A COVID-19 vaccine in the form of nasal drops may appear in one year

A vaccine against coronavirus infection in the form of nasal drops may become available in the fall of 2022. The drug has to undergo clinical trials. This was announced by Rinat Maksyutov, the general director of the Vector Center, TASS reports.

"Vaccines in the form of a nasal spray are also being studied in many laboratories around the world, but mostly on laboratory animals. Given the time needed for clinical trials, I believe that the launch will take place next autumn," Maksyutov said on Monday, August 30, when shown live as part of the educational campaign "Let's learn about vaccines together", which was organized by Znanie society.

Earlier it became known that the Gamaleya Center plans to start clinical trials of its own drug of this type in late 2021 – early 2022, and to register it in 2022. The Vector center is also developing a vaccine in the form of nasal drops.

The Chumakov Center will increase the production of its CoviVac vaccine against COVID-19.

https://gxpnews.net/en/2021/08/a-covid-19-vaccine-in-the-form-of-nasal-drops-may-appear-in-one-year/

The media report on the shortage of a popular drug against rheumatoid arthritis

Russian patients faced an acute shortage of imported medicines for patients with rheumatic diseases, in particular, methotrexate solution, included by the government in the list of vital and essential medicines (VED), Vedomosti newspaper reports with reference to the Russian Rheumatology Association "Nadezhda". This drug is taken on a regular basis by 2-2.5 million people, and a pause in the treatment can lead to serious exacerbations.

Patients with rheumatological diseases in all Russian regions have not been able to get Methotrexate Ebewe, the injection solution from the Swiss company Sandoz (a division of the Novartis group) from pharmacies since the beginning of August 2021, said Polina Pchelnikova, vice president of Nadezhda Association. Sandoz is the largest supplier of methotrexate to the Russian market. According to RNC Pharma, which the publication cites, in just seven months of 2021, pharmaceutical companies delivered 2.2 million packages of the solution, 48% of them were shipped by Sandoz.

The Federal Service for Supervision in Healthcare (Roszdravnadzor) stated that in general there is currently no shortage of methotrexate with the international nonproprietary name. According to Roszdravnadzor, since the beginning of the year, 2.5 million packages (177 series in total) of INN methotrexat in the form of an injection solution have been introduced into civil circulation. According to the federal state information system for monitoring the movement of medicines for medical use, there is currently a sufficient amount of Methotrexate in the regions of the Russian Federation, Roszdravnadzor said.

https://gxpnews.net/en/2021/08/the-media-report-on-the-shortage-of-a-popular-drug-against-rheumatoid-arthritis/

A new drug for the treatment of hemophilia A has been registered in Russia

Japanese Takeda has received a Russian registration certificate for Adenovate (INN rurioctocog alpha pegol), intended for the treatment of hemophilia A, the company reports. The new drug is a recombinant blood clotting factor VIII with a long half-life.

Adenovate has been approved by regulators in other countries, including the FDA (US Food and Drug Administration) and the EMA (European Medicines Agency).

Hemophilia A is a rare genetic disease caused by the congenital absence of clotting factor VIII in the blood. Patients with blood clotting factor deficiency face the threat of haemorrage into soft tissues, joints and internal organs, which can lead to disability and death. Various loads and injuries can provoke bleeding, so patients with hemophilia A are forced to limit their physical activity. An injury which does not present a risk for a healthy person, such as a cut, in patients with hemophilia can cause uncontrolled prolonged bleeding. Since the disease is currently incurable, patients need regular medical support.

Blood clotting factor VIII is used intravenously for the treatment and prevention of bleeding in patients with hemophilia A. Adenovate has an extended half-life, so it can be administered only to twice a week to provide highly effective therapy. The use of the drug helps to reduce spontaneous bleeding and completely prevents the risk of hemoarthrosis, bleeding into joints.

Takeda is a global, research and development-driven pharmaceutical company. The company's research activities are aimed at creating new drugs in a number

of therapeutic areas: oncology, gastroenterology, neurology and the treatment of rare diseases, as well as the development of blood plasma preparations and vaccines.

https://gxpnews.net/en/2021/08/a-new-drug-for-the-treatment-of-hemophilia-a-has-been-registered-in-russia/

Gematek plans to build a medical products plant in the Tver region

Gematek, an international company (part of the German B. Braun group), intends to create an enterprise to manufacture medical products in the "Lazurnaya" industrial zone in the Tver region, the press service of the regional administration reports. The new production can attract investments in the amount of 3 billion rubles and create more than 250 jobs.

The agreement on the implementation of the project was reached in May 2019 in Germany at a meeting between Governor Igor Rudeni with representatives of B. Braun Melsungen AG. The parties decided to build a production and logistics complex with a phased commissioning of production facilities for manufacturing medical devices, suture materials, orthopedic implants, and disinfection products in Tver. The project is scheduled to start in 2022.

"Our region offers investors wide opportunities and convenient conditions for doing business. We are confident that the implementation of joint ideas and plans will receive a new impetus. Today, our task is to find new partners and consolidate the existing cooperation. We are open to sharing experience. The German school of business has always been at a high level, and we would like to spread this experience in our territory, " Igor Rudenya said during the meeting.

