

### **BIOCAD registers rheumatoid arthritis as an indication for Ilsira**

The Russian Ministry of Health has approved the use of Ilsira drug ([levilimab](#)) for the treatment of rheumatoid arthritis (RA), expanding the current list of the indications of the drug, as BIOCAD company stated.

“According to the data of the phase III of SOLAR clinical trial, subcutaneous administration of Ilsira at a dose of 162 mg once a week in adult patients with active RA demonstrated high efficacy and good safety profile. 71% of patients who were administered the drug achieved a 20% improvement according to the ACR criteria at week 12 of the study, and after 24 weeks of treatment, 52% had low activity of rheumatoid arthritis (DAS28-CRP).

<https://gxpnews.net/en/2021/06/biocad-registers-rheumatoid-arthritis-as-an-indication-for-ilsira/>

### **The Ministry of Health describes the steps towards the transition to electronic dossiers for licensing**

The decree of the Government of the Russian Federation No. 291 “On Licensing of Medical Activities” now includes the provision that no copies of documents have to be submitted if the corresponding information is entered in the federal register of medical organizations and the federal register of medical workers of the Uniform State Health Information System (EGISZ), Pavel Pugachev, Deputy Minister of Health of the Russian Federation, said at the VI conference “Digital Industry of Industrial Russia.”

It is mentioned that this is actually a step towards the transition to electronic dossiers for licensing. In addition, according to the new rules, all medical organizations, regardless of the form of ownership, must submit information to the EGISZ.

At the moment, work is continuing on the new version of Federal Law No. 143 “On Acts of Civil Status”. The document has already been adopted in three readings by the State Duma of the Russian Federation and it is expected to have been signed by the president in the near future. According to the new provisions, the federal register of medical birth and death certificates will be formed within

the framework of the EGISZ. This is necessary for the provision of services within the framework of “My Health” super-service. The tool will be instrumental in the analysis of the quality of medical care and demographic indicators.

“We understand it very well that it is only possible to make forecasts and analyze the current state of the industry, as well as to manage patients, if the information systems provide complete and relevant data. The target model is the transition to control and supervision on the basis of primary data provided by medical organizations to the EGISZ,” Pavel Pugachev said.

The session participants also noted that the vertically integrated system, which is being created by the state, will help companies engaged in the development of digital solutions for medicine. It will become possible to use the consolidated data without spending resources on independent collection of information.

<https://gxpnews.net/en/2021/06/the-ministry-of-health-describes-the-steps-towards-the-transition-to-electronic-dossiers-for-licensing/>

### **[The Circle of Kindness has started accepting applications for the purchase of an unregistered drug against SMA](#)**

The Circle of Kindness Foundation has started accepting applications for the purchase of Zolgensma, unregistered in Russia, for children with spinal muscular atrophy, [RIA Novosti](#) reports with reference to the press service of the Ministry of Health.

At the moment, medical documents are being collected and the exact need for the drug in the regions of the country is being clarified, as well as dosages and delivery times.

“Zolgensma will be provided to children under the age of two years who have the indications for it based on the decision of medical boards,” the statement says.

SMA leads to a gradual loss of motor functions, and the affected individuals lose the ability to move and have breathing difficulties. Two drugs for the treatment of the disease have been registered in Russia: nusinersen (Spinraza) and risdiplam.

<https://gxpnews.net/en/2021/06/the-circle-of-kindness-has-started-accepting-applications-for-the-purchase-of-an-unregistered-drug-against-sma/>

### **Russia's government allocates 25 billion rubles for the treatment of coronavirus**

25 billion rubles will be allocated for the treatment of coronavirus. The [order](#) was signed by Prime Minister Mikhail Mishustin.

The funding will have been received by the regional budgets within 30 days. The Federal Fund for Mandatory Medical Insurance (FOMS) has been appointed responsible for the distribution of the funds.

During his visit to the Moscow hospital No. 40 in Kommunarka, Mikhail Mishustin said that the source of funding was the retained balance of FOMS funds. Thanks to the regulatory framework prepared in advance, it was possible to quickly make a decision on additional support for the regions in connection with the spread [of COVID-19](#), he stressed.

“At least 700,000 [COVID-19](#) hospitalizations will be funded by these resources. People will continue to receive treatment completely free of charge, under their CHI policy, in all regions of the country,” the prime minister said at the meeting of the Coordinating Council to Combat the Spread of the Novel Coronavirus on June 25.

