Production of Sputnik V vaccine launched in Serbia

The Russian Direct Investment Fund (RDIF) and the Torlak Institute of Virology, Vaccines and Serums announced the launch Russian Sputnik V vaccine production in Serbia, the RDIF reports.

Serbia became the first state in Southern Europe to produce Sputnik V. It is possible to export the drug to other countries of the region in future. Anti-COVID19 vaccination with a Russian drug started in Serbia on January 6, 2021.

“In accordance with the agreements reached between the RDIF and the Torlak Institute, the production of the Sputnik V vaccine was successfully launched in Serbia in a short time. Serbia was the first European state started production of a Russian vaccine. Since the beginning of this year, the drug has been actively used to vaccinate the people, and due to the establishment of local production, the scale of vaccination will be able to significantly increased, “said Kirill Dmitriev, CEO of the RDIF.

To date, the Sputnik V vaccine has been registered in 60 countries with a total population of 3 billion people. The effectiveness of Sputnik V is 91.6%, as confirmed by the publication of data, in The Lancet, one of the oldest and most respected medical journals in the world. The vaccine is built on a proven and well-studied platform of human adenoviral vectors and uses two different vectors for two vaccinations during vaccination, providing longer immunity than vaccines using the same delivery mechanism for both vaccinations.

<https://gxpnews.net/en/2021/04/production-of-sputnik-v-vaccine-launched-in-serbia/>

Vasily Osmakov appointed First Deputy Minister of Industry and Trade

Deputy Minister of Industry and Trade of Russia Vasily Osmakov will move to the post of First Deputy Minister, where he will replace Sergei Tsyb, who left the post. The corresponding decree is published on the portal of legal information disclosure.

“Sergey Tsyb will make history of industrial policy as a person who came from medicine in 2007 and first created a new department from scratch, and then the Pharma 2020 program. I appreciate both his competence and organizational qualities. And human. I am sure we will remain kind comrades for life. Vasily Sergeevich deserved this promotion due to impeccable work both for Manturov and earlier for Khristenko. While still a student, he prepared analytics for decision-making at the level of deputy prime minister. Since its formation in 2004, the Ministry of Industry and Energy has gone through all the strategies. And it may be time to recognize that he is one of the co-sponsors of the concept of global energy security and global energy dialogue. It was his debut back in 2006 at the G8 summit in St. Petersburg. I am sure that such a basis will also be useful for solving drug safety problems in Greate Eurasia, “said Stanislav Naumov, chairman of the board of the Association of Pharmaceutical Manufacturers of the Eurasian Economic Union (APM ES), ex-deputy minister of industry and trade of the Russian Federation.

Osmakov was born in 1983 in Moscow, graduated from Lomonosov Moscow State University and graduate school at the State University of Management. He started his career in 2004 at the Ministry of Industry and Energy of Russia, where he rose to the rank of chief specialist in the department of public relations. From 2008 to 2012 he was an assistant and adviser to the Minister of Industry and Trade of the Russian Federation. In 2012, he headed the Department of Strategic Development and Project Management of the Ministry of Industry and Trade. August 31, 2016 took the post of deputy minister.

Candidate of Economic Sciences.

<https://gxpnews.net/en/2021/04/vasily-osmakov-appointed-first-deputy-minister-of-industry-and-trade/>

It will be able to produce drugs in Russia without the permission of the copyright holder

The State Duma in the third reading approved a government bill that allows the release of drugs without the consent of the patent holder. It was initiated by the Federal Antimonopoly Service as part of the implementation of the National Plan for the Development of Competition for 2018-2020 Years.

According to the document, the Cabinet will be able to decide on the use of an invention, utility model or industrial model without the consent of the patent holder in case of extreme need, “related to the provision of defense and security, including the protection of the life and health of citizens.” The rightholder must be notified as soon as possible and paid commensurate compensation. The methodology for determining the amount of compensation and the procedure for its payment will be determined by the Cabinet.

The authors of the bill indicate that the changes will provide an opportunity to make up quickly for the absence or lack of foreign patented drugs and medical devices in the country. The document emphasizes that the forced influence of the state on an unscrupulous copyright holder is provided by international acts.

<https://gxpnews.net/en/2021/04/it-will-be-able-to-produce-drugs-in-russia-without-the-permission-of-the-copyright-holder/>

WHO will inspect production of Sputnik V vaccine

World Health Organization delegates intend to conduct an inspection of the production of Sputnik V in May and June, the date of assessing the safety of the vaccine will be determined no earlier than July, RIA Novosti reports with reference to the WHO plan for assessing the safety of drugs against [COVID-19](https://gxpnews.net/terminologiya/covid-19/).

A specific date for assessing the safety of the Russian vaccine by WHO experts will be determined after receiving all additional data and conducting all inspections. For other vaccines that have already received WHO permission for use in emergency situations, inspections at work were not carried out, the document says.

The Sputnik V vaccine has been approved in almost 60 countries with a total population of more than 1.5 billion people. In terms of the number of approvals received by state regulators, Sputnik V ranks second in the world. Vaccine efficacy at 91.6% is confirmed by the publication of data in the leading medical journal The Lancet.

<https://gxpnews.net/en/2021/04/who-to-inspect-production-of-sputnik-v-vaccine/>

Russia and Iran sign an agreement in the field of biotechnology

Russian RegionTransNeft and Iranian Inter Naft Gas Prom Pars (INGP Holding) signed an investment agreement in the field of medicine, biotechnology and bioengineering in Tehran, IRNA news agency reported.

On the basis of the agreement, RegionTransNeft plans to implement a number of projects in Iran in the near future, namely, to launch the production of antiretroviral and anti-COVID drugs. In addition, the group of promising projects included:

– Production of various important medicines with different effects on different human diseases;

– Production of biologically active substances which are in high demand in international markets;

– Creation of several autonomous networks of small specialized medical clinics.

We are also talking about the creation of a specialized Iranian company to implement the following two investment programs:

– Establishment of a network of manufacturing enterprises for the production of medical equipment and for the production of medical devices, followed by sales in Iran and elsewhere in the world;

– Establishment of a trade network for the sale of medical equipment and medical products in Iran and elsewhere in the world.

The parties also agreed on the formation of a network of research commercial medical laboratories. In addition, the agreement includes a clause on the opening of a private Russian-Iranian company. All of the listed projects will be implemented at the expense of investment capital from Russia with the active participation of the company RegionTransNeft.” The company’s activities will be carried out with the support of authorized capital in the amount of €400 thousand.

