The Ministry of Health proposes to increase compensation for complications from vaccination

The amount of the one-off payment for citizens who have complications after vaccination may be increased, according to RBC. At the moment, this payment is 10,000 rubles, having not been indexed since 2000.

“We consider it expedient to review the amount of this one-off payment from the state,” Mikhail Murashko, the Minister of Health, said in his response to State Duma deputy Fedot Tumusov.

This payment may be claimed by Russians who have become disabled after vaccination. Earlier, Tumusov sent a letter to the Ministry of Health, in which he proposed to introduce life and health insurance for 10 million rubles for everyone vaccinated against COVID-19.

“The logic was simple,” he explained to the publication. “If the vaccination is safe, the state will not lose anything, while people will be convinced that if the vaccination actually has any bad consequences, they will receive the payment, and vaccination becomes de facto mandatory.”

In the answer, it is stated that Russians who have complications after vaccination can claim one-off benefits, including disability payments. In case of death from vaccination, family members of the deceased will receive 30,000 rubles, the Ministry of Health recalls. The issue of compensation in case of complications from vaccination is fully regulated by the law, the document says.

https://gxpnews.net/en/2021/07/the-ministry-of-health-proposes-to-increase-compensation-for-complications-from-vaccination/

The Ministry of Health will create a roadmap for improving the drug supply system

The Working Group on the implementation of the regulatory guillotine in the healthcare sector considered the ways to improve the rules for the supply of medicines. The Russian Ministry of Health has to develop a roadmap for the establishment of the drug supply system within a year, Alexander Saversky, Chairman of the League for Patient Protection, wrote on his Facebook page.

He said that the issue of approving the procedure for dispensing medicines was considered at the meeting of the group. In particular, they discussed the provision according to which a patient who has a preferential prescription has to be provided the drug within two to fifteen days.

“The issue that was discussed with the participation of Sergey Glagolev, Deputy Minister of Health, seems to be a technical one: it is the approval of the procedure for the supply of medicines. It also includes a clause stating that medicines (prescribed by the decision of the medical board. – GxP News) are provided on prescriptions within 2 to 15 days (as a result of the negotiations, the upper limit was reduced to 10),” Saversky wrote.

The Chairman of the League for Patient Protection noted that this paragraph caused sharp criticism from both the medical and patient communities. He supported Leonid Roshal, President of the National Medical Chamber, who said: “It is impossible to treat people when drugs, even emergency drugs, are supplied with a two-day delay.” According to experts, the system needs to be changed.

“From the moment when a person falls ill, and even more so when they are diagnosed and receive a prescription, such person, as a citizen, has a constitutional right for medical care, including the right to drug supply according to standards and clinical recommendations. This means that the procedure in the norm under discussion contradicts the Constitution of the Russian Federation, because a person cannot receive the necessary medical care while they are waiting for drug supply for the time specified in the procedure,” Saversky explained.

The Working Group voted for giving the Ministry of Health a year to create a roadmap for the development of the drug supply system, so that the disputed procedure remains in force for only one year.

“That is, in a year the provisions must be revised, and tough decisions may have to be taken,” Saversky writes. He recalled that in 2010, the Ministry of Health adopted the Drug Supply Strategy, but it was not implemented properly.

Russia creates a system for evaluating the effectiveness of cardiac medications

Scientists of the Immanuel Kant Baltic Federal University (BFU) have developed a method that increases the efficiency of cardiovascular diseases treatment and also provides an opportunity to determine the patient’s adherence to prescribed drug therapy and find out whether the patient skips taking medications, RIA Novosti reports.

An important area in fighting heart diseases is the prevention of blood clots, including with the help of a long-term treatment with aspirin. However, according to researchers, patients do not always adhere to the treatment, so the actual clinical effectiveness of such treatment is insufficient.

Therefore, a method was proposed for monitoring medication adherence; it is based on the use of nuclear magnetic resonance (NMR) spectroscopy of a blood or urine sample. Thanks to this method, it is possible to quickly detects the presence of the products of various compounds in the body, in particular aspirin.

"We were the first to determine the metabolites of aspirin after administration of therapeutic doses of 100 mg and tracked the dynamics of their excretion. Our method can be used to check the cardiology patients' adherence to treatment with aspirin or other medications and the effectiveness of the treatment," Professor Vladimir Rafalsky, director of the Center for Clinical Research of the Kant BFU, commented.

NMR spectroscopy data can be used not only to monitor the quality of therapy, but also to determine individual characteristics of drug metabolism. The process does not require complex sample preparation. In the future, this method may provide the basis for an automatic drug adherence monitoring system.

https://gxpnews.net/en/2021/07/russia-creates-a-system-for-evaluating-the-effectiveness-of-cardiac-medications/

Russia has approved the official list of intoxicating substances

The Government of the Russian Federation has approved the list of intoxicating substances. The corresponding decree was published on the official Internet portal of legal information.

The list includes four items:

– nitrous oxide (nitric oxide (I), dinitrogen oxide);

– xenon;

– a mixture of diphenhydramine (diphenhydramine) with ethyl alcohol (regardless of their concentration);

– a mixture of doxylamine with ethyl alcohol (regardless of their concentration).

