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Despite the coronavirus pandemics that has affected virtually all countries of the world, we still hope for the better and continue preparations for Pharmtech. What should we expect after the end of the pandemics? What will the Russian pharmaceutical industry look like?

Both the best-case and the worst-case scenarios are quite plausible at this stage. Obviously, the pharmaceutical industry, both in Russia and in the whole world, will not be the same. This is due to certain things that became perfectly clear and obvious during the pandemics. The first thing is that these are Chinese pharmaceutical ingredients and a minor share of Indian pharmaceutical ingredients. Both Russia and the entire world shuddered when they realised to what extent they depend on China (global dependence on imports of pharmaceutical ingredients from China amounts to 70% and from India — to 25%). When Chinese factories started suspending operations due to the pandemics in the regions to be shut down, this disrupted the logistics chains and the Chinese manufacturers of pharmaceutical ingredients are not operating at full capacity yet. This has a major impact on the prices of the very pharmaceutical ingredients, reagents, components, and intermediates required to manufacture such pharmaceutical ingredients and on the delivery costs. Logistics has become three times more expensive due to a major decrease in the number of planes. India was shut down altogether and did not start reopening until last week — the country suspended all exports and the Indian customs did not work. This is the reason why both Europe and the US encountered a shortage of active pharmaceutical ingredients and are currently taking expedient and extraordinary steps to restore the pharmaceutical industry that once used to be the signature of Europe and that Europe has lost. The example of Sanofi — the company that is creating a giant holding in Europe and comprises about 10 manufacturers of pharmaceutical ingredients — is very illustrative.

In a similar vein, Russia realised the extent of the problem that may result from the shortage of active pharmaceutical ingredients, and in the best case, it will create a dedicated target programme within the umbrella Pharma 2030 programme. The programme will be introduced in order to create the process chains that include both production of pharmaceutical ingredients and production of intermediates and chemical synthesis ingredients in the Eurasian Economic Union, that is, in the area that is intelligible in terms of logistics and common policy of investment incentives. Unless this happens, I am afraid that we may expect a shortage of pharmaceuticals at the very least, and in the worst case — discontinuation of supplies of pharmaceuticals and pharmaceutical ingredients.

It is critical to emphasise that China is becoming self-sufficient.

It makes much more economic sense for China to manufacture pharmaceuticals and export them in the form of FPP to the international market than to export pharmaceutical ingredients. I expect this to be the trend of the five years to come. Therefore, we have no choice but to restore the production of active pharmaceutical ingredients both in Russia and in Europe and the US. I hope that the first seedlings of cooperation and communication between the European Union and Russian Federation will evolve into strong, friendly, and full-fledged relations.

Pricing is the second fundamental aspect. It is currently becoming apparent and obvious that certain regulatory bodies are too sluggish to respond to the current changes in the market environment expediently. The second quarter of this year will be decisive. Will we be able to overcome the bureaucracy that fears radical and creative steps or not? We see a very interesting situation with coronavirus drugs and medical products — masks, lung ventilators, tests for coronavirus and antibiotics — the relevant bodies are making radical decisions that have not been made for years in this area. Today, registration of a medical product included in the list of facilities used to treat or prevent COVID-19 takes just a few days. This means that you may bring a coronavirus test, start using it, and have it registered under an expedited procedure. Besides, on 18 April, the Government enacted a resolution that sets VAT for all headings included in this list to zero — this is a powerful stride and we should thank Mr. Mishustin for this decision. However, the issue concerning re-registration of prices for the pharmaceuticals included in the list of vital and essential drugs (VED) remains intractable. We still have certain headings in the list that are priced at the same level as five and even ten years ago. Manufacturers say that they cannot and will not operate at a loss. We have a number of black synergy factors — appreciation of the pharmaceutical ingredient in US Dollars, devaluation of the Rouble to the Dollar, and logistical problems. - What is the reason for making pharmaceuticals that make companies run at a loss then? - Because this is the list of socially important drugs that are priced under one hundred Roubles.