An order is also being prepared on the allocation of 25 billion rubles for the provision of specialized and high-tech medical care by federal medical organizations. The source for the tranche was also the unallocated resources of the FOMS.

“Such medical care should continue to be available to citizens. For many people, this is not just a matter of restoring their health: it is about saving lives,” Mikhail Mishustin emphasized at a meeting of the Coordinating Council.

<https://gxpnews.net/en/2021/06/russias-government-allocates-25-billion-rubles-for-the-treatment-of-coronavirus/>

### **The Gamaleya Center states the time required to update the vaccine so that it protects against new variants**

The Gamaleya Center will be able to modify its coronavirus vaccine within a week if the vector technology is registered, as Alexander Ginzburg, the director of the Center, said on Sunday in an interview with the Rossiya-1 TV channel.

“If a new strain, with a dramatically different sequence of S-protein that binds to our receptors, emerges, then, most likely, it will be necessary to use updated vaccine variants. If the vector technology is registered, then we can really respond to the new threats within a week,” [TASS](#) quotes him as saying.

The director of the Center also noted that the antibodies in those vaccinated with Sputnik V are more active in their action against the virus than the antibodies in those who recovered from [COVID-19](#). According to him, “memory cells” can protect the body from the virus, but antibodies are more effective against new strains.

As Ginzburg said earlier, the Gamaleya Center specialists have developed a technology that makes it possible to quickly create vaccines effective against several variants of COVID.

<https://gxpnews.net/en/2021/06/the-gamaleya-center-states-the-time-required-to-update-the-vaccine-so-that-it-protects-against-new-variants/>

### **[Binnopharm Group has started production of levofloxacin hemihydrate pharmaceutical substance](#)**

Binnopharm Group, a pharmaceutical manufacturer, has registered levofloxacin hemihydrate production and released the first 100 kg of the pharmaceutical substance, which is the main active component for Levofloxacin antibiotic, the company reports.

“The Russian Ministry of Health has included this drug in the [COVID-19](#) treatment protocols. The substance produced by the Group is included in the registration certificate of the drug manufactured at the Binnopharm Group site in Kurgan: now the company is able to perform the whole cycle of this medicine production. By the end of 2021, the production of Levofloxacin will also be localized at the facility in Obolensk village of the Moscow Region,” the report says.

“Levofloxacin is an antibiotic used for the prevention and treatment of [COVID-19](#). In order to meet the sharply increased demand for this drug from patients and medical institutions, we increased the production by 3.3 times in 2020, which meant that the workload of our production facilities in Kurgan reached the capacity limit,” says Rustem Muratov, General Director of Binnopharm Group. “Taking into account the high social significance of the drug and the fact that we

are the largest manufacturer of the antibiotic, it was decided to organize its production at the production site of OAO Sintez from our own pharmaceutical substances.”

According to AlphaRM, in 2019, Levofloxacin sales in Russia amounted to 13.9 million packages, and in 2020, the consumption of this antibiotic increased to 30 million packages.

<https://gxpnews.net/en/2021/06/binnopharm-group-has-started-production-of-levofloxacin-hemihydrate-pharmaceutical-substance/>

### **The Chumakov Center will release about 300,000 doses of Covivak next week**

The Chumakov Center of the Russian Academy of Sciences will release about 300,000 doses of the Kovivak coronavirus vaccine next week, as Konstantin Chernov, Deputy General Director for project activities and innovations of the center, said in an interview with the Echo of Moscow radio station.

“The current capacity allows us to make about 10 million doses per year. More than a million doses have already been produced. Next week, about 300 thousand doses will pass quality control,” [TASS](#) quotes him as saying .

Chernov added that the Chumakov Center is not in charge of the distribution of the vaccine.

“Everything is distributed by a special commission of the Ministry of Health,” he said.

On February 19, the Ministry of Health registered Covivak, an inactivated whole-virion vaccine developed at M. P. Chumakov Federal Scientific Center for Research and Development of Immunobiological Drugs of the Russian Academy of Sciences.

<https://gxpnews.net/en/2021/06/the-chumakov-center-will-release-about-300000-doses-of-covivak-next-week/>

### [Peskov commented on the WHO's complaints about Sputnik V](#)

The competent Russian agencies are strictly monitoring the production of [COVID-19](#) vaccines for the compliance with all the applicable rules, Dmitry Peskov, the press secretary of the head of state, told [TASS](#).