According to the decree, the list was compiled in accordance with the Federal Law "Concerning the Restriction of the Circulation of Nitrous Oxide in the Russian Federation", which prohibited the production, sale and advertising of this substance except for medical, industrial, and technical purposes. In addition, according to this law, nitrous oxide can not be used by individuals, unless it is required in connection with a medical intervention.

The list of intoxicating substances was first compiled in 1996 by the Standing Committee on Narcotics Control, an interdepartmental organization under the Ministry of Health. The Committee was officially disbanded in 2011, and since that time the list of intoxicating substances has not been legally established. At the same time, the term "intoxicating substances" is used in a number of regulatory acts, for example, in the Code of Administrative Offenses of the Russian Federation.

https://gxpnews.net/en/2021/07/russia-has-approved-the-official-list-of-intoxicating-substances/

The Ministry of Health has delisted nine more medicines

The Ministry of Health of the Russian Federation has canceled the state registration of nine medicines and excluded them from the state register of medicines. These include:

– Nebolin® caps (ibuprofen), capsules 200 mg, 400 mg, manufactured by Marksans Pharma Limited (India). Nonsteroidal anti-inflammatory drug (NSAID);

– Desmopressin (demospressin), nasal spray, dosed 10 mcg/dose, produced by Inpak AS (Norway). A drug against diabetes insipidus;

– Opra (citalopram), film-coated tablets, 20 mg, 40 mg, manufactured by ACTAVIS h. f. (Iceland), MEDA Manufacturing GmbH (Germany), ZAO ZiO-Zdorovye (Russia). Antidepressant drug;

– Galantamine-Teva (galantamine), film-coated tablets, 4 mg, 8 mg, manufactured by Teva Pharmaceutical Industries Ltd. (Israel). Anti-Alzheimer's drug;

– Neotigazon® (acitretin), capsules, 10 mg, 25 mg, manufactured by Pateon Inc. (Canada), F. Hoffman-La Roche Ltd.(Switzerland), Senexi (France), Roche Pharma AG (Germany). Tissue repair stimulator;

– Syndroxocin (doxorubicin), lyophilizate for the preparation of a solution for intravascular and intravesical administration, 10 mg, 50 mg, produced by S. C. Sindan-Pharma S. R. L. (Romania), Actavis Italy S. P. A. (Italy). Antitumor antibiotic;

– Fosavance® Forte (alendronic acid + colecalciferol), tablets, 70 mg+140 mcg, manufactured by Merck Sharp & Dohme B.V. (the Netherlands). Bone resorption inhibitor used to treat osteoporosis;

– Para plus, an aerosol for external use produced by Laboratoires Omega Pharma France (France), Aeropharm (France). Combined drug against head lice;

– Nevirapine (nevirapine), tablets, 200 mg produced by AO R-Pharm (Russia). A drug for the treatment of HIV infection.

The decisions were made on the basis of the following:

– submission by the holder or owner of the registration certificate of a drug, or another legal entity authorized by the holder or owner, of an application for the cancellation of state registration of medicinal products;

– due to the fact that the state registration of the drug for human use was not confirmed based on the results of an examination of the quality of the drug and/or an evaluation of the expected benefit to possible risk ratio related to the use of the drug.

https://gxpnews.net/en/2021/07/the-ministry-of-health-has-delisted-nine-more-medicines/

Russians buy more medicines against diarrhea and prebiotics

Sales of medicines for the digestive system in Russia have increased by 20%.

From May 3 to July 11, the sales of digestive enzyme preparations and drugs for restoring the intestinal microflora increased by an average of 8%. According to a study prepared for Izvestia by the DSM Group, sales of drugs that reduce gastric secretion increased by 13%, and sales of medicines against diarrhea went up by 20%.

The most significant growth was observed from June 7 to June 14. Over that period, the sales of enzymes increased by 19%, anti-diarrhea drugs by 34%, prebiotics by 32%, and drugs that reduce gastric secretion by 24%.

Doctors believe that one of the reasons for the growth is the spread of the Delta variant of COVID-19. According to Andrey Pozdnyakov, the infectious disease specialist and the chief doctor of Invitro Siberia, many people infected with this strain have diarrhea.

Andrey Pozdnyakov also noted that the growth of sales of medications against stomach-acid issues increased due to the specifics of COVID-19 therapy. Doctors prescribe such medications when the patient takes antipyretics, anticoagulants, antibiotics, as well as anti-inflammatory drugs, including dexamethasone. When dexamethasone is prescribed, it has to be accompanied by a medicine that reduces the amount of hydrochloric acid in the stomach.

Virologist Yevgeny Timakov, who is the chief physician of Lider-Meditsina medical center, confirmed an increase in complaints about gastrointestinal problems during the COVID-19 pandemic compared to the same period before it.

https://gxpnews.net/en/2021/07/russians-buy-more-medicines-against-diarrhea-and-prebiotics/

Ataluren to be purchased for the wards of the Circle of Kindness Foundation with Duchenne MD

The Federal Center for Planning and Organization of Drug Provision for Citizens announced a tender for the supply of Ataluren for the wards of the Circle of Kindness Foundation with Duchenne-Becker myodystrophy.

