

## Pyotr Rodionov: International expansion opportunities are currently limited

*GEROPHARM CEO explains the ways to maintain insulin supplies in Russia while continuing export activities*

Notwithstanding the logistical challenges and the inevitable restructuring of supplier relationships, GEROPHARM, major Russian insulin manufacturer, intends to continue exporting its products. GEROPHARM CEO Pyotr Rodionov admits that exporting these medicines is more profitable as insulin prices are higher abroad. On the other hand, the products that the pharmaceutical company supplies within Russia are more advanced. GEROPHARM is confident in its ability to both fully cover insulin needs of diabetic patients in Russia and to invest in production expansion. Mr. Rodionov tells the Vedomosti how the company intends to reach a 5-fold increase in the production of the vital medicines within a short period of time and why GEROPHARM has no intention to be sold despite the apparent interest of investors.

**Vedomosti: Initially, the import phase-out policy was meant to be implemented in case of partial or full isolation of Russia from the rest of the world. Did it prove to be efficient in the pharmaceutical sector? You appear to be ready for the crisis that virtually every sector faces since the beginning of the special military operation in Ukraine and the unprecedented sanctions against our country that ensued.**

**Rodionov:** Isolation is not a mere remote possibility anymore. Every week, we experience supply interruptions or see some Western importers refuse to deal with Russia. That is why we had to completely revise our list of suppliers. By the end of the year, we hope to find alternative suppliers of all key components in China, India, and Russia.

**Vedomosti: Crisis is another opportunity. Is it the case in the current context? On one hand, there is a chance to expand your domestic market presence; on the other hand, you have a time-tested position as an international company that sold insulins to Venezuela, had agreements with Cuba, and intended to enter the European market.**

**Rodionov:** This year, we were supposed to have a preliminary audit and quality assessment started in the EU, but we did not get a chance. We have to postpone our plans of expansion in EU and focus on the domestic market for the time being.

In the mid-term perspective, we have to expand a projected market share or at least to be ready to do so, should the need for insulins increase. If it happens, we will have to stock up materials and revise our production cycles. By various estimates, GEROPHARM's share of the Russian insulin market is 14 to 20 %, in monetary and physical terms, respectively. Therefore, to fully cover insulin needs of diabetic patients in Russia, we have to increase our output 5 times. As it cannot be done with a flip of a switch, we are getting prepared.

We do not give up on our ambition to become a number one supplier in terms of share in all market segments. At the same time, international expansion opportunities are currently limited. In 2023, we are planning to transfer the insulin biosimilar technology to our Uzbekistan partner's site. Besides, we keep on doing business in Latin America and make a good progress there. Currently, a potential for our product market authorisation and further sales is under discussion with a whole pool of countries.

**Vedomosti: Which countries are these?**

**Rodionov:** Well, almost every Latin American country. We never counted on gaining 100 % of the Russian market as there are other manufacturers and competitors. However, our insulins are sought for in other countries. This demand translates to profits that are funnelled in investments, new products development, and new projects.

**Vedomosti: Are pricing policies significantly different in Russia and other countries?**

**Rodionov:** Insulin prices in Russia are some of the lowest globally. For example, same products are 20 times more expensive in the US than in Russia. In Venezuela and Brazil, prices are higher than in Russia as well. With a stable exchange rate, the difference was by a factor of 2–2.5.

**"We cannot give up on exports"**

**Vedomosti: In case your company must fully cover the needs for insulin in Russia, would you increase your capacities by cutting on what you currently export?**

**Rodionov:** We cannot fully give up on exports as we have commitments to patients in other countries. Every life matters and depends on our steady supplies. It means we have to both continue shipping under the existing contracts and cover the needs in the domestic market.

**Vedomosti: Then you have no sufficient capacities to cover the domestic demand. How are you going to expand them? Do you have any free production lines ready to be launched?**

**Rodionov:** In normal situation, we can increase our output incrementally over a year. If we need to instantly increase output by a factor of 5, it would take us some time to pile up stocks. Having contracts for certain product volumes, we procure hundreds of items of various materials. Starting from excipients to glassware, cardboard, and insulin pen injectors. For increased stock, we would need to expand warehouses and revise our logistics, we would have to hire more personnel to be able to produce more products per unit time.

**Vedomosti: Suppose it is a fact that you have to increase your output 5-fold. How much time would it take you to prepare?**

**Rodionov:** In a normal situation, it would take about one year. In emergency, twice shorter time but at a higher cost.

In addition, we need some actions at the government level to be taken to secure demand for increased product volumes. Without that, there is no point manufacturing products that would end up sitting on warehouse shelves.