<https://gxpnews.net/en/2021/04/russia-and-iran-sign-an-agreement-in-the-field-of-biotechnology/>

Ministry of Health issued permission for EpiVakKorona-N vaccine clinical study

The Ministry of Health of Russia issued permission to conduct phase I and II clinical trials of the Epivakkorona-N coronavirus vaccine of center Vector. This is evidenced by the data of the state register of permits for research of the ministry.

Volunteers between the ages of 18 and 60 will take part in the tests.

Research started on April 8, 2021, and will stop in September 30, 2021,” the message is clarified on the State Register of Medicines (SRM) website.

“EpiVacCorona-H” is a vaccine based on peptide antigens, according to registry data.

<https://gxpnews.net/en/2021/04/ministry-of-health-issued-permission-for-epivakkorona-n-vaccine-clinical-study/>

RDIF asked Slovakia to return Sputnik V vaccine batch

The Russian Direct Investment Fund (RDIF) asked the Slovak government to return the Sputnik V vaccine batch due to violations of the terms of the contract, the fund said in a statement published on the official Twitter of the vaccine.

“The Russian Direct Investment Fund (RDIF) asked the Slovak government to send the vaccine to an EU certified laboratory for testing and sent a letter asking to return the vaccine batch due to numerous contract violations so that it could be used in other countries,” the statement said.

Vaccine developers said that, in violation of the existing contract, the Slovak State Institute of Drug Control conducted Sputnik V tests in a laboratory that is not part of the EU’s network of official drug control laboratories, despite the fact that such laboratories were available.

Earlier, Magdalena Yurkemikova, secretary of the State Institute of Drug Control, who acts as a pharmaceutical regulator in the republic, reported that the Russian coronavirus vaccine, the first batch of which arrived in Slovakia on March 1, does not correspond to the characteristics that were indicated in The Lancet magazine.

<https://gxpnews.net/en/2021/04/rdif-asked-slovakia-to-return-sputnik-v-vaccine-batch/>

Pentaxim vaccine production is planned to be localized in Russia in 2022

The production of the Pentaxim five-component vaccine (the development of the French Sanofi) is planned to be localized in Russia next year, TASS reports citing Maxim Stetsyuk, executive director of the Nanolek manufacturing company.

“We are in the localization process, our plans have moved a little bit to 2022,” Stetsyuk said as part of the Innoprom international industrial exhibition.

According to him, currently the production of the drug is localized in Russia by 30-40%. The vaccine is used to prevent diphtheria, tetanus, whooping cough, polio and hemophilic infection. Vaccine included in the Russian national calendar of preventive vaccinations.

<https://gxpnews.net/en/2021/04/pentaxim-vaccine-production-is-planned-to-be-localized-in-russia-in-2022/>

The state will provide benefits for Sputnik V vaccine production

The production of a Sputnik V vaccine will be organized as part of an agreement on the protection and promotion of investment (APPI), Izvestia reports citing a letter from First Deputy Prime Minister Andrei Belousov to President Vladimir Putin.

Chairman of the Board of Directors of R-Farm (the initiator company of the project) Alexei Repik told that the APPI was concluded in January 2021, and now work on the territory of the Technopolis Moscow special economic zone worth about 11 billion rubles. close to the final. He noted that production is expected to start in mid-April.

In total, the Ministry of Economic Development has already concluded 29 APPI totaling more than 1 trillion rubles, their implementation will generate 20 thousand jobs and help in the implementation of the goals of national projects.

Earlier, Moscow Mayor Sergei Sobyanin said that the plant will produce up to 10 million doses of vaccine per month, when it will reach full capacity.

<https://gxpnews.net/en/2021/04/the-state-will-provide-benefits-for-sputnik-v-vaccine-production/>

EEC approves procedure for use of national RC (registration certificate) for medical products

Council of the Eurasian economic commission approved changes in the Agreement on the uniform principles and rules of medical products (products of medical purpose and medical equipment) circulation within the Eurasian Economic Union of December 23, 2014 which allow to use national registration certificates of medical products until the end of their validity period, EEC reports.

The amendments provide that medical products registered according to the national norms of one of the EAEU states can be issued in the territory of this state before the expiration of national registration certificates. It will be possible to change the registration file of the medical product according to national rules until the end of 2026.

“For medical devices with a national registration certificate with a limited validity period, it is possible to re-register such medical devices until December 31, 2026 with the issuance of indefinite national registration certificates,” the EEC said.

Manufacturers will be able to register medical products according to national standards only until the end of the year. From January 1, 2022, registration will be held in accordance with the requirements of the EAEU.

<https://gxpnews.net/en/2021/04/eec-approves-procedure-for-use-of-national-rc-registration-certificate-for-medical-products/>

The first major batch of EpiVakKorona was sent to the Russian regions

More than 230 thousand sets of doses of the EpiVakKoron coronavirus vaccine of the Novosibirsk Scientific Center Vector were sent to 40 constituent entities of the Russian Federation, TASS reports citing the press service of Rospotrebnadzor.

“The first large batch of Epivakkoron vaccine was sent to the regions. On April 5, more than 230 thousand sets of Epivakkoron vaccine were sent to more than 40 areas of the Russian Federation, “the report said.

The supervisory authority noted that the Natsimbio holding of Rostec state corporation is engaged in the supply of the drug to the regions.

Epivakkorona was the second anti-COVID19 vaccine registered in Russia in October 2020. Later, the developers received permission to conduct post-registration studies, including among the elderly.

<https://gxpnews.net/en/2021/04/the-first-major-batch-of-epivakkorona-was-sent-to-the-russian-regions/>

RDIF presents robot-conveyor for coronavirus tests production

The Russian Direct Investment Fund (RDIF) introduced a robot-conveyor that produces 300 [COVID-19](https://gxpnews.net/terminologiya/covid-19/) tests per hour and does not require staff, TASS reports citing CEO of the fund, Kirill Dmitriev.

“Now we will announce some new breakthrough: our tests are in great demand at airports and other places outside the laboratories, and we will announce a robot-conveyor that can do 300 tests per hour and does not require highly qualified personnel. We believe that this will be a key decision not only for Russia, but also for other countries – to automate the passing of tests outside the laboratories, “said the general director of the fund during a meeting with Russian President Vladimir Putin.