Kommersant has published an open letter by the leading pharmaceutical manufacturers concerning discontinuation of certain drugs due to a low ceiling price and uneconomic production costs. This is not the first step. This kind of conversations and debates have been there for many years already. I will give you a real-life example. We have a hormone known as prednisolone. De facto, we currently have a single manufacturer of prednisolone in the market — Hungarian company Gedeon Richter. Why? Because Gedeon Richter managed to register the highest price — 70 Roubles. Thus, Gedeon Richter is still theoretically able to supply it. However, the company has production quotas for this product, and therefore, has to supply it in limited quantities. This is the reason why prednisolone is currently in short supply. And yet, this is a vital hormone. The Russian companies that registered production of this hormone do not actually manufacture it because the price of the pharmaceutical ingredient is higher than the registered shipping price that cannot be increased. At that, there is a new resolution that was mentioned by the Ministry of Health and Federal Antimonopoly Service enabling these agencies to respond with flexibility and revise the heading prices on a fast-track basis. However, as I have learnt from my conversations with the manufacturers (and our company — ActiComp JSC — supplies pharmaceutical ingredients virtually to all Russian drug manufacturers), many of them tried to do so, but have not succeeded so far. They are still unable to persuade the relevant bodies that the prices should be raised. Unless we change this situation and transform the approach by making it more flexible and socially-oriented, we will end up having none of these pharmaceuticals.

What inspires optimism is the position of the Ministry of Industry and Trade that has embarked upon an ongoing meaningful dialogue with business. The Ministry of Industry and Trade has always stood out from the other ministries due to its eagerness to help and obtain feedback from business regarding updates and innovations. At present, however, the Ministry is indeed doing this on an ongoing basis by organising conference calls with distributors', retailers', and manufacturers' representatives. We exchange information that is used to make certain decisions. Obviously, this dialogue should be expanded by involving the representatives of the Federal Antimonopoly Service and Ministry of Health so as to engage the public officials from these agencies that equally influence the pharmaceutical industry.

Besides, the list of backbone businesses has been expanded. ActiComp JSC has been included in this list, and I hope that apart from this honourable title, we will see some specific steps aimed at supporting the manufacturers. First of all, in the form of incentive subsidies and preferential loans to the benefit of all parties involved. At this point, these measures are necessary and timely indeed.

Will China retain its positions as the leading manufacturer of pharmaceutical ingredients? Or will India take its place?

It all depends on the specific period we are talking about. I think that over the next four or five years, China will definitely maintain its leadership in supplies of active pharmaceutical ingredients, but its share will decline due to the reasons I have mentioned above. Besides, we should not forget about the environmental reform that has not been cancelled in China despite the coronavirus. Chinese factories that fail to comply with the environmental standards still have to be shut down or work 2 or 3 days a week. China has cancelled GMP certification. The FDA and EDQM inspections that used to come to China and be welcome there currently encounter certain problems as they are unable to tour Chinese factories. Our European colleagues often tell us that they are not allowed to visit certain production facilities or are put on the waiting list and have to wait for years. China has taken a very straightforward stand: you don't want it, you don't take it. Chinese manufacturers of pharmaceutical ingredients have enough customers to sell pharmaceutical ingredients inside China. We have a real-life example involving ActiComp. We manufacture a vitally important antibiotic — Azithromycin — that is both included in the VED list and is deemed to be efficient in case of COVID-19 if combined with Hydroxychloroquine. This product is currently in short supply. We have our supplier of raw materials from China who informed us as early as in March that they have a long queue of Chinese, French, and US drug manufacturers. ActiComp ended up on the fourth or fifth place in the waiting list. We received the backing of the Ministry of Industry and Trade and leadership of Russia's Trade Mission in China: they officially requested the Chinese to ship these intermediates to our company. By now, we have received a confirmation for the supply of one-tenth of the intermediates we requested. Nobody is mentioning the prices any longer — the primary concern is to receive these raw materials.

This is the reason why China will retain its leadership positions, but its share will decline due to the efforts of the Europeans who have significantly changed their perspective and realised that stable provision of EU citizens with pharmaceuticals is exposed to certain risks and it is necessary to take drastic steps that will give incentives to business and promote the creation of holdings in order to establish the production of the key active pharmaceutical ingredients in Europe.

A similar change of perspective is taking place in the US.

I have high hopes that Russia will follow suit.

We have already mentioned India that is about to adopt a new legislative package aimed at overcoming the dependence on China in terms of supplies. In a similar vein, the Indians are going to promote their pharmaceutical industry after they have learnt the extent of their dependence on China.

People used to have a certain illusion that India is able to produce intermediates and chemical synthesis components, but it proved to be false. The Indians still import the basis for pharmaceutical ingredients from China, but China restricted exports and India faced short supply. This is the reason why India adopted the relevant resolutions in March that prohibited any shipments of local pharmaceutical ingredients to foreign countries. Definitely, the share of Chinese pharmaceutical ingredients in the world market will go down. We will now witness a hunt for Chinese chemists who know how to prepare these pharmaceutical ingredients and a restoration of production facilities in the other countries that used to be shut down and laid-up. Inevitably, new production facilities will be created as well.