**Vedomosti: What is the current export situation, did you cut shipments?**

**Rodionov:** No, we did not, we stick to our commitments under the existing contracts. Both in Russia and abroad.

**Vedomosti: In 2021, what percentage of proceeds your exports accounted for versus domestic sales?**

**Rodionov:** Our exports accounted for 17 % of our annual revenues from insulin sales segment (Vedomosti: GEROPHARM did not disclose the amount of revenues; under Russian Accounting Standards, RAS, the company's 2021 revenues amounted to RUB 11.5 bln). Some 35 % of this number are the packaged products. In Russia, we mostly sell insulins in single-use pen injectors while cheaper vials are exported.

We export our products to 12 countries. These are CIS countries (except Ukraine), Georgia, and Venezuela. Of these, Venezuela, Azerbaijan, and Kazakhstan buy insulins through bidding procedure. The regions with export expansion potential are Latin America, South-East Asia, Middle East, North Africa, and the Persian Gulf.

### **"Insulin prices were hardly adjusted"**

**Vedomosti: The pen injectors you use, do you buy them in Russia or abroad?**

**Rodionov:** We buy them from Swiss company Ypsomed. So far, the shipments continue; however, we are willing to start manufacturing pens in Russia. It is not an easy task but it is doable.

**Vedomosti: Are you fine with the Russian Government's approach to raising maximum sale prices for the drugs listed as vital and essential medicinal products (including insulins)? Under this approach, one may apply for price revision only if one can prove there is a risk of shortage of such drug.**

**Rodionov:** Pricing in the Russian market is one of the priority items on our agenda. Over the years, insulin prices were hardly adjusted. At the same time, the situation with raw materials and components procurement changed, and the costs increased even though later the foreign exchange market stabilised.

The prime cost of a package of five pen injectors is quite high as the manufacturing process is complex and requires high precision. Like other companies, including foreign insulin manufacturers, we applied for and were granted the Federal Antimonopoly Service's authorisation to re-register bidding prices for certain drugs in pen injectors.

Unfortunately, it does not affect the actual prices of public procurement as long as the minimum minimorum principle is applied to calculation of a starting maximum contract price of re-registered insulins. Therefore, Order No. 1064H of the Ministry of Health has to be amended as soon as possible in order for the price re-registration to start working.

At the same time, diabetic patients have nothing to worry about. They will continue getting their insulin using either a federal or a regional quota, with no risk to continuous treatment.

**Vedomosti: Which of the imported products are you trying to replace with alternatives?**

**Rodionov:** There are lots of products. Take some of such seemingly simple products as glucose. We use a special anhydrous glucose in insulin substance production. Our current supplier, Spanish company Panreac withdrew from the Russian market. Currently, we are in the process of switching to suppliers of the same products from other countries. To date, we have secured procurement of filters, caps, stoppers, plungers for branded products and insulins. In August, we will start testing a new glass primary package.

**Vedomosti: From Asian countries?**

**Rodionov:** Yes, mostly from Asia. We are looking in Russia as well. We look for more suppliers even for those products for which future shipments are secured. For each item, we try to get two to three alternative suppliers, preferably outside Europe, the US, and Japan.

**Vedomosti: Does the quality of new suppliers' products significantly differ from the previous ones'? Can it affect your products?**

**Rodionov:** No, it does not affect our products, for sure. There is a small risk it might affect the efficiency of the manufacturing process. When a supplier is replaced, it takes some time to adjust the process back to the original efficiency. Suppose, we used to produce 1 kg of product in one manufacturing cycle; now, we will make 950 g or perhaps more. We just have to try and see what happens. In any case, all the raw materials are controlled for quality as always.

**"For the time being, we are not ready to let anyone in"**

**Vedomosti: The Russian Direct Investment Fund (RDIF) is one of your shareholders. As of 2020, it held 1.96 % in the company's authorised capital. How did the sanctions against RDIF and its CEO Kirill Dmitriev affect the company?**

**Rodionov:** So far, they did not. Currently, they hold some 2 % of our equity and have no say in the company's decision making.

**Vedomosti: Do you plan to re-acquire RDIF's stock or offer it to any new partners?**

**Rodionov:** It is not a priority for us at the moment.

**Vedomosti: Is anyone interested in the company right now?**

**Rodionov:** It's a perfect time to acquire, isn't it? When there are good offers and free cash at hand, one should not hesitate, go ahead and buy as the prices lowered. From time to time, potential investors look towards GEROPHARM. Just recently, we talked with one of them about equity investment. However, for the time being, we are not ready to let anyone in. Instead, we prefer to invest our own funds in new projects.

**Vedomosti: And who is interested?**

**Rodionov:** Funds and banks.

**Vedomosti: Russian ones?**

**Rodionov:** Of course, there are no others anymore.

**Vedomosti: Which funds does the company invest in development? Own or borrowed?**

**Rodionov:** It terms of current investments, these are both own and borrowed funds. As to serious investments in major projects such as setting up new large-scale production, those are on hold for now.