In May this year, the members of the expert council of the Circle of Kindness Foundation reviewed and approved applications from the executive healthcare authorities of the constituent entities of the Russian Federation for the supply of Ataluren for patients with Duchenne-Becker myodystrophy.

Ataluren is available in the form of a lyophilizate used to prepare a solution for oral administration. The initial (maximum) contract price is 233,869,132.20 rubles. Applications for participation in the auction are accepted until August 2, and the auction itself will be held in electronic form two days later, on August 4.

Two weeks ago, it became known that the expert council of the Circle of Kindness Foundation included drugs for 80 children with Duchenne muscular dystrophy

with the corresponding mutations in the list of purchases. The list includes Exondys, Vyondys, and Viltepso.

https://gxpnews.net/en/2021/07/ataluren-to-be-purchased-for-the-wards-of-the-circle-of-kindness-foundation-with-duchenne-md/

The Moscow authorities are planning rehabilitation for people who have had COVID-19

The most important task of Moscow healthcare in the coming years will be comprehensive rehabilitation and prevention of complications in people who have had COVID-19, Moscow Mayor Sergei Sobyanin said in his blog on July 27.

He supported the chief doctor of the State Clinical Hospital No. 52, Maryana Lysenko, who, shortly before the meeting with candidates for deputies of the State Duma, explained that the disease often results in long-term health problems in people who recovered from it, including the working-age population.

Sobyanin did not specify who was supposed to be eligible for such rehabilitation and what the planned funding for this medical service may be. According to the mayor, work on the provision of rehabilitation will have to start after the COVID-19 incidence decreases.

The Mayor of Moscow also recalled that a program of in-depth medical examination initiated by the president is offered to citizens who have had COVID-19 and suffer from chronic diseases; the program started in the Russian regions on July 1.

Earlier, it became known that the government will also allocate more than 5.8 billion rubles to the regions for conducting in-depth medical examinations of citizens who have recovered from the novel coronavirus.

https://gxpnews.net/en/2021/07/the-moscow-authorities-are-planning-rehabilitation-for-people-who-have-had-covid-19/

Rospotrebnadzor offers a cheap and fast way to track COVID-19 mutations

Specialists of the Central Research Institute of Rospotrebnadzor have suggested tracking coronavirus mutations in a new way. Instead of sequencing not the entire genome, the method involves studying only the part the mutations in which affect important epidemiological properties. This was reported to RIA

Novosti by Kamil Khafizov, the head of the research group for the development of new methods for diagnosing human diseases of the Central Research Institute.

“Targeted sequencing of individual fragments of the S-protein gene reduces the costs of sample preparation and sequencing by about ten times compared with the full-genome sequencing of the coronavirus infection. Testing takes half as much time, one of the reasons for which is that there is less “culling” of biological material in targeted sequencing. That is, a larger percentage of samples passes through all the stages of research and reaches the genomic sequence itself,” Kamil Khafizov explained.

According to the scientist, whole genome sequencing is the most reliable and accurate method, but it is costly and requires a significant time investment. He noted that the virus is constantly mutating, but its properties change only because of some of the mutations. It is proposed to sequence significant coronavirus mutations concentrated mainly in one part of the genome.

Vector has previously announced the effectiveness of EpiVacCorona against COVID-19 mutations.

https://gxpnews.net/en/2021/07/rospotrebnadzor-offers-a-cheap-and-fast-way-to-track-covid-19-mutations/

An experiment on the labeling of antiseptics starts in Russia

From August 1, an experiment on the labeling of antiseptic and disinfectants will begin in the Russian Federation. The corresponding government decree was signed by Mikhail Mishustin, the Chairman of the Government of the country.

Labeling antiseptics was suggested by the manufacturers in order to combat illegal trafficking of pharmaceutical and medical products during the coronavirus pandemic. This initiative was supported by the Ministry of Industry and Trade of Russia.

According to Denis Manturov, the head of the ministry, the experiment will last until August 31, 2022. Participation in it is voluntary.

“In the course of the experiment, together with the business, we will test the methods of applying digital labeling on packages of antiseptics and disinfectants and its traceability from the moment of production or import to the product’s

withdrawal from circulation. If there are bottlenecks in the process, we will deal with them in practice to remove them. Optimal solutions for manufacturers and suppliers will be found," the minister explained.

Initially, the Federal Ministry of Industry and Trade planned to launch an experiment on antiseptics labeling on May 15 this year, having announced it in March.

The information that the sphere of application of mandatory labeling requirements can be extended to include dietary supplements and antiseptics was published in October 2020.

https://gxpnews.net/en/2021/07/an-experiment-on-the-labeling-of-antiseptics-starts-in-russia/

Veterinary drug manufacturers ask to be classified as a separate industry

Russian manufacturers of veterinary drugs have applied to the Federal Ministry of Economic Development and the Ministry of Agriculture with a request to allocate the production of medicines for veterinary use to a separate industry and include it in the All-Russian classifier of economic activities (OKVED). This is reported by the "Zoo Inform" publication.

According to Alexander Isaev, the executive director of the National Veterinary Association, domestic veterinary drugs producers cannot receive state support (none of them has received any assistance in connection with the coronavirus pandemic). This creates obstacles for import substitution and the development of the existing export potential.