According to Maxim Zakharchenko, General Director of OOO "Gematek", all issues related to the preparation for the implementation of the project were resolved with the assistance of the regional government, the administration of Tver, as well as the Ministry of Economic Development of the Tver region.

https://gxpnews.net/en/2021/08/gematek-plans-to-build-a-medical-products-plant-in-the-tver-region/

The creators of CoviVac published the first research article about their vaccine

Specialists of the Chumakov Center, who developed CoviVac, a whole-virion vaccine, published their first research article about it. The work is published in the Emerging Microbes&Infections journal published by Taylor&Francis.

The article describes the findings of preclinical studies of the vaccine, which lasted more than a year. It is noted that CoviVak did not show toxicity and protected experimental Syrian hamsters, mice and common marmosets from severe pneumonia during intranasal infection with live coronavirus.

“In this work, we examined the effect of the whole-virion CoviVac vaccine inactivated with β-propiolactone, evaluated its safety, protective efficacy, immunogenicity, and stability of the immune response in rodents and primates. The vaccine showed no signs of acute / chronic, reproductive, embryonic, and fetal toxicity or teratogenic effects, and also did not show allergenic properties in the studied animal species,” the article says.

The scientists concluded that the drug provides a stable humoral immune response, with the production of IgG and NAb antibodies. The protective effectiveness of the vaccine was studied on Syrian hamsters. The reliability of the production process was demonstrated by the evaluation of four batches of the vaccine and comparing their immunogenic properties in mice.

The researchers had to check for a possible negative effect of the drug on pregnant women, so CoviVac was separately tested on pregnant mice. The vaccine had no effect on the intrauterine or postpartum development of the offspring.

The CoviVac vaccine is currently in phase 3 of clinical trials on humans, it has already been registered and is used for immunization of the population.

https://gxpnews.net/en/2021/08/the-creators-of-covivac-published-the-first-research-article-about-their-vaccine/

The government to allocate 650 million rubles for the purchase of oxygen equipment for hospitals

More than 650 million rubles will be allocated for the purchase of oxygen concentrators for hospitals in 20 Russian regions, TASS reports with reference to Prime Minister Mikhail Mishustin.

"The government has allocated over 650 million rubles for the purchase of oxygen concentrators for hospitals in 20 regions of the Russian Federation. These are the regions that experience the most severe shortages. It is important to maintain the oxygen supply at a sufficient level. Regional authorities should plan the need in advance and be especially careful when monitoring the condition of the equipment, as people's lives depend on it," Mishustin said at a briefing session with deputy prime ministers.

The head of the Cabinet of Ministers noted that in the context of the spread of COVID-19, medical organizations in general need more oxygen.

"Without it, it is impossible to provide assistance to patients with the severe form of the disease," the prime minister added.

In July, the government instructed the Ministry of Industry and Trade to submit proposals for additional supplies of medical oxygen to hospitals.

https://gxpnews.net/en/2021/08/the-government-to-allocate-650-million-rubles-for-the-purchase-of-oxygen-equipment-for-hospitals/

The Chumakov Center is developing a version of the COVID-19 vaccine targeting the Delta variant

The Chumakov Center is preparing a version of the coronavirus vaccine against the delta strain, which can be made in the form of a combined vaccine, said Aidar Ishmukhametov, the director of the center.

"Yes, absolutely ... we have already isolated the delta strain, and we are doing all the preparatory steps to make a new vaccine. It is not about updating our existing vaccine, it would be a little bit wrong to say that, <...> instead of the alpha variant, this vaccine will contain the delta variant," Ishmukhametov said on Rossiya-24 TV channel.

According to him, the new vaccine may contain two components.

"We are now working on these things, it can be a combination or a complex vaccine ... Of course, these are two components of the same vaccine, otherwise there would be no sense, it would be two different vaccines, " Interfax reports Ishmukhametov's statement.

The head of the Chumakov Center urged residents of the Russian Federation not to expect the emergence of new drugs and to get vaccinated with already registered ones.

The Chumakov Center has already developed an anti-COVID-19 vaccine CoviVac, which is a whole-virion vaccine. Like most coronavirus vaccines in use, it consists of two components. The drug was registered in Russia on February 19, 2021.

https://gxpnews.net/en/2021/08/the-chumakov-center-is-developing-a-version-of-the-covid-19-vaccine-targeting-the-delta-variant/

The Ministry of Health announced the approval of Sputnik Light for people over 60 years old

Experts have allowed the use of the Sputnik Light vaccine for people aged over 60, said the Health Minister Mikhail Murashko. He noted that this drug is mainly used for repeated vaccination.

The minister also said that in the structure of deaths from coronavirus, 85% are among the 60+ population. “The risk is enormous,” RIA Novosti quotes the minister as saying . According to Murashko, many of patients admitted to hospitals with COVID-19 regret that they were not vaccinated.

Sputnik Light was registered in Russia in early May. It is a single-dose version of Sputnik V. The drug shows an effectiveness of 79.4%, which is higher than many vaccines that require two injections. No serious adverse events were registered after immunization with Sputnik Light.

https://gxpnews.net/en/2021/08/the-ministry-of-health-announced-the-approval-of-sputnik-light-for-people-over-60-years-old/

Payments of pharmaceutical companies in favor of the healthcare of the Russian Federation in 2020 decreased to 14 billion rubles

Pharmaceutical companies that are members of the Association of International Pharmaceutical Manufacturers (AIPM) spent 14.3 billion rubles in 2020 on payments to Russian specialists and healthcare organizations, as well as on research and development, FV reports together with MV. This is 11% less than in 2019, when the amount exceeded 16 billion rubles.