“The competent control agencies certainly control the process. They do it in the strictest manner possible,” Peskov stated.

According to Peskov, the manufacturers of Sputnik V in Russia have adjusted the production process taking into consideration the complaints from the WHO. He noted that it is impossible to meet the demand for Sputnik V abroad in the short term, but gradually all the obligations on its supply will be fulfilled.

Earlier, it became known that the European Medicines Agency (EMA) did not make any critical comments either on the production or on the clinical trial of the Russia's Sputnik V vaccine.

<https://gxpnews.net/en/2021/06/peskov-commented-on-the-whos-complaints-about-sputnik-v/>

### [Tomsk researchers create a test system for detecting tumor cells](#)

Researchers from the Tomsk National Research Medical Center (NRMC) are developing test systems to identify circulating tumor cells that give rise to metastases in breast cancer, the [press service](#) of the Ministry of Education and Science reports.

“The unique test systems will also help researchers determine the sensitivity of these cells to chemotherapy and targeted therapy in order to prescribe effective treatment,” the report says.

The NRMC researchers emphasize that hematogenous (distant) metastasis is the main cause of death in cancer patients; in most cases, it does not respond to therapy. Cells from which hematogenic metastases are formed, or those which are responsible for the formation of a favorable ground for the development of a tumor in distant organs, can be found in the blood of patients. Researchers of the Tomsk NRMC are searching for minimally invasive cell markers to assess the risk of hematogenous metastases development and prevent metastasis early.

“There is an urgent need for comprehensive studies of various types of circulating tumor cells,” Liubov Tashireva, senior researcher at the Department of General and Molecular Pathology at the Oncology Research Institute, said. As part of a team of researchers, she develops new approaches to the prediction and prevention of long-term metastasis.

According to the researcher, the obtained priority data on the mechanisms and markers of distant metastasis will form the basis for a personalized approach to breast cancer treatment.

With the help of the developed test systems, it will be possible to identify cancer stem cells, which are responsible for metastases, among a heterogeneous population of CTCs. The selection of drugs to target these cells will prevent metastasis.

The study was supported by a grant from the Russian Research Foundation No. 19-75-30016 “New technology for predicting and preventing distant metastasis based on the detection of circulating metastases-initiating and niche-forming cells and their specific targets”.

<https://gxpnews.net/en/2021/06/tomsk-researchers-create-a-test-system-for-detecting-tumor-cells/>

### **[The EU has lost its legal bid against AstraZeneca for failure to supply vaccine on time](#)**

The European Union has lost a lawsuit against AstraZeneca over the supply of vaccines to Europe, [Reuters](#) reports.

Earlier, AstraZeneca had committed to deliver 300 million doses to EU by the end of June, but production delays led it to revise this to 100 million vaccines. This affected the course of vaccination in Europe.

AstraZeneca said the EU had lost its legal case, but European Commission President Ursula von der Leyen said the court ruling supported its view that the Anglo-Swedish pharmaceutical giant had failed to honour its commitments.

The court also ruled that AstraZeneca must deliver only 80.2 million doses by a deadline of Sept. 27. The drugmaker said it would “substantially exceed” that. The court said in a statement that AstraZeneca must deliver 15 million doses by July 26, another 20 million by Aug. 23 and a further 15 million by Sept. 27, to

reach a total of 50 million doses, which are in addition to 30 million that had been given to the EU when the legal case began.

“Should it miss the deadlines in the ruling, AstraZeneca would face a penalty of 10 euros per dose not delivered”, the judge said,

Previously, the EU had asked all 300 million doses to be delivered by the end of September. EU data shows the company has already shipped nearly 70 million doses, more than half of which were delivered after the start of the legal proceedings.

<https://gxpnews.net/en/2021/06/the-eu-has-lost-its-legal-bid-against-astrazeneca-for-failure-to-supply-vaccine-on-time/>

### **Russia receives the first batch of Oncaspar for children**

A batch of Oncaspar for providing emergency medical care to children with acute lymphoblastic leukemia has arrived in Russia, Moscow Endocrine Plant [reports](#).

“Onkaspar (INN pegaspargase) is under patent protection and is not registered in Russia, so the government instructed FSUE “Moscow Endocrine Plant”(under the Ministry of Industry and Trade of Russia) to organize the purchase, import and delivery of 1970 packages of Onkaspar”, the report says.