Experts also described the status of veterinary drugs manufacturers as underdetermined. They do not belong to agricultural producers, and, therefore, no state support through the Ministry of Agriculture is possible. There can be no assistance under the programs of the Ministry of Industry and Trade, since the ministry regulates only the manufacturing of drugs for human use. In this connection, the industry experts proposed to the Ministry of Agriculture to amend the Federal Law "On the Development of Agriculture".

https://gxpnews.net/en/2021/07/veterinary-drug-manufacturers-ask-to-be-classified-as-a-separate-industry/

Putin announces the need to accelerate vaccination against COVID-19

Russian President Vladimir Putin stated at a meeting with members of the Russian government that the main task now was to increase the rate of vaccination against coronavirus in the country.

According to the head of state, this summer has become “another challegne” in the fight against the novel coronavirus infection.

“This insidious, reoccuring epidemic is causing a lot of problems for us. This is happening not only in our country, but also in the vast majority of other countries around the world. It is difficult to understand many colleagues who still continue to distinguish between the pandemic in their country and somewhere else, and slow down the registration of vaccines which are definitely safe and effective, in particular, our vaccine. I hope that we will still be able to organize this work together, since doing it in silos is meaningless,” Putin said.

The Russian president said that “it is extremely important to convince people to get vaccinated.”

“This is the only way to block the epidemic. At the same time, it is necessary to provide a detailed and professional explanation of the complex issues concerning vaccination that citizens have questions about. It is very important that most people understand that they need to be vaccinated to save themselves, their relatives, and friends. It is necessary not to impose the vaccine but explain the reasons why it is needed. I would like to emphasize that the epidemic is a very stressful experience for people,” Putin said.

He recalled that vaccinations against coronavirus are not included in the national vaccination plan, which means they are optional. But according to the law of 1998, the governors of regions, acting in accordance with the recommendations of the chief sanitary doctors, have the right to introduce mandatory vaccination for certain categories of citizens in the case of a sharp increase in the incidence of a disease. Many heads of regions have used this right.

“It is necessary that people know about this, and they should also know who must not be vaccinated, and for what reasons, for example, due to a health condition. It is necessary, of course, to monitor the rights of people who are concerned about this vaccination campaign due to their chronic diseases that mean that they cannot not be vaccinated,” the President of the Russian Federation explained.

Vladimir Putin added that an important component of the vaccination campaign is the logistics and distribution of the vaccine. If it is in stock in warehouses, it should be distributed among medical institutions in a timely manner.

Putin earlier commented on the introduction of mandatory vaccination in some regions, and also revealedthat he had been vaccinated with the Sputnik V.

https://gxpnews.net/en/2021/07/putin-announces-the-need-to-accelerate-vaccination-against-covid-19/

Russia has developed unique technologies for the treatment of hepatitis B

The National Medical Research Center of Phthisiopulmonology and Infectious Diseases (FSBI "NMRC PPI") of the Ministry of Health of the Russian Federation has created unique technologies that allow treating chronic hepatitis B with the help of nucleases.

Currently, treatment is based on nucleotide analogues (nucleosides) and pegylated interferon, which reduce the amount of virus in the body and prevent the progression of the disease. But it is impossible to completely recover from chronic hepatitis B today. The development and introduction of drugs that contribute to the complete elimination of the hepatitis B virus from the human body is one of the priority areas of research in the world, the center noted.

For the first time in the world, the laboratory of genetic technologies and translational research of the FSBI "NMRC PPI" of the Ministry of Health of the Russian Federation has developed a prototype of a pharmaceutical substance (active substance) based on the site-directed nucleases technology. They are able to destroy more than 99% of the viral genomes in infected cells within a few days. A single dose of the drug that will be created based on this active substance will affect the parameters of the viral cycle and reduce the levels of antigens (HBsAg) and HBV DNA by 90-99%. An important feature of this substance is that it is non-toxic and safe.

More than 250 million people living with chronic HBV infection are registered in the world. More than a million people die from the disease every year.

https://gxpnews.net/en/2021/07/russia-has-developed-unique-technologies-for-the-treatment-of-hepatitis-b/

Testing of an anti-cancer radiopharmaceutical begins in Russia

A clinical trial for radiopharmaceuticals for the treatment of prostate cancer at an an advanced stage starts in the Russian Federation, RIA Novosti reports with reference to Andrey Kaprin, the chief consultant oncologist of the Ministry of Health of the country, General Director of the National Medical Research Radiological Centre.

“We are starting to test Lutetium-177, and everything is going as planned. The state assignment was received for the first time. Next, we will work with actinium,” Kaprin said during a briefing.

According to him, prostate cancer progresses rapidly and gives rise to metastases. Lutetium-177, which is based on actinium, will affect liver metastases and peritoneal metastases.

The chief consultant oncologist of the Federal Ministry of Health added that radiopharmaceuticals are the medicines of the future. The countries that are developing them expect to receive multibillion-dollar revenue. Russia, as Andrey Kaprin stressed, is diligently creating its own drugs.

https://gxpnews.net/en/2021/07/testing-of-an-anti-cancer-radiopharmaceutical-begins-in-russia/

The Russian vaccine Sputnik V will be delivered to Peru

The Peruvian authorities have concluded an agreement with the Ministry of Health of the Russian Federation on the supply of Sputnik V vaccine against COVID-19, RIA Novosti reports.