The publications analyzed the reports of 41 pharmaceutical companies. According to the data obtained, the amount of payments to doctors in 2020 decreased by 36%, from 3.9 billion rubles to 2.5 billion rubles. In 2019, the amount of payments in favor of doctors increased by 11% compared to 2018, when it was 3.5 billion rubles. As a result, the share of payments in the total amount of payments in favor of healthcare professionals decreased from 24% to 17%.

The cost of the valuables transferred in favor of healthcare organizations and in connection with research and development has also decreased, but the dynamics in this case is less dramatic compared to the same type of payments to doctors. Payments to healthcare organizations decreased by 7%, from 5.4 billion rubles in 2020 to 5 billion rubles. Research costs decreased by 1%, from RUB 6.9 billion to RUB 6.8 billion.

As a result, the shares of these two types of payments have increased. As a result, in 2020, research accounted for almost half of the payments, 48%. In 2019, they occupied 43%. The share of payments to organizations increased from 33% to 35%.

Among the doctors who disclosed individual data, only three people received more than a million rubles from pharmaceutical companies. These are Igor Tyurin, Doctor of Medical Sciences, Head of the Department of Radiology and Radiology of the Russian Medical Academy of Continuing Professional Education; Maxim Vyskub, employee of the State Autonomous Medical Institution “Medical Center” Cosmetology Clinic; and Dzhanashia Ketevan, specialist of OOO Ritz Medical. In 2019, 22 doctors received the corresponding amount. The average amount of payments among doctors who disclosed the data also decreased. In 2019, it was about 72,000 rubles, and last year, 47,000 rubles.

Pfizer became the most active company cooperating with doctors and healthcare organizations in 2020, having spent 1.3 billion rubles. A little more than a billion was transferred to the benefit of Russian healthcare by Sanofi. In 2019, four companies spent more than a billion rubles: Bayer, with 1.3 billion rubles, AstraZeneca, MSD and Janssen, with 1.2 billion rubles each.

https://gxpnews.net/en/2021/08/payments-of-pharmaceutical-companies-in-favor-of-the-healthcare-of-the-russian-federation-in-2020-decreased-to-14-billion-rubles/

The Ministry of Health proposes to include off-label drugs in the clinical testing of prevention methods

The Ministry of Health of the Russian Federation has submitted draft amendments to the Regulation on the organization of clinical testing of methods of prevention, diagnosis, treatment and rehabilitation, and medical care, due to the fact that there are currently no provisions for off-label drug use in clinical testing. The document is published on the regulation.gov.ru portal.
The draft amendments are intended to improve the provision of medical care within the framework of clinical testing in medical organizations. If adopted, it will enter into force on March 1, 2022.
According to the document, it is allowed to use in clinical testing medicines and medical devices registered in accordance with the established procedure in the Russian Federation for indications not specified in the instructions for their medical use and/or in the operating manual, by the decision of the council of doctors or the medical commission of the medical organization where the clinical testing is carried out, if there are references in the protocol of clinical testing to effectiveness and safety clinical studies for the dosage regimen of the drug and/or the method of use of the medical device for the corresponding disease, or references to leading domestic and/or foreign peer-reviewed research journals and publications.
A method of prevention, diagnosis, treatment and rehabilitation is considered effective if it has scored at least one point in total for each efficiency indicator specified in the evaluation algorithm, which:

– requires lower financial costs, but at the same time is no less effective for prevention, diagnosis, treatment and rehabilitation compared to the method already used in clinical practice;
– requires more financial costs, but at the same time its additional advantages for prevention, diagnosis, treatment and rehabilitation justify the additional costs.
The discussion of the project will last until September 15.

https://gxpnews.net/en/2021/08/the-ministry-of-health-proposes-to-include-off-label-drugs-in-the-clinical-testing-of-prevention-methods/

WHO considers Russian enterprises producing Sputnik-V safe

WHO has already inspected nine sites of clinical trials and production of the Sputnik V vaccine, Soumya Swaminathan, the Chief Scientist at the WHO, said in her interview to Izvestia. The WHO is still evaluating the results of the last four inspections.

In general, the manufacturing sites of Sputnik V vaccine do not cause concerns for the WHO. The only exception is the detection of non–compliance with all the requirements of good manufacturing practice in the territory of OAO "Pharmstandart — Ufimskiy Vitaminny Zavod" in Bashkortostan.

"Five clinical trial sites were inspected jointly with the European Medicines Agency (EMA) for good clinical practice, four more production facilities were checked for good manufacturing practice (of the four facilities, two were visited jointly with the EMA)," Soumya Swaminathan said.

Subject to the compliance with certain requirements, the WHO will continue to evaluate Sputnik V vaccines from different production sites and will publish decisions on their EUL status when all data are available and the review is completed.

https://gxpnews.net/en/2021/08/who-considers-russian-enterprises-producing-sputnik-v-safe/

Scientists have developed a variant of Sputnik V vaccine against the delta strain

The Gamaleya Center has developed a variant of the Sputnik V coronavirus vaccine modified for the delta strain, Interfax reports with reference to Alexander Ginzburg, the head of the institution, Academician of the Russian Academy of Sciences.