According to Dmitriev, the RDIF has already delivered more than 15 million tests in 17 countries, including the UAE, Austria, France. The head of the RDIF also noted that the fund with partners is engaged in the production of the world’s first registered drug against COVID-19 based on the Avifavir favipiravir.

“About 300 thousand have already been delivered to Russia, we saved tens of thousands of lives. Capacities doubled to 200 thousand courses per month, and we delivered the drug to 30 countries, “he said.

Earlier, the Indonesian Drug and Food Control Agency (NADFC) issued a registration certificate for the Russian anti-COVID19 drug Avifavir (favipiravir). Since the beginning of June 2020, Avifavir has been delivered to all regions of Russia.

<https://gxpnews.net/en/2021/04/rdif-presents-robot-conveyor-for-coronavirus-tests-production/>

Sputnik V deliveries may become a major area of non-resource exports of Russia

Russia can earn $10-15 billion in 2021 from sales of anti-COVID19 vaccine Sputnik V, reports RT, citing Alpari specialists information and Analytical Center.

In addition, over two years of deliveries of the drug abroad, the country’s revenue can reach $30 billion, experts say. They note that such indicators are comparable to the main items of Russian exports. Economists do not exclude that in the next few years, the implementation of the coronavirus vaccine will become one of the major areas of non-resource supply to Russia to other countries.

“The total revenue from the sale of the drug may be about $30 billion. Given that everyone wants to burn and vaccinate, respectively, we will receive about half of this amount this year and half in the next, “said Alexander Razuvaev, head of the analytical center.

According to the latest data from the Russian Direct Investment Fund, the Sputnik V vaccine has been approved in 59 countries with a total population of over 1.5 billion people. The cost of one dose of the drug for international markets is less than $10 (two doses are needed to vaccinate one person).

<https://gxpnews.net/en/2021/04/sputnik-v-deliveries-may-become-a-major-area-of-non-resource-exports-of-russia/>

Gamalei Center develops Way to Adapt COVID-19 Vaccine to New Strains

The Gamalei National Research Center for Epidemiology and Microbiology has developed a way to update the coronavirus vaccine, RIA Novosti reports with reference to the Institute CEO, Alexander Ginzburg.

“This is the same technology based on adenoviral vectors, where, according to the sequence of the spike protein, with a changed primary structure, a new sequence is synthesized literally during the day, and the next day it is inserted into the used vector, and practically you have a genetic engineering design that allows it to be used as a vaccine drug, ready,” said the scientist.

According to Ginzburg, the question is now being discussed whether in this case it is necessary to conduct all phases of the trials of the new vaccine. He recalled that in world practice there are examples when the drug was checked on a limited sample of up to a hundred people.

“If it gives the same adequate protective effect, but already against a new strain, it can be launched immediately into mass production. I hope that in the near future similar acts will be adopted with us, “said the scientist.

In August 2020, the Ministry of Health of Russia registered the world’s first vaccine for the prevention of [COVID-19](https://gxpnews.net/terminologiya/covid-19/), developed by the Gamalei Research Center, which was called Sputnik V. Also registered in Russia are EpiVakKorona vaccines from the Vector Center of Rospotrebnadzor and KoviVak from the Chumakov Center of the Russian Academy of Sciences.

<https://gxpnews.net/en/2021/04/gamalei-center-develops-way-to-adapt-covid-19-vaccine-to-new-strains/>

RDIF and Chinese TopRidge Pharma agree to produce Sputnik V vaccine

The Russian Direct Investment Fund (RDIF) and the Chinese TopRidge Pharma (a division of Tibet Rhodiola Pharmaceutical Holding) have entered into an agreement of the production in China of more than 100 million doses per year of the Sputnik V coronavirus vaccine, the fund reports.

This volume of production will provide vaccination for more than 50 million people. RDIF and TopRidge Pharma also agreed to cooperate in the registration and further promotion of the vaccine in China.

TopRidge Pharma will be eligible to distribute the vaccine to mainland China, as well as Hong Kong, Macau and Taiwan after regulatory approval.

“The partnership with Tibet Rhodiola will expand the production capabilities for the production of the Sputnik V vaccine in China and ensure the supply of the drug to partners to defeat the pandemic. China is one of the largest hubs for the production of the Sputnik V drug, and we are ready to expand partnerships with manufacturers in the country to meet the growing demand for the Russian vaccine. The Sputnik V vaccine with an efficiency of 91.6% is one of the best tools for fighting coronavirus in the world, “said Kirill Dmitriev, CEO of the RDIF.

The Sputnik V vaccine is registered in 58 countries with a total population of over 1.5 billion people. Its efficacy is 91.6%, as confirmed by the publication of data, in The Lancet, one of the oldest and most respected medical journals in the world. The drug is built on a well-studied platform of human adenoviral vectors and uses two different vectors for two vaccinations during vaccination, providing longer immunity than vaccines using the same delivery mechanism for both vaccinations.

<https://gxpnews.net/en/2021/04/rdif-and-chinese-topridge-pharma-agree-to-produce-sputnik-v-vaccine/>

Murashko denied reports of the approach of the third wave of coronavirus in Russia

The infection rates of [COVID-19](https://gxpnews.net/terminologiya/covid-19/) in Russia don’t indicate the possibility of a third wave of the virus spread, said Health Minister Mikhail Murashko on March 30.

“We are talking about the incidence today. It decreases every day, and the wave is characterized by a subsequent rise. Today, the incidence is declining daily, but it’s premature to talk about the third wave, but you can’t relax, “the minister said.

He noted that reports of the approach of another wave of morbidity that appeared on this day in the media are misinformation.

Earlier, TASS, citing Deputy Minister of Health of the Russian Federation Tatyana Semenova, reported that the infection rates of COVID-19 in Russia indicate a possible third wave of the spread of the virus in the country.

<https://gxpnews.net/en/2021/04/murashko-denied-reports-of-the-approach-of-the-third-wave-of-coronavirus-in-russia/>

The National Vaccination Calendar will expand in Russia

The national vaccination calendar of Russia will be expanded to the most complete list of vaccines against infections, TASS reports citing the government’s press service.

The Cabinet notes that the plan of measures approved by Prime Minister Mikhail Mishustin to implement the Strategy for the Development of Immunoprophylaxis of Infectious Diseases until 2035 involves expanding the national calendar of preventive vaccinations and vaccinations according to epidemiological indicators.