“The government of Peru is pleased to inform the citizens that it has signed an agreement on the supply of Sputnik V vaccine,” the message of the Ministry of Health of the Latin American country reads.

The Interim Peruvian President Francisco Sagasti announced the signing of a contract for ten million sets of the vaccine in a video message that appeared on social networks. That is a total of 20 million doses, since each vaccine consists of two doses.

As it became known last week, the Sputnik V vaccine had been approved in Nigeria. Nigeria has become the 68th State to approve the use of the Sputnik V vaccine. The total population of all countries that have approved Sputnik V is more than 3.7 billion people, about half of the world's population. In terms of the number of approvals received by state regulators, the vaccine is the second in the world.

According to the results of the data analysis in respect of 3.8 million vaccinated Russians, the effectiveness of the vaccine is 97.6%. According to The Lancet, the efficacy is 91.6%.

https://gxpnews.net/en/2021/07/the-russian-vaccine-sputnik-v-will-be-delivered-to-peru/

A new method of treating HIV patients has been developed in Russia

Specialists of the National Medical Research Center for Phthisiopulmonology and Infectious Diseases of the Ministry of Health of the Russian Federation have developed and patented a new highly effective method of treating HIV patients, RIA Novosti reports, referring to the center.

They recalled that it is impossible to completely recover from this disease, so patients are administered medications all their lives, and they are highly likely to develop some adverse reactions. 90% of the treatment regimens include the tenofovir, a drug with long-term toxic effect on the kidneys and bones. The new method of treatment first uses a triple scheme with tenofovir, and six months later, after the primary effect of treatment is achieved, patients are transferred to a two-drug scheme: dolutegravir and emtricitabine.

The two-drug therapy is enough to completely suppress the virus, since after six months of primary treatment, the body forms its own immune response against HIV. Both components reinforce each other. According to the developers, the scheme has no immediate or delayed toxicity. It also has the highest possible long-term effectiveness and tolerability. The authors have patented their invention; this method had not been previously used for patient treatment.

https://gxpnews.net/en/2021/07/a-new-method-of-treating-hiv-patients-has-been-developed-in-russia/

Drug manufacturing to be launched in the special economic zone near Novgorod

It is planned to open new drug and microelectronic products manufacturers, rapeseed processing plants and a number of other production facilities in the Novgorod region. On July 20, a government decree on the creation of a Special Economic Zone in the region comes into force, the Parlamentskaya Gazeta reports.

Novgorodskaya SEZ will be located in the Novgorodsky and Chudovsky districts, as well as in Veliky Novgorod. Its total area will exceed 180 hectares. The companies will produce monoclonal antibody drugs , microelectronic products, semi-trailer equipment, and there will also be plants processing rapeseed and manufacturing heat and sound insulation materials.

Companies that are residents of the special economic zone intend to invest about eight billion rubles in the regional economy. It is also expected that more than 700 jobs will be created. Due to this, tax revenues to the consolidated budget of the Novgorod region will increase by almost 800 million rubles.

The territory allocated for the SEZ has some of the required engineering and transport infrastructure. Then it will be equipped by the regional authorities, which allocate 1.3 billion rubles for the works.

Special economic zones are intended to develop the manufacturing industry, high-tech sectors of the economy, tourism, and port infrastructure. Their residents are entitled to tax and customs benefits.

The project for the creation of the Novgorodskaya SEZ was prepared by the Ministry of Economic Development of the Russian Federation.

https://gxpnews.net/en/2021/07/drug-manufacturing-to-be-launched-in-the-special-economic-zone-near-novgorod/

Mishustin orders an inventory of the COVID-19 vaccine stocks

Russian Prime Minister Mikhail Mishustin instructed the Ministry of Industry and Trade and the Ministry of Health to conduct an inventory of coronavirus vaccines to obtain up-to-date data on the stock, predict the need for the vaccine and form a reserve. This is reported on the official website of the Russian government.

The order is due to delays in the delivery of vaccines to the Russian regions against the background of increased demand. Such situations must be excluded in the future. The two ministries mentioned above will report on the work done to the federal government by July 21.

As Mishustin noted at the meeting of the coordinating council, the epidemiological situation in the country is still challenging. The Prime Minister recommended that the heads of the regions continue to form a sufficient reserve of beds, personal protective equipment and medicines for COVID-19 patients. Also, the governors were recommended to monitor compliance with the requirements of Rospotrebnadzor by the population and organizations.

It is necessary to continue testing citizens, promptly receiving the results of research. However, some commercial laboratories do not transmit the full amount of the data on the tests performed to the state information systems. Therefore, Rospotrebnadzor has incomplete epidemiological data. To solve this problem, it will be necessary to amend the government decree on temporary rules for recording information in order to prevent the spread of COVID-19. The Ministry of Health and the Ministry for Digital Development, Communications and Mass Media will consider the possibility of issuing such a draft resolution by July 20.