"The ready vaccine structure is already in the refrigerator," the scientist said. He admitted that it is too early to talk about the degree of effectiveness of this vaccine.

"Everyone has started developing a vaccine based on the sequence of the delta variant, but no one can say whether it is going to be more effective than existing vaccines against the delta," Ginzburg said.

High mortality rates from coronavirus against the background of the decline in the number of new cases in the Russian Federation are associated with the dominance of the delta strain; other mutations are possible in the future, but it is impossible to say whether they will be more dangerous, Ginzburg added.

"Now virtually all the patients have the delta variant. In unvaccinated patients the infectious process takes not two or three weeks, as with other variants, but four or five days. And our immune system produces antibodies in 10 to 14 days.

With other variants of the coronavirus, it managed to do that, and brilliant resuscitators helped the infected people to survive until the immune system got in. And in the case of the delta variant, the immune system does not have enough time, " Ginzburg said in his answer to the corresponding question.

The scientist believes that new strains may appear. The academician also added that an accurate forecast was not possible.

https://gxpnews.net/en/2021/08/scientists-have-developed-a-variant-of-sputnik-v-vaccine-against-the-delta-strain/

Representatives of the authorities spoke about the Sanitary Shield program

The Sanitary Shield program will include several areas: from ensuring a sufficient supply of personal protective equipment and effective test systems to creating high-quality vaccines in the shortest possible time, Deputy Prime Minister Tatyana Golikova said at the round table "The Sanitary Shield of the country means safety for citizens".

"The first is the timely and early prediction of possible epidemics, the elimination of the risk of their import and spread over the territory of the country. At the same time, it is very important that this happens without border closing. We expect to install 241 checkpoints on the entire external perimeter," she said.

At the same time, a quick diagnosis of infections should be available for every resident of the country at any point. The Deputy Prime Minister also noted the need to develop a laboratory network: each city with a population of 100,000 people should have its own laboratory.
The deputy prime minister added that the pandemic also showed the need to train medical personnel of "a different quality". This refers to specialists who deal with issues of epidemiological safety.

"We propose to make this information clear, accessible and accompany it with recommendations on health protection. Another important innovation area that the president identified in his address is the research component: tests should be developed in four days, vaccines, in four months," Tatyana Golikova said.

The Deputy Prime Minister stressed that in the coming years, 30 billion rubles will be allocated for the creation of a fundamentally new system for providing medical care and building biological safety.

“We will have to rethink the work that was done earlier, not only within the framework of the program, but also within the framework of the law on biological safety, which was signed by the president at the end of last year. We must be ready to respond to potential new threats,” Golikova said.

At the same time, the Sanitary Shield should not create obstacles to communications and movement of citizens, said the first vice-speaker of the Federation Council, Andrei Turchak. He recalled that now, when entering a number of countries, it is necessary to undergo several PCR tests, one after the other. He believes that in the Eurasian Economic Union space, where the activity of Russians is especially intense and important, it is necessary to ensure the recognition of PCR tests taken in the Russian Federation, as well as QR codes obtained in the public services website (gosuslugi).

The head of Rospotrebnadzor Anna Popova supported the proposal and, according to her, the Sanitary Shield program as a whole will contribute to reinforcing the network of state laboratories, expanding the availability of services for the population, and the formation of a sanitary culture.

“The pandemic has very clearly shown that the speed of infection spread today is the speed of movement of an airplane. We must understand how threats arise and how we can prevent their entry into the country. To do this, we provide express diagnostics possible at all checkpoints,” the head of Rospotrebnadzor said.

Russia will expand the network of collaborating laboratories outside the country. They are now available in the CIS and in some other countries. At the same time, it is important to ensure the availability of laboratory services.

“The cost and speed of obtaining test results should be reduced. The increased laboratory capacity will allow us to decipher any unknown infection in 24 hours. We set a task according to which test systems for an unknown infection must be developed in four days. The faster we learn to recognize it, the fewer opportunities there will be for the spread of infection,” Anna Popova stressed.

https://gxpnews.net/en/2021/08/representatives-of-the-authorities-spoke-about-the-sanitary-shield-program/

Pharmacies are required to stop selling Drastop, a drug under a patent dispute

OOO Diamed-Pharma, which had previously obtained an order from the FAS to ban the distribution of Drastop, a drug for the treatment of the musculoskeletal system, in the Russian Federation, began sending letters to pharmacies which, according to the company, continue to sell the drug. Diamed-Pharma demands that the networks stop selling Drastop and that each of the organizations pay 5 million rubles as compensation for the batches of the product already sold.

The letters were received by more than 20 pharmacy chains and distributors, including Katren, Novosibirskaya Aptechnaya Set, ASNA, Aliya Pharm, Apteka Service Plus, and others (GxP News has copies). Representatives of Diamed-Pharma demand to immediately stop the sale of Drastop in violation of the exclusive rights of OOO Diamed-Pharma to the invention under the patent and pay compensation to the patent holder in the amount of 5,000,000 rubles (the amount of claims to each of the pharmacies is the same), or to conclude an agreement with the copyright holder on compensation for the quantity of Drastop that has already been sold.