“There will be included the most complete list of infectious diseases that are controlled by vaccines… In particular, the national calendar will replenish vaccines against chickenpox, rotavirus infection, meningococcal infection, human papillomavirus,” the report said.

In addition, “the issue of vaccinating adults against pneumococcal infection, as well as immunization against pertussis of adults and older children, will be worked out.” Also, according to the press service of the Cabinet, it is planned to develop vaccination programs for certain categories of citizens, including people with chronic diseases, pregnant women and the elderly.

<https://gxpnews.net/en/2021/04/the-national-vaccination-calendar-will-expand-in-russia/>

The world’s first anti-COVID19 vaccine for animals registered in Russia

The world’s first animal [COVID-19](https://gxpnews.net/terminologiya/covid-19/) vaccine developed by Rosselkhoznadzor scientists has been registered in Russia, TASS reports citing Konstantin Savenkov, deputy head of the supervisory authority.

“Sorbed inactivated vaccine for carnivores” Carnivak-Cov, “developed by the Federal Center for Animal Health, subordinate to the Rosselkhoznadzor, is registered in Russia. It is the first and to date the only preventive drug for animal COVID-19 in the world, “said Savenkov.

According to him, in April, mass production of the vaccine may be launched on the basis of the country’s largest platform of the Federal Center for Animal Health.

Savenkov added that in the clinical trials of the vaccine, which started in October last year, dogs, cats, sands, minks, foxes and other animals were involved.

“The results of the studies make it possible to conclude about the harmlessness of the vaccine and its high immunogenic activity, since all the vaccinated animals tested in 100% of cases developed antibodies to coronavirus,” the representative of the Rosselkhoznadzor added.

Savenkov also noted that Rosselkhoznadzor scientists continue to study how long immunity is developed after the introduction of the drug.

“To date, this indicator is at least six months,” he said.

Interest in Russian development is shown by other countries, including Greece, Poland, Austria, as well as the USA, Canada and Singapore. The vaccine is of particular importance because, as noted by the World Animal Health Organization (OIE), some species of animals are susceptible to COVID-19.

<https://gxpnews.net/en/2021/04/the-worlds-first-anti-covid19-vaccine-for-animals-registered-in-russia/>

Russian pharmaceutical company Geropharm will start to produce insulin in Venezuela

The government of Venezuela and the Russian company Gerofarm have concluded an agreement on long-term cooperation, which involves the localization of insulin production in the Bolivarian Republic, the press service of the pharmaceutical company reports.

The document was signed by the CEO of Gerofarm Petr Rodionov and the Minister of People’s Power of Health of Venezuela Carlos Alvarado. The ceremony was also attended by Deputy Chairman of the Russian Government Yuri Borisov, Executive Vice President of the Bolivarian Republic Delsi Rodriguez and others.

The long-term agreement covers the period from 2021 to 2026. As part of the project, Gerofarm acts as an investor.

“The company will transfer to ESPROMED BIO the know-how for the production of ready-made insulin preparations, invest in the modernization of existing equipment on the site, and will also transfer the technology for bottling a ready-made dosage form of human genetically engineered insulins and provide training for personnel who will be engaged in production,” the statement said.

The company will continue to supply insulin analogues from Russia.

The Venezuelan government, in turn, will provide the necessary assistance to the pharmaceutical manufacturer in the implementation of the project and guarantees the purchase of insulin products for the company in the future for the next five years – until 2026.

“It is worth noting that, according to the data of the Ministry of People’s Power for Health of the Bolivarian Republic of Venezuela, the five-year need for the country’s health system is at least 34 million packages of insulin,” the Geropharm said in a statement.

The company has been supplying insulin drugs to Venezuela since 2019. At that time, international manufacturers almost completely stopped the supply of this drug to the country. At the same time, there are no local insulin producers in Venezuela. At the moment, Gerofarm has delivered more than 3 million packages of drugs to Caracas.

<https://gxpnews.net/en/2021/04/russian-pharmaceutical-company-geropharm-will-start-to-produce-insulin-in-venezuela/>

First PCR test to detect malaria registered in Russia

The Central Research Institute of Epidemiology of Rospotrebnadzor developed and registered the country’s first PCR test for diagnosing malaria, the supervisory authority said.

“The test has high analytical sensitivity, allowing infection detection even at low infection rates, as well as in the incubation and initial periods of the disease. This method avoids false positive results of microscopic analysis in the case of analysis of blood preparations of poor quality or by a specialist with insufficient qualifications, “the report said.

The AmpliSens set of reagents Plasmodium spp/P. falciparum/P. vivax-FL is designed to diagnose diseases caused by a group of malaria plasmodia (unicellular organisms) by qualitatively determining their DNA by PCR with hybridization-fluorescent detection of amplification products. The sensitivity of the method reaches 1-0.1 kl/μl of blood, which far exceeds the capabilities of current diagnostic methods – light microscopy and rapid tests. They have less sensitivity, as a result of which they can give false negative results.

The CNI Epidemiology kit can be used to screen residents of endemic territories, diagnose acute and chronic stages of disease in imported cases of malaria, as well as an additional method to microscopy in malaria-endemic territories.

The department notes that the registration certificate for the set of reagents was received on March 10, 2021, the number of the registration dossier RD-38593/103748 from 30.12.2020.

In 2020, 57 imported cases of malaria were registered in the Russian Federation, in January-February four imported cases.

<https://gxpnews.net/en/2021/03/first-pcr-test-to-detect-malaria-registered-in-russia/>

RDIF and China’s Shenzhen Yuanxing Gene-tech agree to produce Sputnik V

The Russian Direct Investment Fund (RDIF) and the Chinese biotechnology company Shenzhen Yuanxing Gene-tech have entered into an agreement on the production of more than 60 million doses of the anti-COVID19 Sputnik V vaccine, the fund said.

Produced volume will ensure the vaccination of more than 30 million people. The start of commercial production of the drug is scheduled for May 2021.

The Sputnik V vaccine has already been registered in 57 countries with a total population of over 1.5 billion people. The effectiveness of Sputnik V is 91.6%, as confirmed by the publication of data in The Lancet, one of the oldest and most respected medical journals in the world.

Sputnik V is one of the best coronavirus vaccines in the world, approved by over 50 countries. Partnership with Shenzhen Yuanxing Gene-tech for the production of Sputnik V in China will expand the opportunities for the production of additional volumes of the Russian drug, the demand for which is increasing around the world, “said Kirill Dmitriev, CEO of RDIF.

