important?

Russian products participate in government tenders; hence, it is important that local products be given some preference, since government procurement makes up to 30% of the pharmaceutical market. They have indeed been given for 3 years already according to the Resolution of the Ministry of Economic Development on 15% preference points when making public procurement in accordance to the Federal Law FZ-94. However, in reality these preference points appear to be inefficient, since the technical documentation for the tender is drawn in such a way that domestic manufacturers cannot take advantage of their preference points.

What should be done to make the preference point system work?

First, political will is required. Second, the current Federal Law FZ-94 with price being the major driving force is against both patients and Russian manufacturers. We would propose to provide a separate article in the Law (or even a separate Law) to regulate drug procurement. The reason for that is that drugs are goods that cannot be regulated based on general criteria. What do I mean? The Federal Law on technical regulation assumes that quality is determined by a buyer. If he liked a certain type of sausages, he would buy them again. If not, he simply would not buy them. This cannot be said about drugs, since their effect or quality can be tested only under laboratory conditions. I can provide the following example: the effect of statins used to prevent cardiovascular diseases cannot be felt; it can only be assessed according to analysis results.

Another point is that drugs possess a special property that other products lack. It is the so-called placebo effect, when a person expects amelioration of his condition and even feels it, but the amelioration is not necessarily caused by the drug. The waiting process can also contribute to it.

Hence, I deem it necessary to adopt a separate law in which the following provisions will be made. First, if several domestic manufacturers (e.g., two, as is in Belarus) participate in a public tender, participation of drugs produced by foreign companies should be prohibited. Second, the participants in the tender should be obligated to hold a GMP certificate. The reason for that is that the pharmaceutical industry is very heterogeneous now. There are companies that are in compliance with world standards. The net cost of the drugs produced by them is higher than that of drugs produced by companies that are not in compliance with GMP standards. However, the quality of the drug is guaranteed in the former case. According to the third provision, supply volume and product prices should be guaranteed.

Vladimir Shipkov, Executive Director, Association of International Pharmaceutical Manufacturers

The Ministry of Industry and Trade has offered different criteria for defining a domestically produced drug. What is your sense as to how the question should be solved?

Indeed, the Ministry of Industry and Trade has not resolved this question yet. I am not sure whether that is a good or bad thing. The last project prepared by the Ministry has provided additional motivation depending on the extent of production localization. On one hand, I would appreciate this approach, although it has not been implemented thus far in the form of normative documents in force. On the other hand, the ef-

Vladimir Shipkov: The idea that only the medications whose full-cycle production was carried out in Russia should b regarded as Russian ones makes no sense

forts at defining a local product or a local manufacturer under the conditions of joining the WTO make little sense. Since the pharmaceutical industry is among the most globalized ones, it would be more reasonable to think about supporting manufacturers who produce goods in accordance with the generally accepted international quality standards. The potential customer should not care where a certain drug was produced: in Russia, Ukraine, Kazakhstan, France, the USA, or somewhere else. What really matters is that the drug corresponds to strict international requirements.

In your opinion, what preference points should be given to Russian manufacturers?

The preference points that are being given right now look a disservice to me. It is wrong to give 15% preference points for products manufactured in the Russian Federation (starting in 2012, in Belarus as well), since it is given to any medications regardless of whether they were produced in compliance with GMP standards or under dubious conditions. The manufacturers should be motivated to invest into modernization by encouraging GMP implementation. Hence, the preference points should be given only to those manufacturers who work in compliance with these standards. However, I think that, much higher preference points (about 30–35%) should be given in our situation. In this case there will be real motivation. Do you want to gain preference points? Do you want to enter the markets of third-world countries instead of hiding behind the "iron curtain?" In this case, implement GMP at your production facilities. Furthermore, a differentiated approach should also be used: a deeper localization process means higher preference points (but provided that a manufacturer is in compliance with GMP standards). After a while, when all enterprises implement GMP standards, this requirement can be dropped.

What requirements to the degree of localization do you think there should be?

All localization forms should be encouraged. The idea of regarding only those medications whose full-cycle production took place in Russia as Russian ones makes no sense. Among Russian manufacturers very few deal with full-cycle production (including substance synthesis). There is no way inept requirements to full-cycle production can attract investments. Instead, a differentiated preference point system for all localization degrees is needed (e.g., secondary package – 5%; a drug in its final dosage form – 15%, full-cycle production – more points). If an investor today wants to invest into packaging and use the minimum preference points, this should be encouraged as well. After working under these conditions for a certain period of time and seeing that the other manufacturers are awarded more preference points because of a deeper degree of localization, he eventually will implement deeper localization as well, increase investments, hire workers, and establish better production conditions. ●

Prepared by Ekaterina Borovikova