In December 2020, the Federal Antimonopoly Service Administration for the Moscow Region ordered OOO Trokas Pharma to stop introducing Drastop into civil circulation in Russia by the end of January, in connection with the violation of the exclusive rights of Diamed-Pharma to a patented invention. The claimant in the case was OOO Diamed-Pharma, which owns a patent for the production of Mukosat. The company managed to prove to the regulator that Drastop is produced based on a patented invention.

After that, Trokas Pharma filed a lawsuit with the Arbitration Court of the City of Moscow demanding that the FAS decision be recognized as unlawful. As follows from the Commercial Case File Database, the Arbitration Court of Moscow in case No. A40-2379/2021 refused to satisfy OOO Trokas Pharma claims for invalidation and cancellation of the decision and the order of the Federal Antimonopoly Service for the Moscow Region. The appellate instance also supported the opinion of the court, and on 17.06.2021, the decision on the case entered into legal force.

According to the message of OOO DIAMED-Pharma to pharmacy organizations, the circulation of Drastop in violation of the exclusive rights of OOO DIAMED-Pharma for an invention under patent No. 2612014, including its sale through pharmacy organizations, is illegal.

GXP news has a response from ASNA, one of the networks that received the claim. The lawyers of the network write that neither OOO ASNA nor any of its subsidiaries sold Drastop. Representatives of the pharmacy also write that they

do not have the opportunity to monitor patent proceedings of all drug manufacturers in real time and "expect reasonable actions from the party whose right is violated, including at least a notice to market participants about the fact that the court decision has entered into force".

Representatives of OOO Trokas Pharma did not respond to a request from GxP News.

https://gxpnews.net/en/2021/08/pharmacies-are-required-to-stop-selling-drastop-a-drug-under-a-patent-dispute/

The FAS imposes a RUR 100,000 fine on the manufacturer of Miramistin

The Federal Antimonopoly Service (FAS) fined Infamed K, a manufacturer of antiseptics d(Miramistin, Okomistin) for 100,000 rubles for inaccurate advertising; the corresponding resolution was published in the department's database.

In January-February 2021, commercials for Miramistin were on air in Channel One, Rossiya 1, NTV, and TNT. The commercial ended with a packshot and the statement: "Miramistin is your safety rule number one," and the drug in its package was shown.

According to the section "indications for use", the drug is used for the complex treatment of acute and chronic otitis media, sinusitis, tonsillitis, laryngitis, pharyngitis; complex treatment of acute pharyngitis and/or exacerbation of chronic tonsillitis in children aged three to fourteen years. It follows from the advertising that Miramistin is a drug of first choice at the early symptoms of a cold.

"Accordingly, the advertising statement "Miramistin is your safety rule number one" expresses the advantage of Miramistin in comparison with other medicines that can be used to treat colds," the FAS resolution states.

At the same time, it follows from the instructions for the use of Miramistin, firstly, that the drug is used only as part of the complex therapy of acute and chronic otitis, sinusitis, tonsillitis, laryngitis, pharyngitis, and secondly, it is not intended for the prevention of otolaryngological diseases.

The FAS concluded that the advertising contained false information about the advantages of Miramistin over other drugs used in the treatment of diseases, which is a violation of paragraph 1 part 3 of Article 5 of the law "On Advertising".

https://gxpnews.net/en/2021/08/the-fas-imposes-a-rur-100000-fine-on-the-manufacturer-of-miramistin/

Moscow Endocrine Plant confirmed its compliance with the EAEU GMP standard

The Ministry of Industry and Trade of Russia has issued certificates of compliance with the rules of good manufacturing practice of the Eurasian Economic Union to FSUE "Moscow Endocrine Plant", Endopharm reports.

The inspection conducted by the authorized regulatory body of the Russian Federation provided an inclusive examination of production organization and equipment, the quality assurance and quality control processes in respect of medicines produced at Endopharm production sites.

The details of the EAEU GMP certificates of each production site issued to Endopharm are published in the state register on the website of the Ministry of Industry and Trade of the Russian Federation.

The inspected sites produce more than 100 names of drugs used in various fields of medicine, including anesthesiology, ophthalmology, cardiology, psychiatry, gynecology, neurology, and gastroenterology. Most of the drugs are in the list of vital and essential medicines, including a portfolio of centrally acting analgesics in a wide range of dosage forms.

The compliance with the GMP rules has also been confirmed for the production of various types of active pharmaceutical substances from raw materials of animal and plant origin obtained by biotechnological and chemical synthesis methods.

https://gxpnews.net/en/2021/08/moscow-endocrine-plant-confirmed-its-compliance-with-the-eaeu-gmp-standard/

The Circle of Kindness has started purchasing drugs for Q1 of 2022

The Circle of Kindness Foundation is currently purchasing medicines for the first quarter of 2022 in order to prevent a shortage of drugs, as Alexander Rumyantsev, the Chairman of the Expert Council of the Foundation, president of the Rogachev National Medical Research Center for Pediatric Hematology,

Oncology and Immunology, Chief pediatric hematologist of the Ministry of Health of Russia stated for the First channel.

“We are making purchases, including those for the first quarter of next year, in order to avoid a shortage that often occurs in the first months of the year,” he said. Rumyantsev noted that the Foundation had already purchased 12 medicines worth 15 billion rubles.

In addition, according to Rumyantsev, 19 billion rubles “have already been reserved in connection with drug supply contracts.”

“Two drugs against spinal muscular atrophy have already been fully delivered to the consumer,” he added.