The vaccine is built on a proven and well-studied platform of human adenoviral vectors and uses two different vectors for two vaccinations during vaccination, providing longer immunity than vaccines using the same delivery mechanism for both vaccinations.

<https://gxpnews.net/en/2021/03/rdif-and-chinas-shenzhen-yuanxing-gene-tech-agree-to-produce-sputnik-v/>

The Government of the Russian Federation has established a procedure for centralized coronavirus data collection

Information about [COVID-19](https://gxpnews.net/terminologiya/covid-19/) in Russia will be temporarily centrally collected and analyzed in an interdepartmental format. The corresponding government decree is published on the website of the Cabinet.

Federal and regional organizations conducting molecular genetic studies of viruses will have to send information of genome decoding to the Central Research Institute of Epidemiology of Rospotrebnadzor.

“The results of genome decryption should be transmitted to the Central Research Institute of Epidemiology within 24 hours of their receipt. The procedure for interaction, requirements for the composition and volume of information will be approved by Rospotrebnadzor… Mutations of a new coronavirus infection can potentially affect the epidemic process as well as the course of the disease. Prompt monitoring of the change in new coronavirus infection is extremely important for a timely response, “the document says.

It is planned that the Central Research Institute of Epidemiology will collect information and send it to Rospotrebnadzor. Based on these data, for example, when identifying new strains of coronavirus, the department will assess the epidemiological situation and decide on the organization of preventive measures.

<https://gxpnews.net/en/2021/03/the-government-of-the-russian-federation-has-established-a-procedure-for-centralized-coronavirus-data-collection/>

The vaccine of the Chumakov center “KoviVak” launched into civil circulation

The third, all-virion Russian anti-COVID19 vaccine KoviVak of the Chumakov Center launched into civil circulation, Interfax reports. The head of the Ministry of Education and Science Valery Falkov on March 25 launched the production of the drug and personally launched the packaging of the first batch.

Over the next few days, the vaccine will arrive in the regions of the country, the press service of the Ministry of Education and Science told the agency.

The Chumakov Center started the third phase of post-registration trials of its vaccine.

“It has already started (phase III). We are already preparing documents, we are already preparing for the receipt of permits and then all the necessary tests, “said Falkov.

Aidar Ishmukhametov, CEO of Chumakov Center, said on March 24 that the third phase of tests with the participation of 3 thousand people would be completed within six months.

“The study will involve volunteers with comorbidities – oncological, autoimmune, with diabetes mellitus,” he said.

At the end of phase III, in the fall, it is planned to submit documents for the pre-qualification of the vaccine to WHO, necessary for assessing the quality, safety and effectiveness of drugs. So far, documents have been submitted for only one Russian coronavirus vaccine – Sputnik V of the Gamalei Center.

<https://gxpnews.net/en/2021/03/the-vaccine-of-the-chumakov-center-kovivak-launched-into-civil-circulation/>

On April 12, the Russian GMP Inspectorate will celebrate its 5th anniversary

On April 12, 2021, the Russian state GMP inspectorate, created on the basis of the State Institute of Drugs and Good Practices (SID&GP) of the Ministry of Industry and Trade of Russia, celebrates its 5th anniversary. The first inspection of foreign pharmaceutical companies for compliance with GMP standards took place in 2016 on Cosmonautics Day.

Since that time, Russian GMP inspectors have conducted more than 2,300 inspections in 71 countries around the world. From the very beginning, striving for breakthroughs and innovations has become the hallmark of the national inspectorate. Among the proposed innovations are the introduction of the practice of inviting foreign regulators to inspections as Observers, the development of tools for conducting remote GMP inspections, and much more.

Prior to the 5th anniversary of the GMP inspectorate, GxP News launches a series of publications about the history and achievements of domestic GMP inspectors and invites representatives of the pharmaceutical industry to share their comments and wishes for the GMP inspectorate, as well as stories of interaction with it.

<https://gxpnews.net/en/2021/03/on-april-12-the-russian-gmp-inspectorate-will-celebrate-its-5th-anniversary/>

R-Pharm plans to launch Sputnik V vaccine in Germany

The Russian company R-Pharm, which produces the Sputnik V vaccine, plans to start drug production in Germany in the summer of 2021, TASS reports citing the DPA agency.

According to the German agency, production can be deployed in June or July at a plant in the Bavarian city of Illertissen.

“We are making every effort to ensure that production starts in the summer. We already have equipment and personnel there… We expect the decision of the European Medicines Agency (EMA), because it will be the legal basis on which we can start production, “Alexander Bykov, Director of Health Economics, said in an interview with DPA.

EMA on March 4 announced the start of a sequential examination procedure for the Sputnik V vaccine. It is expected that the process will be completed by mid-May, after which the developers will be able to apply for a registration certificate. Russian Minister of Health Mikhail Murashko said that a group of EMA experts will come to Russia on April 10 to control the tests of the Russian vaccine.

<https://gxpnews.net/en/2021/03/r-pharm-plans-to-launch-sputnik-v-vaccine-in-germany/>

RDIF applies for Sputnik V to participate in COVAX program

The Russian Direct Investment Fund (RDIF) has applied for the participation of the Sputnik V coronavirus vaccine in the COVAX program, TASS reports citing foundation director Vladimir Primak.

“An application has been submitted for the participation of Sputnik V in the COVAX program,” he said.

The COVAX program involves 190 countries and economies. Under the terms of the programme, high-income countries pay for vaccines for less prosperous States. According to the plans, as part of the mechanism, by the end of 2021, 2 billion doses of coronavirus vaccines should be produced and evenly distributed around the world.

On February 5, 2021, the World Health Organization, Coalition for Epidemic Preparedness Innovations (CEPI), the GAVI Vaccine Alliance, and their key implementing partner UNICEF published the first preliminary forecast of vaccine distribution under COVAX.

<https://gxpnews.net/en/2021/03/rdif-applies-for-sputnik-v-to-participate-in-covax-program/>

Swedish pharmaceutical companies are ready to join the production of the Sputnik V vaccine

Several Swedish pharmaceutical companies are ready to produce the Russian vaccine against the Sputnik V [COVID-19](https://gxpnews.net/terminologiya/covid-19/) after the Swedish government instructed the Vinnova Innovation Agency to consider this possibility within the country, TASS reports citing the Svenska Dagbladet newspaper.