Will Russia be able to overcome its dependence on imported pharmaceutical ingredients? Can we expect Russia to increase its exports of pharmaceutical ingredients and FPP?

I really hope so. I remember that when ActiComp was launching its production back in 2007-2008, everybody was saying that it was useless. They used to say that China had much cheaper labour resources and electricity, much lower environmental standards, and huge capacities to produce inexpensive headings. How could we compete against them? Multiple Soviet-era factories had been shut down: Pharmakon — a huge chemical and pharmaceutical factory in St. Petersburg — had been destroyed, while Ussolye-Siberian Pharmaceutical Plant had scaled down — just two workshops out of 30 operated. But the situation has changed drastically. At present, the salary of a Chinese operator preparing a pharmaceutical ingredient, or of a Chinese R&D specialist, or of a Chinese quality control and assurance officer is 30-40% higher than the salary of a Russia specialist with similar competences and sometimes is even twice as high. Electricity has appreciated in China due to environment-related changes and the environmental standards have become stricter. As a result, the cost of a Chinese product has become equal to the cost of a product manufactured in Russia or India or even exceeded it by a large margin. Should we add logistics that has appreciated significantly and is not expected to depreciate in the near future, we will reach an obvious conclusion: Russia has become quite competitive. Considering that Russia still has competent chemists and dedicated universities that are able to create field-specific departments and chemists' and analysts' classes to work on chemical synthesis, we definitely have good prospects. However, this must be a multi-faceted and strategic programme for a period exceeding one year. We should identify the facilities that will be able to manufacture basic reagents — methyl and isopropyl alcohol, ethanol, facilities that will be able to manufacture intermediates, and facilities that will be able to manufacture active pharmaceutical ingredients. We should agree at the government level upon the list of companies responsible for manufacturing specific pharmaceutical ingredients so that at least two companies in Russia manufacture a specific type of pharmaceutical ingredients, at the very least — the pharmaceutical ingredients from the VED list. We should divide them according to the following attribute: biological and those produced by chemical synthesis, and agree who exactly will produce what. We should make government contracts, offset agreements and agree on tax incentives to exempt the relevant companies from the corporate income and property taxes.

You must be aware of our difficulties with the SPIC that we have been trying to sign for a year and a half already. We have significant backing on the part of the Ministry of Industry and Trade with this issue. A petition must be submitted to the State Duma in order to amend the law for our company and for Generium. But we are still beating the head against the wall and certain factors, in particular, the coronavirus, play a certain part.

Furthermore, such strategic programme should include all links in the chain, not just the Ministry of Industry and Trade, but also the Ministry of Health, Federal Antimonopoly Service, Ministry of Economic Development, and Ministry of Finance. Most importantly: we need a project manager from the government at the level of Deputy Prime Minister who would supervise this strategy, since it is of crucial social importance for the Russian Federation. If we succeed, we will be able to talk about exports easily. Our pharmaceutical ingredients will enjoy high demand abroad. But to do that, we need a strategist at the government level. Unfortunately, we will be unable to create such strategy at the level of private companies: it is impossible to bring everyone together on an individual basis, as every company has different interests. This must be a clear-cut governmental strategy for the next 10 years. In this case, we will have a chance to succeed. Individual stars like ActiComp or Polysan will rise, but they will rather serve as exceptions from the general rule. We have no comprehensive approach so far.

What are the FPP or pharmaceutical ingredients that Active Component Company is currently focusing on?

As for the coronavirus and production of a cure for this disease: we are currently engaged in fast-track research and development activities and looking at such pharmaceutical ingredients as Remdesivir and Favipiravir. We are contemplating full-cycle production, discussing the matters concerning expedited registration with the patent holder and Ministry of Health, adjusting laboratory synthesis, and waiting for the testing results for Remdesivir drug in the US and in Europe. We will receive the first results in early May. Concurrently, we are working on our own drug that is also positioned as a drug for the coronavirus disease (it is currently subjected to diverse clinical trials), and in addition, we are adjusting synthesis on a fast-track basis.

The construction of your plant in Pushkin is about to be completed. What is the current status of the project? Has the coronavirus affected the construction works?

We are now completing the construction phase and finalising the commissioning works. I hope that we will be able to complete them by the end of May. The coronavirus did affect the project. We encountered delays with the supplies of certain basic construction components, but I hope that the project will be completed in June.