Earlier, the Circle of Kindness Foundation signed contracts for the supply of Qarziba (dinutuximab beta) and Zolgensma (onasemnogene abeparvovec), which are not registered in Russia.

https://gxpnews.net/en/2021/08/the-circle-of-kindness-has-started-purchasing-drugs-for-q1-of-2022/

Scientists have assessed the impact of Sputnik V vaccine on male reproductive health

Vaccination with Sputnik V does not have a negative impact on reproductive health, RIA Novosti reports, citing research data. Russian scientists have also found that the semen parameters in men who have had COVID-19 undergo significant deterioration.

The effect of the coronavirus infection and the Sputnik V vaccine on male reproductive function was studied with the use of advanced molecular genetic methods by a group of researchers led by Leyla Adamyan, Academician of the Russian Academy of Sciences, chief consultant specialist in gynecology of the Ministry of Health, Anton Buzdin, chief physician of the State Clinical Hospital No. 15, and Valery Vechorko, a MPhTI professor.

First, a comprehensive examination of 50 men aged 22 to 50 years was conducted, including an analysis of spermogram indicators, blood tests, an assessment of the parameters of the hormonal profile, an examination by a urologist/andrologist. Then biologists and specialists in bioinformatics joined the work to conduct an in-depth genetic analysis.

"It turned out that the semen parameters deteriorate significantly after COVID-19. The genes that experience the most severe impact are those associated with the processes of mitochondrial energy production and with the transmission of signals from the so-called Toll-like receptors. Moreover, in samples obtained after COVID-19 the expression of all protein-coding genes of the mitochondrial genome is reduced," the study says.

Specialists also analyzed the reproductive function of 44 men vaccinated with Sputnik V vaccine. The data obtained indicate that vaccination has no effect on the level of hormones and spermogram indicators. The study did not reveal anomalies similar to those found to the after-effects of COVID-19.

https://gxpnews.net/en/2021/08/scientists-have-assessed-the-impact-of-sputnik-v-vaccine-on-male-reproductive-health/

Promomed is testing an injectable form of Areplivir in patients with COVID-19

Promomed Group has started an effectiveness and safety trial for the injectable form of Areplivir in patients hospitalized with COVID-19, according to the data of the State Register of Medicines. The company reported that a phase 1 clinical trial of the new dosage form of the drug in various dosages in healthy volunteers has been completed.

"The study will be multicenter and is to last until December this year. We expect the first statistically significant results this autumn, which will give us an opportunity, if the tests are successful, to apply for a temporary registration certificate in accordance with Federal Law 441. This means that full-scale production and delivery to hospitals can start as early as in the third quarter," the report says.

The group of companies that the benefits of treatment with the injectable form of the drug are still hypothetical. The developers suggest that the new form of the drug has a higher bioavailability (which is important due to the effect of COVID-19 on the gastrointestinal mucosa), provides a more intense and uniform penetration and distribution of the drug in cells, a longer retention of therapeutic concentration, and it can be administered to patients who have difficulty in swallowing tablets or experience adverse symptoms of the gastrointestinal tract.

Promomed specialists do not rule out that the injectable form of Areplivir can be included in the updated version of the Ministry of Health recommendations as it is more convenient and effective for hospitals than the oral form.

https://gxpnews.net/en/2021/08/promomed-is-testing-an-injectable-form-of-areplivir-in-patients-with-covid-19/

The Ministry of Industry and Trade proposes to evaluate the localization of medical products manufacturing with a system of points

An assessment system with points is gradually being introduced for medical devices in Russia to reflect the level of their localization in the country. As part of this process, the Ministry of Industry and Trade of the Russian Federation has taken the initiative to provide such a system for 22 specific types of medical products, gradually increasing the percentage of Russian components that are used in their manufacturing, according to the official website of the ministry.

This change will contribute to the increase of Russia's industrial, scientific and technical potential, as well as the development of the medical industry in general and the production of medical devices in particular. The draft resolution, as well as other implemented measures to support domestic manufacturers, is aimed at stimulating localization of the production of medical products at deeper levels and is intended to reduce the dependence of the Russian market on foreign supplies.

All interested organizations can share their suggestions and comments on the draft resolution at https://regulation.gov.ru/p/119010, where the draft is posted for public discussion.

The Ministry of Industry and Trade earlier announced the expansion of "the third one out" list.

https://gxpnews.net/en/2021/08/the-ministry-of-industry-and-trade-proposes-to-evaluate-the-localization-of-medical-products-manufacturing-with-a-system-of-points/

Three pharmaceutical plants to be built in Moscow

Almost 10 billion rubles will be invested in the construction of three pharmaceutical enterprises under offset agreements concluded with the Moscow government. This was reported by the press service of the capital's Department of Investment and Industrial Policy.

According to Vladimir Efimov, the Moscow vice-mayor for economic policy and Land and Property Relations, as part of offset contracts, investors will create three pharmaceutical facilities to localize production in the city.

"The total investment in the creation of production facilities will amount to 9.8 billion rubles. The city will purchase medicines from these plants for a total of 33.5 billion rubles. The creation of the pharmaceutical enterprises will ensure an uninterrupted supply of 116 medicines that Muscovites need," Vladimir Efimov said.

The official noted that offsets encourage businesses to invest in the creation or modernization of production of goods necessary for Moscow, and they also create new jobs. Entrepreneurs, in turn, can count on stable long-term procurement on behalf of the city.