“Of course, there are challenges here, since today’s production facilities are not designed for such production. However, we undoubtedly have the opportunity to release a vaccine. We are not necessarily talking about the construction of a large plant, but only about trying to develop those opportunities with those actors that are already available, “said the head of the Vinnova department, Lars Hammarstrom.

Earlier, the coordinator of the vaccination campaign, Rickard Bergstrom, announced the possibility of producing a Russian vaccine in Sweden and negotiations between the Russian and Swedish sides.

The Russian Direct Investment Fund has already reached agreements with companies from Italy, Spain, France and Germany to launch the production of the Sputnik V vaccine. Negotiations are also underway with a number of manufacturers to increase production in the European Union.

<https://gxpnews.net/en/2021/03/swedish-pharmaceutical-companies-are-ready-to-join-the-production-of-the-sputnik-v-vaccine/>

The State Duma adopted in the first reading a law on the “compulsory” licensing of drugs for export

On March 17, the State Duma adopted a government bill in first reading, according to which the Cabinet of Ministers is empowered to make a decision on the use of inventions for the production of drugs without a patent, followed by compensation to the patent holder, TASS reports.

The Civil Code is supplemented by a new provision according to which the Government has the right, under the conditions provided for by international treaties, “to decide on the use of the invention for the production in the Russian Federation of a medicinal product for the purpose of its export without the consent of the patent holder, with notification of it as soon as possible and with payment of commensurate compensation to it.”

The text of the decision should contain information on the amount of drug production determined by the needs of the foreign state to which it will be exported. The packaging of such a medicament shall have a special designation.

The bill specifies that the procedure for deciding on the release of drugs and the payment of compensation will be determined by the government.

<https://gxpnews.net/en/2021/03/the-state-duma-adopted-in-the-first-reading-a-law-on-the-compulsory-licensing-of-drugs-for-export/>

Valenta Pharm launches to the Russian market a unique drug for the MS treatment

The Kinesia drug manufactured by Valenta Pharm JSC, which returns mobility to patients with multiple sclerosis, will be available to Russian patients in 2021, the company said.

The pharmaceutical manufacturer Valenta Pharm has been conducting its own developments for more than eight years to create a medicine that will allow patients with MS to return mobility. Numerous clinical trials of the Russian fampridine molecule proved its effectiveness and safety, and the company’s corresponding drug underwent all registration procedures.

“As a socially responsible company, we work in close dialogue with the patient community, understand its needs, and based on this we make strategic decisions. This happened with multiple sclerosis, when we see unique solutions that exist in other countries, but are absent in Russia. Decisions that bring MS patients back to life reduce the burden on the healthcare system due to the progression of disability. Almost a decade of painstaking work by our scientists, and now the long-awaited drug that returns mobility to people with MS, is finally available in Russia, “said Ekaterina Zakharova, Director of Science, Expertise and Treatment of MS and BAA of Valenta Pharm.

Zakharova added that this year the company is launching an early access program to the drug, as well as an observation program based on Russian medical institutions.

“We also plan to provide therapy for more than 500 patients, conduct training for neurologists on the features of drug prescribing, and also give them the opportunity to get their own experience in applying our development,” said a representative of Valenta Pharm.

The drug is produced in Russia directly on the basis of the Valenta Pharm research and production complex. The company’s high-tech R&D cluster, located in Schelkovo, Moscow Region, was commissioned in 2017 and is one of the largest high-tech pharmaceutical industries in Eastern Europe.

<https://gxpnews.net/en/2021/03/valenta-farm-launches-to-the-russian-market-a-unique-drug-for-the-ms-treatment/>

Pharma-2030 includes the Russian anti-HPV and chickenpox vaccine production

The Russian pharmaceutical industry is ready to produce its own anti-HPV, chickenpox and rotavirus vaccine under the Pharma-2030 program, said Mikhail Nekrasov, CEO of NANOLEC pharmaceutical company, at the XVI International Conference “Pharmaceutical Business in Russia – 2021” on March 11.

“There is no doubt, we will pass the task of the Pharma-2030 strategy. The task is set by 2025 to produce vaccines against these infections. We are ready for this, “he said.

Mikhail Nekrasov noted that today we need to prescribe a mechanism for its implementation within the framework of this program.

“I like offset contracts most of all at the moment… If we are ready to invest our money in the production of vaccines, we must have guarantees that the vaccine will be in demand, will be purchased. These vaccines should be introduced into the National Vaccination Calendar, should be purchased by the state from those enterprises that have solved this problem, “said NANOLEC SEO, stressing that he does not deny the acceptability of other ways of implementing the strategy.

The Ministry of Industry and Trade presented the Pharma-2030 strategy in July 2019. According to the document, it is planned to create a high-performance export-oriented sector in the industry. The new strategy provides that by 2030, exports of domestic drugs should grow by about five times compared to 2018, to $3.8 billion. Deliveries abroad of medical devices over the same period should increase tenfold, to 39 billion rubles.

<https://gxpnews.net/en/2021/03/pharma-2030-includes-the-russian-anti-hpv-and-chickenpox-vaccine-production/>

Rospotrebnadzor extended the rules for transporting and storing the Sputnik V vaccine

The head of Rospotrebnadzor Anna Popova extended the rules for transporting and storing anti-[COVID-19](https://gxpnews.net/terminologiya/covid-19/) vaccine Sputnik V until January 1, 2022. Initially, their validity expired on March 1 of this year. The corresponding resolution is published on the portal of legal information.

For the transport of Sputnik V, the principle of a “cold chain” of four stages is used. The temperature conditions must be strictly observed on each of them. You can store and transport the vaccine only at a temperature of -18 ° C. In freezing equipment, even with its maximum load, it is necessary to ensure free air circulation. At long distances, the vaccine is carried in auto-refrigerators. When transporting by ordinary transport, special dry ice thermosumes are used.

You can transport Sputnik V at a temperature not higher than -21 ° C. Vaccine storage is carried out in freezers, health workers must constantly check the temperature inside the cells.

An already opened ampoule with a vaccine can be stored for no more than two hours. One ampoule is enough to vaccinate five people.

<https://gxpnews.net/en/2021/03/rospotrebnadzor-extended-the-rules-for-transporting-and-storing-the-sputnik-v-vaccine/>

Slovakia second in the EU OK’d the use of the Sputnik V vaccine

The Russian anti-COVID19 vaccine Sputnik V coronavirus was registered in the Slovak Republic, Russian Direct Investment Fund (RDIF) reports.