“The first batch of Onkaspar will go to 70 medical organizations in Russia. The prompt cooperation between the Government and executive authorities and the experience accumulated by Moscow Endocrine Plant have made it possible to provide the necessary medical care to our children in a timely manner. The import of the remaining 575 packages of Onkaspar to the Russian Federation is scheduled for August this year,” said Denis Manturov, Minister of Industry and Trade of Russia.

Less than a month after the decree of the government of the Russian Federation, Moscow Endocrine Plant imported the first batch of 1,395 packages of the vital drug.

<https://gxpnews.net/en/2021/06/russia-receives-the-first-batch-of-oncaspar-for-children/>

### [Geropharm R&D Center becomes the first accredited commercial GLP laboratory in the Russian Federation](#)

The Geropharm Research Center has become the first commercial laboratory in Russia and also the first center that conducts in vitro tests in accordance with GLP standards, the pharmaceutical manufacturer reports.

“The pharmacology laboratory of the Research Center has confirmed its compliance with international GLP standards by receiving national GLP accreditation. The inspection was carried out by experts of the Federal Service for Accreditation of the Russian Federation,” the report says.

At the moment, there are 12 centers in Russia that have received GLP accreditation, eight of them are functioning and are included in the register of testing laboratories that comply with the principles of good laboratory practice. Four more have their GLP compliance status temporarily suspended. These organizations are state-owned and conduct in vivo tests (on laboratory animals). The Geropharm Research Center has become the 13th accredited GLP center in Russia.

“When building the operations of the company’s research center, we were guided by the GLP standards from the very beginning. In 2019, the first step was taken in obtaining documentary confirmation of this: we passed the voluntary certification of the Russian Register Certification Association, and now we have received national GLP accreditation. This is a new phase and the beginning of a long way to accreditation with foreign, namely, European regulators. It will make a significant contribution to the company’s export potential development and will help Geropharm products to enter the EU markets sooner,” said Roman Dray, Director of Geropharm Research Center.

The GLP rules are used worldwide as a mandatory quality standard for preclinical laboratory tests. They establish a single, rigorous system that ensures the objectivity and reproducibility of the data. It concerns all the processes in the organization, including the procedure for conducting research, the equipment used, staff qualifications, reporting methods, and other aspects.

<https://gxpnews.net/en/2021/06/geropharm-rd-center-becomes-the-first-accredited-commercial-glp-laboratory-in-the-russian-federation/>

## [The State Duma Adopted in the First Reading the Bill on Off-Label Drug Use in Pediatrics](#)

The State Duma adopted in the first reading a bill allowing off-label drug use in the treatment of seriously ill children, the press service of the State Duma [reports](#). According to one of the authors of the bill, Deputy Chairman of the State Duma Irina Yarovaya, the patients concerned include those with cancer, rheumatological, haematological, or nervous system diseases, as well as with a number of other conditions.

It is explained that the use of off-label drugs is due to the fact that no alternative therapies are available, and there are no post-registration trials that could expand the patient population to which the medicines can be administered.

“Today, most of the instructions for the use of antitumor drugs in the world do not contain indications for the possibility of their pediatric use, i. e., children with cancer, rheumatological, haematological, or nervous system diseases, as well as with a number of other conditions, are currently treated solely on the basis of off-label drug use. Thus, without the use of off-label drugs, it is impossible to cure children with severe chronic diseases,” Irina Yarovaya said.

“We have done a lot of joint work with the Government of the Russian Federation, which helped us to reach a fully shared understanding of the fact that the proposed approach and procedures for off-label drug use for children with cancer and children with hematological diseases can be considered in a broader context, which will solve some of the related problems that exist in the provision of medical care to children in general,” she added.

Yarovaya emphasizes that off-label drugs included in clinical recommendations or prescribed by a medical commission “will be allowed for treating children, subject to the established procedure for mandatory notification of the patient.” Before starting off-label drug use, the attending physician must inform the patient or their legal representative about the drug, the expected effect of the treatment, the safety of the drug and the degree of risk to the patient.

“The novelties proposed by the draft law have been discussed and supported by leading Russian pediatric specialists and form pediatric procedures and treatment options that are accommodating, safe and adjusted to the general system of medical care,” the explanatory note to the bill says.