The first offset agreement in the pharmaceutical industry in Moscow was signed by Biocad in 2017. According to its terms, the investor invests 3 billion rubles in the creation of an enterprise that produces 40 oncological and immunological drugs.

Earlier it became known that the Moscow authorities concluded an offset agreement with the Moscow Endocrine Plant.

https://gxpnews.net/en/2021/08/three-pharmaceutical-plants-to-be-built-in-moscow/

BratskKhimSyntez and Reshetnev SibSU have created a training program for synthesis equipment operators

Technologists of the enterprise and the university faculty participated in the development of the program. It will provide a deeper understanding of the technological process of organic synthesis and will promote optimization of resources. This was reported by Pharmasintez's press service.

The training will take place in a blended learning form, with the use of distance learning technologies. Practical classes will be conducted by SibSU faculty at the workplace of the employees. The first training group, consisting of 17 BratskKhimSyntez synthesis equipment operators, will start on September 9. After completing the training, they will receive certificates of qualification as synthesis equipment operators.

Synthesis equipment operators are some of the most crucial employees of the plant. They are directly involved in the synthesis of pharmaceutical substances and the transfer of technologies from the research laboratory to production.

https://gxpnews.net/en/2021/08/bratskkhimsyntez-and-reshetnev-sibsu-have-created-a-training-program-for-synthesis-equipment-operators/

Possible legalization of medicines for human use for the needs of veterinary medicine

The Ministry of Agriculture of the Russian Federation supported the proposal of deputies to allow treating animals with human medicines. According to the author of the proposal, Vladimir Burmatov, chairman of the Parliamentary Committee on Ecology and Environmental Protection, the corresponding legislative initiative will be prepared by the end of this week.

According to Burmatov, the ministry supported the introduction of amendments to the legislation regarding the accelerated expert examination of medicines for veterinary use. Due to this, the list of veterinary drugs should be significantly expanded by the addition of medicines for human use, and it is also expected that the change will make anesthesia for animals more effective and provide an opportunity to treat complex diseases.

“Now the list of veterinary drugs is very short and includes only 2,000 drugs, while the list of” human drugs is nearly ten times longer, with more than 18 thousand items,” Burmatov commented.

According to him, domestic animals often have diseases similar to human conditions. But veterinary doctors use drugs for human use at their own risk.

“Officially, veterinary clinics cannot buy these drugs and need all sorts of twists and turns to save animals. We intend to legalize their use in veterinary medicine. It is a good thing that now they have the support of the Ministry of Agriculture,” the State Duma deputy said.

https://gxpnews.net/en/2021/08/possible-legalization-of-medicines-for-human-use-for-the-needs-of-veterinary-medicine/

Production of a vaccine against any infections can be resumed in Russia

In Russia, the production of a vaccine against any infections, a drug called VP-4, may be resumed. It was developed many years ago and was manufactured for some time, but then the production stopped due to some issues that arose. This is reported by life.ru with reference to Vitaly Zverev, the head of the I.I.Mechnikov Scientific Research Institute of Vaccines and Serums.

Vitaly Zverev said that preparation for the production of this vaccine, which was previously used in the clinic by Academician Chuchalin, is currently underway.

VP-4 stimulates or reinforces innate immunity (non-specific immunity). That is, it acts in the same way in case of contact with any pathogen and in any cases.

“This vaccine can be called universal. It can work against, let’s say, any pathogen,” Zverev said.

He explained that number 4 in the name of the drug means that it contains four important components.

“It includes four components of various bacteria, the so-called ancient antigens. They provide non-specific stimulation of the innate immune response system. It includes the interferon system and the so-called anti-inflammatory cytokines that prevent the development of a virus or bacteria that has entered the human body,” the source said.

https://gxpnews.net/en/2021/08/production-of-a-vaccine-against-any-infections-can-be-resumed-in-russia/

Risdiplam to be included in the VED list for the treatment of SMA

Risdiplam, a drug for the treatment of spinal muscular atrophy, will be included in the list of vital and essential drugs (VED). This was announced by Olga Germanenko, the director of the SMA Families Foundation, on her Facebook page.

Risdiplam has been supported by the commission on the drug lists of the Ministry of Health of the Russian Federation for inclusion in the vital and essential drugs list in 2022,” Olga Germanenko wrote.

The VED list now includes one drug for the treatment of SMA: Spinraza. It is injected into the spine through a puncture, which can only be done at a hospital. Ridisplam is simply diluted with water and can be administered at home. In addition, it is significantly cheaper: the cost of one ampoule is about one million rubles, and an ampoule of Spinraza costs eight million rubles.

To recall, Spinraza was included in the list of VED in November 2020.

https://gxpnews.net/en/2021/08/risdiplam-to-be-included-in-the-ved-list-for-the-treatment-of-sma/

Russia at risk of immunoglobulin shortage

The Ministry of Industry and Trade warned about the risk of immunoglobulin shortages in the Russian Federation due to the fact that the established maximum selling price for the drug is low. This was reported to TASS by the press service of the ministry.

"In June, the Ministry of Industry and Trade of Russia informed Roszdravnadzor about the risk of a inventory shortage of INN "normal human immunoglobulin" due to the low established maximum selling price for this drug, as well as due to the insufficient amount and high cost of raw materials (blood plasma) necessary for the production of the drug," the ministry noted.