In addition, the Prime Minister of the Russian Federation gave instructions related to the prevention of influenza. The procurement of influenza vaccines is already being planned, and the Ministry of Health, the Ministry of Finance and Rospotrebnadzor will submit proposals to the government by July 19 stating the amount of budget funds required for that.

https://gxpnews.net/en/2021/07/mishustin-orders-an-inventory-of-the-covid-19-vaccine-stocks/

A biochip to be developed for coronavirus testing

The Research Institute of Rospotrebnadzor has started working on the creation of a biochip for COVID-19 testing. This was stated on the official website of the Agency today.

Rospotrebnadzor published the results of studies of the COVID-19 infection by the Academician I. N. Blokhina Nizhny Novgorod Scientific Research Institute of Epidemiology and Microbiology. The report states that a biochip to indicate the

actual pathogens of community-acquired pneumonia, including the SARS-CoV-2 virus, is being developed.

“It is planned to characterize the regional features of the etiological structure of community-acquired pneumonia. The outcome will provide the basis for the development of a prototype DNA biochip,” the agency explained.

Specialists of the Engineering Center for Microtechnology and Diagnostics of SPbSETU “LETI” also participate in the creation of a biochip for COVID-19 testing. For several years, they have been researching and developing multimodal biosensors to determine biomarkers, viruses and microorganisms by express method. This includes biomarker diagnosis of acute myocardial infarction, stress, and rapid diagnosis of SARS-CoV-2 coronavirus with the use of peptides.

The scientific and technological foundations were developed for the creation of biochips that can identify pathogens and test their antibiotic resistance. The Institute’s partners are the Research Institute of Influenza of the Ministry of Health of the Russian Federation, the State Research Institute of Highly Pure Biopreparations, and the Saint Petersburg Pasteur Research Institute of Epidemiology and Mictobiology.

To recall, according to the statement of one of the Russian epidemiologists, the collective immunity to coronavirus infection in the country has reached 60%. But this level does not mean it is time to feel relieved, as the necessary level is 90%.

https://gxpnews.net/en/2021/07/a-biochip-to-be-developed-for-coronavirus-testing/

Peskov describes the situation with the solution to the issue of mutual recognition of vaccines

No solution to the problem of mutual recognition of vaccines has been found yet, according to Dmitry Peskov, the press secretary of the President of the Russian Federation.

“No, the solution has not been found yet, but we are aware that the problem exists,” TASS quotes the Kremlin representative as saying.

He also added that the modernization of treatment protocols will help to minimize mortality from coronavirus in the future.

“Unfortunately, the mortality figures (from coronavirus) are quite high, it is true thatthe mortality rate has increased. The virus is becoming more aggressive and more contagious. Unfortunately, despite all the efforts made, despite all the existing treatment protocols, the virus is claiming many lives. Nevertheless, these treatment protocols are being improved, the number of vaccinated people is increasing, and this will help to minimize these sad figures again over time,” Peskov said.

He also noted that the vaccination discipline of Russians and their compliance with sanitary measures leave much to be desired.

https://gxpnews.net/en/2021/07/peskov-describes-the-situation-with-the-solution-to-the-issue-of-mutual-recognition-of-vaccines/

The Ombudsperson proposed to introduce certificates for the purchase of medicines for critically ill children

Anna Kuznetsova, the Commissioner for Children’s Rights for the President of Russia, proposed to include in the people’s program of the United Russia party an item on the introduction of electronic certificates for the purchase of medicines for children with serious diseases, TASS reports .

“We propose to consider the possibility of introducing electronic certificates that would provide compensation to the parents for the independent purchase of necessary medicines (in a similar way that it is done with technical means of rehabilitation). Then it would be possible, firstly, to provide this drug to patients on time, and secondly, to compensate for its cost through the electronic certificate,” Kuznetsova said on Thursday during the strategic session “Improving the quality of life of disabled people as a priority of the United Russia people’s program”.

According to her, the provision of medicines for children with disabilities is always on the agenda of the Commissioner. Kuznetsova recalled that “the Circle of Kindness Foundation has made a significant contribution to the provision of medicines to children with severe rare diseases”.
“At the same time, we continue to receive complaints concerning the long terms that the provision of prescribed drugs takes. Unfortunately, this is often due to the glitches that occur as a result of procurement procedures implementation,” the Ombudsperson explained.

Earlier, the Expert Council of the Circle of Kindness approved the decision on the procurement of medicines for children for the first quarter of 2022 to ensure the continuity of treatment of children in 2021 and 2022.

https://gxpnews.net/en/2021/07/the-ombudsperson-proposed-to-introduce-certificates-for-the-purchase-of-medicines-for-critically-ill-children/

FAS granted Miratorg's request to acquire 50% of Heparinus

The Federal Antimonopoly Service has granted the request of Miratorg agricultural holding to acquire 50% in the authorized capital of Heparinus, a company registered in the Kursk Region, TASS reports with reference to the agency's statement.

"The FAS of Russia has granted the request of OOO "Agropromyshlennyi Complex Miratorg" for a preliminary consent to the acquisition of a 50% share in the authorized capital of OOO Heparinus, a company registered in the Kursk Region and a part of the Van Hessen Group of companies (Germany)," the report says.

The agency clarified that the Heparinus joint venture is planning to process waste from Miratorg's economic activities.