The bill also offers a solution to the issue of ensuring the continuity and integrated approach to the treatment of a disease with the onset in childhood, i.

e., after reaching the age of 18, a teenager can continue to receive treatment in a children's center where it was started.

<https://gxpnews.net/en/2021/06/the-state-duma-adopted-in-the-first-reading-the-bill-on-off-label-drug-use-in-pediatrics/>

### **Rosneft Launches Apteka Avto Service at Gas Stations**

Rosneft has launched Apteka Avto, pharmacies along roads, at gas stations, where customers now can buy over-the-counter medicines and non-medicinal drugs, [Vedomosti](#) reports.

At the moment, the service is operating in pilot mode at two gas stations in St. Petersburg, and in the near future it will be available at two more gas stations in the Leningrad Region.

“The opening of the new network of road pharmacies not only expands the list of goods and services provided by Rosneft gas stations, but also improves public health, which is especially important in the current epidemiological situation,” Avril Conroy, Rosneft's Vice President for Retail Business, told the publication.

The project is implemented jointly with Aloe, a federal pharmacy chain with more than 300 pharmacies. For this purpose, the sales areas of the gas station were reconstructed to comply with the requirements for equipment and storage conditions required for the sale of medicines.

<https://gxpnews.net/en/2021/06/rosneft-launches-apteka-avto-service-at-gas-stations/>

### **The Law Authorizing the Production of Medicines without the Consent of the Patent Owner was Signed**

Russian President Vladimir Putin has signed a federal law that authorizes the government to make decisions, under international agreements, on the use of an invention for the production of a medicinal product in Russia for export purposes without the consent of the patent owner. The document is published on [publication.pravo.gov.ru](http://publication.pravo.gov.ru), the official portal of legal information.

According to the law No. 212-FZ of 11.06.2021, the patent owner will receive notification of the use of their invention as soon as possible, as well as subsequent proportionate compensation.

After taking a decision on such use, the Cabinet of Ministers will have to specify the volume of production of the medicinal product necessary for the needs of a foreign state to which the product will be supplied. In this case, the packaging of the manufactured drug will feature a special sign.

The document also gives the Cabinet of Ministers the right to approve the procedure for sending a notification, the basis and the procedure for making a decision on the production of a medicinal product to be exported.

<https://gxpnews.net/en/2021/06/the-law-authorizing-the-production-of-medicines-without-the-consent-of-the-patent-owner-was-signed/>

#### **[The bill on the inclusion of vaccination against COVID-19 in the vaccination calendar was removed from the State Duma agenda](#)**

The State Duma of Russia has removed from its agenda the issue of including the coronavirus vaccine in the vaccination calendar, [RIA Novosti](#) reports, with reference to Vladimir Zhirinovskiy, LDPR leader.

The website of the lower chamber of the Russian parliament [states](#) that “the date of the future consideration of the bill has not been determined.”

In August 2020, the country registered Sputnik V, the world’s first [COVID-19](#) prevention product developed by the Gamaleya Research Institute of Epidemiology and Microbiology. Russia now has several other vaccines against [COVID-19](#): EpiVacCorona (developed by the Vector Center of Rospotrebnadzor) and KoviVak from the Chumakov Center of the Russian Academy of Sciences.

In early May, the Ministry of Health registered Sputnik Light, the first component of Sputnik V. According to Kirill Dmitriev, the head of the Russian Direct Investment Fund (RDIF), the light version is mainly intended for foreign markets which have significant epidemic foci.

<https://gxpnews.net/en/2021/06/the-bill-on-the-inclusion-of-vaccination-against-covid-19-in-the-vaccination-calendar-was-removed-from-the-state-duma-agenda/>

### **The Ministry of Industry and Trade granted the authority to approve the rules for medicines storage**

The Ministry of Industry and Trade of the Russian Federation has developed amendments to the Regulations on the Ministry of Industry and Trade approved by Government Order No. 438 of June 5, 2008, [the agency reports](#). The amendments grant the Ministry of Industry and Trade the authority to approve the rules of storage of medicinal products for human use.

At the moment, the entities involved in the circulation of medicines, including manufacturers, are guided by the departmental acts of the Ministry of Health on storage issues.

“At the same time, storage at production sites is also regulated by the GMP rules of the Eurasian Economic Union approved by the decision of the Council of the Eurasian Economic Commission No. 77 of November 3, 2016,” the Ministry of Industry and Trade reports.