One of the reasons is the access to technologies. Should we decide to do business with European or American suppliers, it would either be too expensive, or take too long, or they would plain out refuse to sell to Russia. We have no other choice but look for alternative suppliers or somehow make do just like Iran used to do, purchasing equipment through third parties. That would cost additional 30–100 %.

**Vedomosti: How much would it cost to increase production output 5 times?**

**Rodionov:** At present, we do not have such estimates. Funds are too expensive now. Prime cost of our products is high, and it is too expensive to keep 2 to 3-month stock. It would mean freezing the funds in those stocked materials.

**Vedomosti: How much are you losing this way?**

**Rodionov:** I cannot give you exact numbers; however, prime cost of low-margin products is increasing significantly.

**Vedomosti: Do you have sufficient own funds to hire more personnel, adjust equipment for auxiliary components from new suppliers?**

**Rodionov:** We are not in need of additional funds.

### **“We are competing for workforce”**

**Vedomosti: What percentage of imported materials and components is there in a finished product?**

**Rodionov:** It differs from product to product. In vials, the percentage of imported raw materials and consumables is not so significant. In single-use pen injectors however, the percentage is much higher as we buy the pens in Switzerland. That is, from 10 to 70 %. In substance production, we use imported sorbents and excipients; however, most of the raw materials are produced in Russia.

**Vedomosti: Do you face any issues with maintenance of imported equipment?**

**Rodionov:** So far so good, almost all of our equipment is new. We keep a year's supply of spare parts. However, with supplies halted, we may face difficulties. That is why even now we are looking for alternative equipment suppliers from India, China, and within Russia. That applies to production of new drug products as well.

**Vedomosti: How much has the cost of insulin production grown? How much can it impact the ultimate price?**

**Rodionov:** I cannot give you any exact numbers as these change along with everyday developments and may be irrelevant on the date of publication. With the exchange rate stabilised, there is at least some certainty. When the rate bounced by 10 roubles up and down, we avoided buying.

The percentage of the logistic component reached some absurd values in terms of cost. International seaports do not ship to Russia, while the number of available air routes has drastically decreased. The only option is the land routes: by roads or railroads. There, freight rates increased because of higher traffic load. There are certain issues with freight insurance, and all this put together affects our prime cost.

Also, we still cannot tell how the global energy crisis would affect our prime costs. So far, its tide just has not reached us.

**Vedomosti: GEROPHARM produces all types of insulins except ultra-rapid acting insulins. Do you plan to start their production?**

**Rodionov:** Ultra-rapid acting insulins (for example, ultra-rapid acting insulin aspart) represent a minor modification of the existing product. We have already developed its analogue and its clinical studies are about to start this year. We expect to start producing the entire insulin line in Russia in the next few years.

**Vedomosti: The IT sector is facing an exodus of developers. Is there a similar situation with scientists?**

**Rodionov:** It's a shame that the support measures announced by the government proved to be inefficient and so many companies left the Russian market. I really hope most of them will come back when the situation improves. There is more mobility in the IT sphere, while it is impossible to move factories in our sector. People working at these factories are bound to them in a certain way. Hopefully, we will be able to raise the pay of the production personnel.

**Vedomosti: While others cut costs and downsize staff, you are willing to raise pays?**

**Rodionov:** Specialists tend to migrate from one manufacturer to another within the sector. In a situation when the cost of living is racing up and the competition for workforce is so intense, we have no other choice but to do it [raise the pay].

### **“No one ever paid cash for their insulin”**

**Vedomosti: How much insulin have Russian patients stocked up during the feverish demand in March?**

**Rodionov:** Not so many managed to stock up for the future. Perhaps, some made a two-month stock but there cannot be too many lucky guys like this.

Historically, the share of insulin retail in Russia is very low, not more than 2–3 % of the total sales. In other words, there are very few people who pay their own cash for insulin. Public procurements account for the major part. I mean, no one ever paid cash for their insulin; people normally get it for free at special pharmacies.

That is, during the feverish demand in March, pharmacies had two or three cartons of insulin which were immediately bought by those patients who were worried about potential interruptions in supplies. At the same time, manufacturers mostly focus on public tenders and have no firm retail commitments. That is why retail pharmacies were short on insulin. As soon as retail pharmacies have enough of it, there will be no panic and the product will sit on shelves as no one would need it.

At the same time, the refugees still have no access to free insulin. They have no other choice but buy it.

**Vedomosti: How many of them are there according to your estimation?**

**Rodionov:** We never estimated the number of such patients but it cannot be on the order of thousands. We did our best to help those who asked for help through our website, for example.