In June, Miratorg asked the Federal Antimonopoly Service (FAS) for a preliminary consent to the acquisition of 50% in Kursk-based OOO Geparinus. This company was registered at the end of last year, and is 100% owned by the Dutch Van Hessen, which, as stated on its website, supplies meat offal, components for the pharmaceutical industry, including for the production of heparin (a blood thinning medication).

https://gxpnews.net/en/2021/07/fas-granted-miratorgs-request-to-acquire-50-of-heparinus/

RDIF refutes Reuters article about the failure of the timely registration of Sputnik V

The Russian Direct Investment Fund (RDIF) has refuted the information from Reuters about the failure to meet time constraints for the registration of Sputnik V vaccine in the EU. The Fund stated this in its Telegram channel.

This concerns the agency's June article, which states that the manufacturers of the Russian vaccine failed to submit all the documents to EMA by June 10. Now the outlet adds that at the beginning of June, the regulator received almost no information about the production of the vaccine, and the data on its clinical trials were incomplete.

The agency notes that the developers of the vaccine have failed to provide evidence to the French side that the master cell bank complied with EU regulations. According to the same sources, the EMA rates such data shortcomings on a scale that goes from "critical" – the most serious – to "major" to "minor."

The RDIF claims that "the article by the Reuters' Paris office concerning registration of the Sputnik V vaccine in the EU is based on false comments of anonymous sources and is an example of fake news and the disinformation campaign against the Russian vaccine, organized by the Western pharmaceutical lobby."

"The Reuters report contains glaring errors and misleads readers regarding the Sputnik V vaccine, its characteristics and interaction between the developers of the pharmaceutical and EMA specialists, and RDIF highlighted this to the Reuters editorial board before the publication. The RDIF refutes the information published by Reuters on the basis of anonymous sources," the fund said in its statement.

The Fund notes that it is continuing to cooperate with the EMA for the registration of the vaccine in the EU.

"In particular, EMA inspectors have completed an assessment of compliance of the vaccine with the standards of clinical trial and conducted an inspection of the production sites as part of the assessment of the good manufacturing practice in respect of the product," the RDIF reported.

They also noted that as a result of the inspection, the EMA specialists did not provide any critical comments and gave a positive feedback in their evaluation of

the Sputnik V clinical trial. RDIF expects that the registration of the vaccine by the EMA may occur in the coming months.

The RDIF was particularly critical in respect of the fact that Reuters' article is mainly based on anonymous sources. The only expert named not anonymously, Cecil Czerkinsky, officially denied his citation made by Reuters concerning the fact that the French team was "disheartened".

"These rumors have been scientifically refuted since that time, and I note that our exchange of opinions of May 2 was reflected in your publication only 2 months later, and, apparently, the material is aimed at undermining confidence in Sputnik V," Czerkinsky wrote.

RDIF also thanks Reuters for including the Fund's position in the publication, but asks "to conduct an internal investigation in the Reuters Paris office and take measures against agency employees who spread deliberately false and incorrect information."

https://gxpnews.net/en/2021/07/rdif-refutes-reuters-article-about-the-failure-of-the-timely-registration-of-sputnik-v/

The media report an increase in the share of imports of medical equipment in the Russian Federation

Over the past five years, the rate of import of medical equipment to the Russian Federation has continued to grow, and the share of domestic products in the market does not exceed 30%, Kommersant reports, citing a study by the National Rating Agency (NRA). It was planned that in five years the share of products made in the Russian Federation would reach 40% for basic types of equipment and products, but it actually turned out to be one and a half times lower.

Thus, the subprogram on import substitution of medical equipment and products up to 2020 adopted in 2015 by the Ministry of Industry and Trade within the framework of the Federal Targeted Program "Development of the Medical and Pharmaceutical Industry" has not reached its target indicators. The Auditing Chamber confirmed to the outlet that by the end of 2020, the share of Russian products was 28.8%, and in 2019, with a plan of 36%, the actual figure was 27.2%.

4.38 billion rubles were allocated from the budget for the implementation of the subprogram of the Ministry of Industry and Trade for the current year. But the cash execution of the budget was 15% lower than planned, according to the Auditing Chamber. It is specified that the reason is the delayed timing of competitive procedures and the lengthy approval of regulations determining the provision of subsidies to local producers.

On the contrary, the average import of medical equipment and medical products in 2015-2020 doubled, the outlet reports with reference to the NRA. According to the agency's analyst Maria Sulima, the maximum growth was shown by equipment for pulmonary therapy (medical ventilators), MRI and X-ray. Thus, $577.9 million was allocated for the purchase of medical ventilators in 2020, which is twice as much as in 2015. Last year, MRI devices were purchased for $143.7 million, which is double the amount spent in 2015, and X-ray equipment was purchased for $843 million, which is three times more than in 2015. The main suppliers are China, Germany, and the USA. The Accounting Chamber attributes the increase in the share of imports in monetary terms, among other things, to an increase in prices for foreign products, the newspaper notes.

https://gxpnews.net/en/2021/07/the-media-report-an-increase-in-the-share-of-imports-of-medical-equipment-in-the-russian-federation/

RDIF: Sputnik V is effective against various COVID-19 strains

Sputnik V vaccination results in production o protective neutralizing antibody titers against new strains, including British, South African, Brazilian, Indian variants and variants B.1.1.141 and B. 1. 1. 317 identified in Moscow with mutations in the receptor-binding domain (RBD), the Gamaleya Research Institute of Epidemiology and Microbiology and the Russian Direct Investment Fund (RDIF) report. The confirming data were obtained based on the analysis of the neutralizing activity of blood serum taken from vaccinated patients.