The ministry plans to issue a departmental act, which will oblige pharmaceutical companies to store their products in accordance with the rules of the EAEU, as well as, if necessary, the establishment of specific storage requirements for certain categories of medicines, e. g., those containing potent substances.

“The changes were developed with the support of the Ministry of Health of Russia and a working group that included representatives of the expert and business community for the implementation of the “regulatory guillotine” in the field of pharmaceuticals and medical products. They are aimed at eliminating the redundancy in the medicines storage requirements for manufacturers,” the Ministry of Industry and Trade commented in its statement.

<https://gxpnews.net/en/2021/06/the-ministry-of-industry-and-trade-granted-the-authority-to-approve-the-rules-for-medicines-storage/>

### **In the EAEU, trials duplication will be reduced in respect of pharmaceutical production transfer**

According to EAEU [press service](#), the Board of the Eurasian Economic Commission approved the guidelines for the member states of the Union on the transfer of production and analytical methods in pharmaceutical drugs manufacturing.

“The document will reduce the number of redundant studies in situations when medicines production is transferred, without compromising the quality and safety of the products”, the report states.

The Guidelines also regulate the documentation of the process of manufacturing transfer from one site to another and quality control of medicines, and provides explanations on the necessary sequence of actions in the organization. The document can also be used in other biomedical applications, for example, when transferring analytical techniques between clinical laboratories.

<https://gxpnews.net/en/2021/06/in-the-eaeu-trials-duplication-will-be-reduced-in-respect-of-pharmaceutical-production-transfer/>

### **Cristiano Gomes appointed as Managing Director MSD Russia**

Cristiano Gomes appointed as Managing Director of MSD Russia and EAEU countries, effective June 1, 2021. Cristiano succeeds Marwan Akar, who managed the company for the last four and a half years, and who was recently appointed as President and Managing Director of Merck Canada.

**Cristiano Gomes:** *“I have been working in pharmaceutical industry for more than 15 years, and I am happy to continue my career in Russia running such a strong team. In the upcoming years our company will continue its efforts in increasing patients’ access to innovative medicines and vaccines with the focus on oncology and infectious diseases, taking into account Russian healthcare system’s priorities.”*

Cristiano was born and raised in São Paulo, Brazil and holds a bachelor’s degree in Communications and an MBA in Marketing. He started his career in MSD in 2006 as a sales representative in Brazil. In 2013 he led the Oncology sales and marketing teams before later joining the Latin America regional team as Chief Marketing Officer. Before his promotion to Managing Director of MSD Russia, Cristiano was Managing Director for MSD Colombia and Ecuador for the past two years.

<https://gxpnews.net/en/2021/06/cristiano-gomes-appointed-as-managing-director-msd-russia/>

### **Pharmasintez will create the production of cardiological drugs in the Tyumen region**

The company “Pharmasintez” will create a large production of cardiological drugs in the Tyumen region, the volume of investments in the project will be

more than 4 billion rubles. The corresponding agreement on Thursday at the St. Petersburg International Economic Forum (SPIEF) was signed by the governor of the region Alexander Moor and the president of Pharmasintez Vikram Singh Punia. According to the head of the region, the new import substitution production will close 20% of Russia's need for medicines for the treatment of cardiovascular diseases. The volume of investments in the project will amount to more than 4 billion rubles, it is planned to create about 200 new jobs.

<https://gxpnews.net/en/2021/06/pharmasintez-will-create-the-production-of-cardiological-drugs-in-the-tyumen-region/>

### **Moscow will increase production of innovative drug for HIV treatment**

Pharmaceutical companies GSK and Servier agreed at SPIEF to increase the production of a drug for the treatment of HIV infection at the Moscow factory "Servier RUS." This was reported on Wednesday by the press service of the department of investment and industrial policy of the capital. "Within the framework of SPIEF, international pharmaceutical companies GSK and Servier agreed to increase the production of a drug for the treatment of HIV infection at the Moscow company Servier RUS. This will allow you to flexibly increase the production of medicines, taking into account the needs of the country's health system," the report said. On the part of GSK, the statement was signed by Sean Riley, vice president and CEO of GSK Pharma Russia, on the part of Servier, Christoph Wlodarczyk, general director of the Servier RUS pharmaceutical plant, signed his signature. "30 large and medium-sized pharmaceutical enterprises operate in Moscow. For the capital, this is one of the priority industries: already now 13% of the country's family industry employees work with us, providing the production of 20% of medicines in Russia. The Moscow plant "Servier RUS" not only makes a significant contribution to the city economy, but also provides vital products. Back in 2016, the company was given the status of an industrial complex, which involves significant tax benefits. This helps the company increase the production of essential drugs," said Alexander Prokhorov, head of the Department of Investment and Industrial Policy of Moscow.