Slovakia became the 39th country in the world and the second state in the European Union approved the use of the Satellite V vaccine. The registration of the drug was carried out as part of an accelerated procedure (EUA) based on the results of the Sputnik V clinical research in Russia and their comprehensive assessment by Slovak experts. The first deliveries of vaccine to the country were carried out on March 1.

“In Europe, the Sputnik V vaccine has been approved in Slovakia, Hungary, San Marino, Serbia, Montenegro, the Republika Srpska, Belarus and Russia, and interest to the Russian vaccine in the region is growing… We received many requests from the EU states for Sputnik V vaccine direct deliveries based on the analysis of data by their national regulators. We will continue to work in this direction, as well as cooperation with EMA in the framework of the procedure for the gradual examination of the drug (rolling review), which was initiated by us in January”, said Kirill Dmitriev, RDIF CEO.

Currently, the use of the Sputnik V vaccine has also been approved in Russia, Belarus, Argentina, Bolivia, Serbia, Algeria, Palestine, Venezuela, Paraguay, Turkmenistan, Hungary, the UAE, Iran, the Republic of Guinea, Tunisia, Armenia, Mexico, Nicaragua, Republika Srpska (entity of Bosnia and Herzegovina), The total population of 39 countries that registered the vaccine exceeds 1.1 billion people.

<https://gxpnews.net/en/2021/03/slovakia-second-in-the-eu-okd-the-use-of-the-sputnik-v-vaccine/>

Binnopharm Group plans to produce anemia medicines at the Zelenograd plant

Binnofarm Group Holding launches at the Zelenograd plant the production of Binnoferum solution for the fight against iron deficiency and the treatment of anemia, which is included from the list of VMED, the company reports. The capacity of the site allows to produce up to 60 million ampoules per year.

“We are actively working on the development of Binnopharm Group’s targeted product portfolio and in the next few years we plan to launch more than a hundred sought-after medicines into production”, said Rustem Muratov, CEO of Binnopharm Group. – The volume of the Russian tender segment of iron deficiency drugs according to various analytical data exceeded 1 billion rubles in 2020, while in the past few years it has grown by an average of about 10% per year. Moreover, iron deficiency drugs are socially significant. ”

“Binnoferum” is an iron-sucrose complex for intravenous administration with a set of necessary elements for normalizing hematopoiesis and filling iron deficiency in the human body. During the course of taking the drug, patients should form a controlled source of iron for the proteins responsible for transmitting and storing iron in the body (transferrin and ferritin, respectively).

The Binnofarm Group pharmaceutical holding combines five production sites located in different regions of Russia: Alium in the Serpukhov district of the Moscow region, Binnofarmin Zelenograd and Krasnogorsk, Synthesis in Kurgan, Biocom in Stavropol. The holding was formed in 2020 as a result of the consolidation of stakes in the pharmaceutical assets of AFK Sistema.

<https://gxpnews.net/en/2021/03/binnopharm-group-plans-to-produce-anemia-medicines-at-the-zelenograd-plant/>

Skvortsova announced the development of a unique anti-COVID19 vaccine

The Federal Medical and Biological Agency (FMBA) plans to complete I phase clinical studies of the Mir-19 vaccine by mid-March, based on the use of microRNAs blocking certain RNA virus sites, said CEO of FMBA Veronika Skvortsova to President Vladimir Putin.

Studies have shown that the drug prevents the most severe forms of coronavirus development. According to Skvortsova, the department received permission for clinical research of a drug that has no analogues. She clarified that the drug is safe for humans, it does not affect the human genome and its immunity, “but at the same time it affects the virus highly (in animal experiments, viral activity is reduced 10 thousand times).”

“Given that this is a new molecule – it is new and patented, has no analogues, we go through the first phase especially carefully, since we need to prove safety already in humans. We will end the first phase by mid-March and we are moving on to work with patients, we are moving on to the second phase, “Skvortsova said.

The CEO of FMBA also told Putin that the department is developing a next-generation vaccine, which differs in that it affects not the S-protein, but other protein components of the virus and “primarily causes the development of not humoral immunity, that is, through the activation of antibodies, but the development of cellular immunity, cytotoxic immunity, the advantage of which is duration.”

“Antibody immunity, as a rule, lasts for months, then cellular immunity – for years, and in experimental certain works it is proved to maintain this immunity until 13-17 years old”, Skvortsova noted.

According to her, the first formulation of this drug, a candidate drug, has now been received. Preparations are underway for clinical research. The head of the FMBA hopes that by the second half of 2021 the drug will be brought to clinical research.

<https://gxpnews.net/en/2021/03/skvortsova-announced-the-development-of-a-unique-anti-covid19-vaccine/>

The first stage of preclinical trials of the anti-COVID19 vaccine Mir-19 has completed

The Federal Medical and Biological Agency (FMBA) has completed the first stage of screening preclinical trials of its Mir-19 coronavirus vaccine, according to the website stopcoronavirus.rf

“The first stage of screening preclinical studies (specific immunogenicity, activation of humoral and T-cell immunity, primary safety) has been completed, as well as a study on the characterization of recombinant antigens regarding binding to natural receptors and virusneuralizing activity of antibodies induced by these antigens, created prototype vaccines based on recombinant proteins”,  follows from the report.

Earlier, the head of the FMBA, Veronika Skvortsova, reported that preclinical trials of the FMBA coronavirus vaccine are planned to be completed in the first quarter of 2021, clinical trials will begin in July 2021, specifying that the first and second phases will be combined, because this is allowed by the vaccine trial protocol.

According to Skvortsova, the FMBA vaccine affects not the S protein, but other protein components of the virus and causes the development of immunity not through the activation of antibodies, but at the cellular level. According to the head of the FMBA, cellular immunity can last from 13 to 17 years.

<https://gxpnews.net/en/2021/03/the-first-stage-of-preclinical-trials-of-the-anti-covid19-vaccine-mir-19-has-completed/>

Ministry of Justice approved changes to the inspection report for compliance with GMP

On March 3, the Ministry of Justice of Russia registered an order of the Ministry of Industry and Trade of Russia dated 29.01.2021 No. 284, which amends annex 2 to the order of the Ministry of Industry and Trade of the Russian Federation dated February 4, 2016 No. 261 “On the approval of application forms for the issuance of an opinion on the compliance of a drug manufacturer (foreign manufacturer) to the requirements of the Good Manufacturing Practice (GMP) rules, the inspection report on the results of the inspection of the manufacturer and foreign manufacturer of drugs for compliance with the requirements of the GMP rules and the conclusion on compliance of the manufacturer (foreign manufacturer) of drugs with the requirements of the GMP rules. ” The corresponding document is published on the official Internet portal of legal information.