"The research methodology is based on the assessment of virus-neutralizing activity (VNA) with the use of a live virus, which allows us to obtain the most reliable data and corresponds to the gold standard. The study compared the VNA of human blood serum after vaccination with Sputnik V on samples of internationally represented strains with VNA against the original strain B.1.1.1. Blood serum was collected from individuals immunized with both components of Sputnik V," the report says.

The research methodology of the Gamaleya Research Institute of Epidemiology and Microbiology is described in an article published in the international journal Vaccines on July 12, 2021. VNA testing has no direct connection with the effectiveness of the vaccine.

It is noted that the obtained data demonstrate that Sputnik V also have protective properties against new strains. Sputnik V was found to have significantly lower decrease in the level of viral neutralizing activity for a number of strains compared to the data published by manufacturers of other vaccines, which previously confirmed the effectiveness of their products against new mutations of coronavirus.

the Gamaleya Research Institute of Epidemiology and Microbiology is actively studying new strains of SARS-CoV-2 to assess the VNA and the efficacy of Sputnik V vaccine as the variants arise in different regions of the world. The Center and RDIF are also considering the possibility of creating mix-and-match sets of vaccines together with other leading manufacturers based on the first shot of Sputnik V.

“Our studies demonstrate good results for Sputnik V vaccine in terms of its efficacy against new strains of SARS-CoV-2. We are getting more and more data from around the world about the ability of the coronavirus to transform and mutate. Today, Sputnik V is one of the most effective vaccines against both the original and new strains of coronavirus due to the unique approach based on the use of two different adenoviral vectors as delivery tools,” said Alexander Ginzburg, director of the Gamaleya Research and Development Center.

Sputnik V was the first vaccine to use two different adenoviral vectors at the same time. Studies of the Gamalei Center have demonstrated the appropriateness of this approach as the virus neutralizing activity of the vaccine against new, more dangerous strains was higher than that of many other vaccines. RDIF will continue to support further research on the effectiveness of Sputnik V against new strains and is analyzing the possibilities of partnership with other leading manufacturers to create mix-and-match of vaccines based on the first shot of Sputnik V,” said Kirill Dmitriev, CEO of RDIF.

To date, Sputnik V has been registered in 67 countries with a total population of more than 3.5 billion people. According to data from regulators from a number of countries, including Mexico, Argentina, Serbia, Bahrain, Hungary, San Marino, the United Arab Emirates, and other states, obtained during vaccination of the population, demonstrate that Sputnik V is one of the safest and most successful vaccines against coronavirus.

https://gxpnews.net/en/2021/07/rdif-sputnik-v-is-effective-against-various-covid-19-strains/

The Circle of Kindness Foundation will buy medicines for patients with Duchenne disease

According to the the Telegram post of the Public Chamber, the Expert Council of the Circle of Good Foundation included in its procurement list drugs for 80 children with Duchenne muscular dystrophy, depending on specific mutations.

The list includes Exondys, Vyondys, and Viltepso.

"The disease destroys muscles: the child first stops walking, and eventually stops breathing. Pathogenetic therapy helps patients maintain their ability to move independently for a long time, and promotes preservation of motor and respiratory functions. Interruptions in therapy lead to a regression of motor activity. About 50 children will be provided with medicines," the report says.

Lumasiran will be purchased for 30 children with primary hyperoxaluria type 1. The disease leads to excessive production of oxalate and pathological deposition of calcium oxalate in many organs. Primary hyperoxaluria type 1 is the most severe and most common (1-3 cases per million) form of this genetic disease, which causes the formation of kidney stones, and in the absence of the necessary therapy can lead to kidney failure and the need for dialysis.

On July 6, the Expert Council of the Circle of Kindness approved the decision on the procurement of medicines for children for the first quarter of 2022 to ensure the continuity of treatment in 2021 and 2022.

https://gxpnews.net/en/2021/07/krug-dobra-zakupit-lekarstva-dlya-paczientov-s-boleznyu-dyushenna-2/

The Ministry of Health is developing new approaches to the treatment of COVID-19

The Ministry of Health is developing a new, 12th version of the temporary guidelines for the treatment of COVID-19, which will also reflect new approaches, as Izvestia report with reference to Vladimir Chulanov the chief specialist of the Department for infectious diseases, deputy director of the

National Medical Research Center for Phthisiopulmonology and Infectious Diseases.

“We are preparing the 12th version, which, hopefully, will be ready in the near future. The working groups hold meetings to discuss the principle which we would like to implement in the treatment, ” he said.

Vladimir Chulanov noted that the expert community is considering new approaches to treatment. Some drugs, he said, which have been used only for inpatients so far, are proposed for outpatient practice or at day hospitals.

At the end of June, the Russian Ministry of Health approved temporary recommendations on the procedure for vaccination of the population against COVID-19, and sent the document to the regions.

https://gxpnews.net/en/2021/07/the-ministry-of-health-is-developing-new-approaches-to-the-treatment-of-covid-19/