<https://gxpnews.net/en/2021/06/moscow-will-increase-production-of-innovative-drug-for-hiv-treatment/>

### **The Ministry of Health has developed a procedure for monitoring the movement of drugs for the Circle of Good wards**

The Ministry of Health of Russia has developed and put up for public discussion on the portal regulation.gov.ru a draft order that approves the procedure for monitoring the movement and accounting for medicines and medical products purchased for a specific child, the ward of the Circle of Good Foundation, according to the FV.

This is necessary to quickly resolve the issue of targeted provision of newly identified patients with medicines, as well as when the need for medicines changes in the event of a change in treatment tactics.

Monitoring is carried out in relation to medicines and medical products purchased in accordance with the Decree of the Government of the Russian Federation dated 06.04.2021 No. 545 through an information resource containing information about children with serious life-threatening and chronic diseases, including rare diseases.

In April, it was reported that a special information resource will operate in Russia to help seriously ill children who need the support of the Circle of Good Foundation. The rules of its jurisdiction were approved by the government. The information resource will be included in the unified state information system in the field of healthcare. It will collect applications from regions for receiving a particular medicine, applications from parents on the basis of which such applications were created, a list of diseases with which the fund works will be posted. The government approved the procedure for helping children at the expense of the Circle of Good Foundation on May 21. The decree states that the funds can be used to pay for unique and resource-intensive methods of treatment, the purchase of drugs, including those not registered in Russia. The possibility of paying for treatment abroad, including covering the costs of transport and accommodation, is also prescribed.

<https://gxpnews.net/en/2021/06/the-ministry-of-health-has-developed-a-procedure-for-monitoring-the-movement-of-drugs-for-the-circle-of-good-wards/>

### **Duopharma Biotech signs agreement to supply Sputnik V to Malaysia**

Duopharma Biotech Berhad, one of Malaysia's leading pharmaceutical companies, has signed an agreement with the government to supply Malaysia with 6.4 million doses of the Russian anti-COVID19 vaccine Sputnik V. This was

reported in a press release of the company. The delivery of the vaccine depends on the fulfilment of the conditions of the preliminary supply arrangements, including the approval of the vaccine by the Drug Control Authority of Malaysia. According to a publication in The Lancet, one of the most respected medical journals in the world, the effectiveness of the Sputnik V vaccine against coronavirus was 91.6%. In addition, it is one of three vaccines in the world to have efficiency rating of more than 90%, there were also no serious side effects associated with the vaccine, the press release noted. The Sputnik V vaccine has been successfully registered in 66 countries. The three countries that registered Sputnik V – Hungary, Slovakia and Argentina – are members of PIC/S. According to the RDIF, to date, 20 million people around the world have received the vaccine.

<https://gxpnews.net/en/2021/06/duopharma-biotech-signs-agreement-to-supply-sputnik-v-to-malaysia/>

#### **Murashko: Production of Sputnik V will be localized in Uzbekistan**

The authorities of Russia and Uzbekistan agreed to localize the production of the Sputnik V coronavirus vaccine in the republic, the Uzbek side has already selected a site for the release of the drug, Russian Health Minister Mikhail Murashko told RIA Novosti on Friday. Murashko visited to Uzbekistan on Friday, where he met with President of the Republic Shavkat Mirziyev. The minister added that the Uzbek side has selected a production site for the release of the Russian vaccine, a project is being worked out. On May 24, a meeting was held between Russian President Vladimir Putin and Kyrgyz President Sadyr Zhaparov. One of the topics of negotiations between the presidents of Russia and Kyrgyzstan in Sochi was the fight against the pandemic. Vladimir Putin recalled what he said at the EAEU summit at the end of last week – Russia will localize the production of a vaccine for coronavirus in the countries of the Union, including in Kyrgyzstan.

<https://gxpnews.net/en/2021/06/murashko-production-of-sputnik-v-will-be-localized-in-uzbekistan/>