The changes relate to the inclusion of the Corrective and Preventive Action Plan (CAPA) evaluation item. As a result of the evaluation of the CAPA system, the inspectors conclude that the classification can be adjusted and the number of inconsistencies identified.

The enterprise CAPA system and its processes should be designed to systematically analyze and respond to quality issues, taking into account risks. The system shall provide for algorithms of corrective and preventive actions to ensure their effectiveness and provide confirmation that these actions will not negatively affect the product.

<https://gxpnews.net/en/2021/03/ministry-of-justice-approved-changes-to-the-inspection-report-for-compliance-with-gmp/>

Russia and WHO discussed the inclusion of Sputnik V in the list of means for use in emergency situations

Russia Health Minister Mikhail Murashko and Director General of the World Health Organization (WHO) Tedros Adanom Gebreisus during a telephone call discussed the consideration by the international organization of an application for the inclusion of the Russian Sputnik V vaccine in the WHO list of medicines for use in emergency situations, the agency said.

During the conversation, the topics of countering the spread of a new coronavirus infection were discussed, including vaccination of the population, strengthening public health and increasing the availability of medical care.

“To date, the Sputnik V vaccine has already received millions of citizens. The vaccine forms resistant antibody and cellular immunity to the [COVID-19](https://gxpnews.net/terminologiya/covid-19/) pathogen and has no serious side effects. The vaccine has essentially become a world bestseller, “said Murashko.

The head of WHO noted that at the moment the organization’s efforts are focused on countering the spread of new COVID-19. The key measures to limit the spread of new coronavirus infection, according to the WHO position, are social distancing measures and vaccination of the population.

The head of the Ministry of Health presented the efforts of the Russian Federation to combat a new coronavirus infection, including the national campaign to vaccinate the population that began in January 2021

A separate topic was the discussion of projects developed by the Ministry of Health of Russia to strengthen the health of Russians and increase the availability of medical care. The Director General of WHO praised the efforts of the Russian Federation to introduce digital technologies into the medical care system.

<https://gxpnews.net/en/2021/03/russia-and-who-discussed-the-inclusion-of-satellite-v-in-the-list-of-means-for-use-in-emergency-situations/>

The Circle of Good Fund will provide medicines for children with three more orphan diseases

The Good Circle fund following the results of a meeting of advisory council was included on March 3 in the list three the autoinflammatory diseases of a disease: family Mediterranean fever; the kriopirin-associated periodic syndrome; the periodic syndrome associated with a tumor necrosis factor receptor is said in the statement on the website of fund.

At a meeting at which reports were made by the chief non-staff children’s specialist rheumatologist of the Ministry of Health of the Russian Federation Ekaterina Alekseeva and the head of the Center of examination and quality control of medical care of the Ministry of Health of the Russian Federation Vitaly Omelyanovsky medicines for treatment of these diseases were considered. As a result experts chose the medicine of the first Kanakinumab line suitable for treatment of all three diagnoses, and sent this decision for the further approval in the board of trustees of fund. Consideration of the list of categories of children on the accepted diseases will take place at the next meeting of advisory council.

Also, on the diagnosis “spinal muscular atrophy” (SMA) which entered earlier the list of fund the advisory council approved the new applications including 422 children from 28 regions of the country. At the previous meetings of advisory council applications more than 480 children from 48 regions were approved. Lists of children from SMA who will receive the help from fund continue to be replenished.

<https://gxpnews.net/en/2021/03/the-circle-of-good-fund-will-provide-medicines-for-children-with-three-more-orphan-diseases/>

The volume of the pharmaceutical market in Russia in 2020 amounted to 2,040 trillion rubles

In 2020, the Russian pharmaceutical market showed growth above forecasts: its positive dynamics in ruble terms amounted to 9.8% instead of the expected 5-6%. The volume of the pharmaceutical market of the Russian Federation in 2020 reached 2.040 trillion rubles, the research company DMS Group reports in the review “Pharmaceutical Market of Russia – 2020.”

In dollars and euros, stagnation was observed in 2020. The March increase in exchange rates led to the fact that in terms of them the market capacity did not increase. So, in dollar terms in 2020, the market volume amounted to $29 billion, which is 0.2% more than in 2019. In the euro, due to higher exchange rate growth, the market, on the contrary, decreased by 1.6%.

According to the results of 2020 year, the share of imported drugs in the market as a whole amounted to 56.3% in rubles and 31.4% in packages. The structure of the drug market by vacation type has grown in favor of over-the-counter drugs. At the same time, 67% in monetary terms falls on prescription drugs.

The bulk of sales of over-the-counter drugs are sold through pharmacies (97% in rubles). In the state segment, RX-drugs occupy 90% of the volume of consumption in tender procurement. Medicines from the list of VMED occupy more than 50% both in kind and in value from the total drug market.

The ATC rating in 2020 was headed by the group “Antitumor Drugs and Immunomodulators” (16% of the market volume in value terms), which includes expensive drugs. The group of drugs for the digestive tract and metabolism fell to the second line, its share in monetary terms is 15%, and they are sold mainly through pharmacies (76% in rubles). The group “Antimicrobials for systemic use” grew the most – by 18% and amounted to 14% in ruble terms of market volume. About 53% of the drugs of this group are purchased for the needs of hospitals, the share of sales in the pharmacy segment was 43.7%, also showing the high dynamics provoked by the coronavirus pandemic.

The bill of the drugs manufactures in pharmacies passed the first reading

The State Duma of the Russian Federation adopted in the first reading a bill that allows pharmacy organizations, veterinary pharmacies and individual entrepreneurs with a license for pharmaceutical activities to use drugs in the production of drugs instead of pharmaceutical stations, Duma TV reports.

In addition, the document removes the ban of the manufacture of drugs registered in Russia, which was valid in relation to such organizations and individual entrepreneurs.

“This norm limited the manufacture of medicines in pharmacy organizations, which led to a significant decrease in the nomenclature and number of dosage forms produced and the mass closure of production pharmacies in all regions of the Russian Federation,” the explanatory note to the bill says.

<https://gxpnews.net/en/2021/03/the-bill-of-the-drugs-manufactures-in-pharmacies-passed-the-first-reading/>