Viktor Dmitriev,

General director,

Association of the Russian pharmaceutical manufacturers

We still hope for the best and continue our preparations for the Pharmtech expo despite the coronavirus pandemic that has spread almost to all countries of the globe. What awaits us after the pandemic comes to an end? What impact will the pandemic have on the Russian pharmaceutical industry? Will it drive development of domestic manufacturers? What will the Russian pharmaceutical industry be like?

Everything depends on the readiness of the society and authorities for changes. My colleagues, whom I meet at conferences, always say that things should not stay the way they were before. At the end of the day, instead of causing new issues the pandemic revealed and exaggerated the existing ones.

Firstly, executive and legislative authorities of all tiers say that we need to use the Soviet experience. This means a uniform governance without any split-responsibility management. Nowadays, the Ministry of Health Care, the Ministry of Industry and Trade, the Russian Federal Health Care Supervision Agency, and the Federal Anti-Monopoly Agency are involved into the industry governance. In fact, no one is responsible for anything. The pandemic outbreak revealed that the person responsible for supply of face masks does not make them, and the person who makes the face masks is not responsible for prices, etc. That's why Mikhail MURASHKO, Minister for Health Care, said that we had to think of establishing the main pharmacy agency. Whatever the title - main or not, pharmacy or Russian FDA or drug supervision agency - drug turnover should be controlled by one authority. The majority of deputies and representatives of various authorities and institutions, to whom I already have spoken, support this concept. However, the Ministry of Industry and Trade is not eager to delegate the powers to a single authority. Various ministries, agencies and departments were established after the enactment of the technical supervision law in 2004 or later. The Ministry of Industry and Trade was entrusted with the state policy (industrial policy), law making, financial support drivers, and setting up conditions for export development. Control and supervision of the turnover - development, manufacturing, storage, clinical testing, preclinical testing, sales and disposal - were supposed to end up with one authority being part of the health care system. This is how it works all over the world - in the USA, Europe, Japan and even the Eurasian Economic Community that happens to be our closest neighbour. We are the only country to establish such a split-responsibility system that is disturbing even in the everyday life let alone an emergency of the kind we are facing now. Hence, it is very important for us to understand after the pandemic that we need to use the positive reach experience of our past that came handy during the Great Patriotic War, the Chernobyl disaster, and the Spitak earthquake.

Secondly, I hope that officials will be more responsible for the documents they sign and the resolutions they make. No one is responsible for anything in our country. The health care system has been undermined, many hospitals shut down and the capacities of the remaining ones materially reduced. In fact we are currently building anew the contagious disease hospitals that were shut down in the past. No sanctions have been imposed for such faults.

Thirdly, we need to change the employment structure. The number of production workers is materially lower and that of officials - dozens of times higher than in the 1990s. The number of sales persons instead of production workers has been significantly increasing ever since. As a result, we depend on the import, make a short list of articles and mostly buy from abroad. We start asking ourselves "What should we do?" and "Where do we buy?" once we face an emergency. With the borders closed, the pharmaceutical industry, which was believed to have levelled up, found itself on a thin ice with many risks beneath it. We cannot import active pharmaceutical ingredients. We cannot import intermediates to make the required active pharmaceutical ingredients in Russia. Even if we import intermediates we know that we do not have Russian equipment to make active pharmaceutical ingredients out of these raw materials.

I fear that if we do not address these issues we will not stay where we are but level down instead. Political willpower and more active social standing are required to level up.

What will the pharmaceutical industry be like? I doubt that it will drastically change. We have not interrupted our activities for a single minute under the given conditions. On the contrary, manufacturers of antiviral drugs and antibiotics have been ramping up their production and running three shifts. We have supplied drugs all over Russia and almost to all countries of the Eurasian Economic Community. We started exporting our drugs even to countries where they were not registered. Having seen that our drugs are more efficient and cheaper than their US or European equivalents, governments of such countries asked us to export the Russian drugs. The fact that other countries show such interest in our drugs confirms their quality and competitiveness. Hence, we need governmental support to develop this field of activities. We also need a financial, structural (i.e. involvement of all departments of trade representatives and embassies), and surely legal support. Sometimes, we cannot import a product because we need to obtain a permit first. However, we need to get lots of certificates and get them signed, approved, etc. by several authorities to obtain it. Decree No. 441 on accelerated registration of medicines is an example of successful debureaucratization and removal of unnecessary formalities. It provides for using off-label drugs and filing documents in soft copy but is time-limited and remains in force until the year end. This decree let us make resolutions that have remained unaddressed for many years within two days. We could do things that previously were forbidden. And those that previously were allowed we could do even faster than before. We cannot go back to the previous standing. This is the most important call. We will level down if we decide to keep the things they were before.