The Ministry of Industry and Trade regularly monitors the availability of medicines on the Russian market, including from the VED list. From time to time, various regions report to the ministry about the lack of immunoglobulin. The gap is bridged with the involvement of Russian manufacturers. In addition, according to the manufacturer of immunoglobulin, AO "NPO "Microgen", all applications received by the organization about the need to supply the drug are satisfied within the shortest possible timeframe.

As it became known earlier, Russian patients with congenital immune disorders receive insufficient quantities of Immunoglobulin.

https://gxpnews.net/en/2021/08/russia-at-risk-of-immunoglobulin-shortage/

Four pharmacy cartels were exposed in the Chelyabinsk region

The Office of the Federal Antimonopoly Service (FAS) for the Chelyabinsk Region is preparing to initiate a case against OOO Rifarm M (Moscow), OOO Pharmsklad (Sosnovsky District of the Chelyabinsk Region), OOO Porter (Moscow Region) and OOO A-Pharm (Ufa). This was reported by the press service of the regional department.

Signs of violation of the antimonopoly legislation were revealed as a result of a joint unscheduled on-site inspection with law enforcement officers in relation to OOO Pharmsklad. In the presence of witnesses and a representative of the organization, employees of the Chelyabinsk Office of the FAS of Russia and the

officers of enforcement authorities examined the premises and studied the documents of the limited liability company at the address of its registration.

As a result of the audit, signs of the conclusion of several anti-competitive cartels-type agreements are observed in the actions of the following economic entities: OOO Rifarm M, OOO Farmsklad and OOO Porter; OOO Farmsklad and OOO Porter; OOO Farmsklad, OOO Porter and OOO A-Pharm; OOO Porter and OOO A-Pharm.

These companies participated in competitive bidding procedures held in accordance with the legislation on the contract system and the legislation on the procurement of goods, works, services by certain types of legal entities, including within the framework of the national projects implementation.

The Federal Antimonopoly Service for the Chelyabinsk Region described the signs of anti-competitive agreements:

– personnel work (recruitment, recruitment and dismissal, transfer of employees) for these economic entities was performed by the employees of OOO Rifarm M;

– the seals of OOO Rifarm M, OOO Farmsklad and other legal entities were found at the registered address;

– during the inspection of the premises, an official note and an explanatory note from the employees of OOO Rifarm M were found, which indicate the deliberate submission of applications from several participants in two auctions. The total amount of the initial prices of contracts in their respect is more than 60 million rubles;

– OOO Rifarm M, OOO Farmsklad, OOO Porter and OOO A-Pharm, when participating in the competitive bidding in 2019-2021, used the same IP address owned by an individual entrepreneur who selected auctions for OOO Rifarm M and OOO Porter during these years;

– the details of the application files match;

– a number of behavioral models were used, including “the carousel”, “the only winner”, “the only supplier”;

– in most of the studied competitive bidding procedures, economic entities submitted applications one after another in a short period of time, not more than several minutes.

https://gxpnews.net/en/2021/08/four-pharmacy-cartels-were-exposed-in-the-chelyabinsk-region/

The EAEU approved the requirements for skin antiseptics

The Board of the Eurasian Economic Commission has made changes to the Unified Sanitary-Epidemiological and Hygienic Requirements for products that are subject to sanitary and epidemiological supervision. They were supplemented with requirements for skin disinfection products, i. e., for skin antiseptics, as well as a list of documents for studying the assessment of their toxicity and safety.

Due to the establishment of uniform requirements for skin antiseptics, it will be possible to optimize the registration process and their release into circulation due to the increased demand of the population, medical and other organizations during the coronavirus pandemic.

In addition, the requirements will be unified and the outcomes of toxicity and safety tests of disinfectants carried out during registration tests in the countries of the EAEU will be comparable.

Now it is possible to assess the toxicity and safety of the disinfectant intended for registration according to any method from the list regulating the testing procedure for the declared type of disinfection products.

https://gxpnews.net/en/2021/08/the-eaeu-approved-the-requirements-for-skin-antiseptics/

Moscow authorities have expanded the list of free medicines

Moscow authorities have expanded the categories of recipients and the list of free medicines, TASS reports with reference to materials for the meeting of the presidium of the Government of the capital.

“The Government of Moscow government has decided to add new categories of beneficiaries and new medicines to be provided for free under medical prescriptions. The order on this issue was signed by Sergei Sobyanin, the mayor of Moscow. In accordance with the amendments, citizens suffering from rheumatic disease, rheumatoid arthritis, systemic (acute) lupus erythematosus,

and ankylosing spondylitis will receive immunosuppressants for free," the message says.

It is noted that patients with glaucoma and cataract will receive free drugs of the prostaglandin group and carbonic anhydrase inhibitors used to treat increased intraocular pressure. Minor children diagnosed with primary immunodeficiency, a hereditary disease that impairs the immune system, will be provided with immunoglobulins free of charge. Previously, patients could receive this drug for free only if they had a disability or a hematological disease.

"It is estimated that the decision will improve the provision of medicines to about 4250 people. Additional budget expenditure will amount to about 87 million rubles a year," the article says.

https://gxpnews.net/en/2021/08/moscow-authorities-have-expanded-the-list-of-free-medicines/