What will happen to the medicine marking project? Will the marking due dates postponed again due to the pandemic?

A bill draft to postpone the marking due dates is in place because the pandemic is undoubtedly a good reason for a postponement. Currently, equipment commissioning teams cannot arrive from abroad. A few days ago, the Ministry of Industry and Trade and the Government found a way to let them come to Russia. We (the industry) should provide details of such team members to arrive to Russia to the Ministry of Industry and Trade that in its turn will send it to the Russian Federal Security Agency. The Russian Federal Security Agency will process the list and make a resolution whether or not to let them come. They will have to undergo a two-week quarantine according to the existing rules. Availability of flights is another issue here. Nowadays, there are next to no flights. Therefore, even if all lists are approved the commissioning teams are most likely to arrive at best by the end of June and start working after the quarantine no sooner than in July. If we want to maintain the drug supply level, July 1 is out of question. I am 97% sure that the due date will be postponed. I leave the remaining 3% to the authority and financial capabilities of the owners of the Promising Technologies Development Centre. I fear that it will cause a collapse of the drug supply and produce a wave so big that it will wash away more than merely the Promising Technologies Development Centre. Hence, it is absolutely wrong to start marking in summer. I heart from the State Duma that the bill draft was ready.

What do you think of online drug trade? Will online drug trade boost?

Nowadays, not all relevant documents are in place. Firstly, the guideline for issuing an online trade permit was recently published. Secondly, both the approving authorities and the industry had lots of questions to the draft decree on approving the guideline for issuing an online trade permit. I am well aware of this issue since as a Co-Chairperson I took part in all meetings of the work team to implement the "regulatory guillotine". Adopting persons knew that the document was raw. They adopted it under a condition that we would analyse the facts and amend it in the year end. Many persons have questions regarding a prerequisite for obtaining a remote trade permit. A pharmacy organization for instance should have a chain of at least 10 pharmacies or a license for pharmaceutical activities for at least a year. Furthermore, pharmacies will need to arrange a designated zone - a premise or a place to be used as online order storage. However, there are no criteria of such zone. A reasonable question is how this zone will be checked and whether or not there will be any requirements to area and outfitting thereof. What should it feature? A table, a chair, or a specific lamp? It is not clear now. There were also some questions to the terms used - delivery and transportation. Is a delivery by car deemed a transportation? Nowadays, drug transportation is also subject to licensing. Things are clear if a pharmacy is in immediate proximity to a delivery designation. However, the nearest pharmacies are located many kilometres away from some destinations in Russia. Hence, orders should be transported by an all-terrain vehicle or a tractor. These questions remain open.

We hope that the system will come to life over 9 months and we will see the first results of its operation. And amend it accordingly. Everyone agrees now that the decree is far from perfect. However, we did not have time to make it perfect, since our task was to let people get drugs without leaving their home. We will improve the document, and our experience will help us make it better.

Are there any plans to review the prices for life-saving and essential medicines due to a shortage of Chinese pharmaceutical raw materials and limited import of foreign drugs?

This is also one of the questions we keep asking. The laws of economics cannot be fooled. The cost of finished drugs will go up now that the USD exchange rate increased and pharmaceutical ingredients are purchased for currency. It is one thing if they let us increase the prises. If not, companies will have to review their profit. It will depend on the portfolio of a company, i.e. whether or not it can compensate for the loss. If not, production of loss-making drugs will be shut down. Everyone knows it. Andrey BELOUSOV, First Vice Premier, and deputies underline it. There is no solution so far. However, this issue has not reached its pivotal point yet. I believe that pricing will be discussed in the near future at the meeting of the cross-fractional drug supply team that is scheduled in the beginning of June to discuss the marking status.

What do you expect from Pharmtech & Ingredients this year? What companies do you think you will see there? What products?

First of all, we expect that the expo will be held offline instead of a video conference. The online communication will never replace the real life. However, I meet most colleagues at video calls more often than offline.

As usual, we expect to get new contacts and contracts at the expo. I believe that under the given circumstances a greater focus will be made on science and scientific developments, hence, participants will show more interest in cooperation with companies that are ready to start clinical research as well as in lab equipment and substations.

The standing of the main pharmacy agency, let's call it this way whether and whenever it comes to life, will play the major part in it. We need to make a stock of local drugs. We have already gained experience in booking export products and waiting for them at closed borders. If we buy local products, we will get an opportunity to ramp up the turnover and, hence, continually purchase raw materials and upgrade equipment.

These are the three aspects we are looking forward to seeing at the expo, and we hope to see them happen.