DRUG SECURITY FORUM

ROSCONGRESS
Building Trust

SPIEF'22
ST. PETERSBURG INTERNATIONAL ECONOMIC FORUM

'ENSURING DRUG SECURITY' RUSSIAN PHARMACEUTICAL FORUM PROGRAMME

June 15 2022, St. Petersburg

Programme accurate as at June 21, 2022

June 15, 2022

10:00–11:30

Pavilion G
conference hall G2

'Ensuring Drug Security' Russian Pharmaceutical Forum

Regular Discussion about Irregular Illness: Prospects for Drug Therapy

The creation of the Circle of Kindness Foundation has changed the way NPOs, the state, and business interact, led to a redistribution of resources between state and charitable programmes, and forced a rethinking of the social contract in place for children with serious and rare diseases. The Foundation's appearance on the scene has altered the dynamic governing relations between the ministry concerned, regional health authorities, medical institutions, and public organizations. The creation of the Circle of Kindness Foundation has also affected the market for expensive drugs and given rise to new opportunities in the country's pharmaceutical industry: the Foundation consistently purchases a significant amount of new, expensive, innovative drugs. All of these factors are constantly presenting the Foundation and, more broadly, society with new challenges, risks, and demands. What impact does the new environment have on the ethical foundations underlying the activities of healthcare professionals? How can the decision-making process be improved to better care for children with serious and rare diseases? What opportunities are opening up for Russian pharmaceutical manufacturers and how quickly and effectively will they be able to take advantage of these opportunities? How can we build more effective and harmonious relationships between the Circle of Kindness Foundation, NPOs, and patient organizations to better serve patients with rare and serious illnesses?

Moderator:

- **Alexander Tkachenko**, Archipiest; Chairman of the Committee for Philanthropy, Civic Education, and Social Responsibility of the Civic Chamber of the Russian Federation; Chairman of the Board, Circle of Kindness Foundation

Panellists:

- **Oleg Ergashev**, Vice-Governor of Saint Petersburg
- **Elena Khvostikova**, Head, Genome Patient Care Center
- **Irina Kirkora**, Deputy Chairman of the Presidential Council for the Development of Civil Society and Human Rights
- **Sergey Kutsev**, Director, Research Centre for Medical Genetics; Chief External Expert in Medical Genetics of the Ministry of Health of the Russian Federation **(online)**
- **Aleksandr Rumyantsev**, Scientific Director, Dmitry Rogachev National Research Centre **(online)**
- **Yuriy Zhulev**, Co-Chairman, All-Russian Union of Patients

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10:00–11:30

Pavilion G
conference hall G3

'Ensuring Drug Security' Russian Pharmaceutical Forum

Export Potential: EAEU and the Global Market

In addition to the countries of the Eurasian Union, Russian manufacturers supplied drugs to another 88 countries (according to 2019 data). With the West imposing sanctions against Russia, trade flows will be bypassing Europe. Russian exports will now be targeting the markets of Latin America, Africa, and Asia. The export of finished dosage forms to other countries are complicated by the fact that direct logistics routes are constrained by the severe sanctions against Russia, which means other means of exports need to be found, including with the participation of the EAEU countries. At present, EAEU countries account for about 39% of Russia's drug exports (in monetary terms). Is it possible that the new geopolitical challenges could become an impetus and not an obstacle to the development of the expert potential of Russia's pharmaceutical industry? Would it not be more profitable to build up the competitiveness of the EAEU by creating Eurasian brands under a single 'Made in the EAEU' brand as European companies (Societas Europaea) have done? What is Russia's role as a pharmaceutical manufacturer as part of the main focuses for the economic development of the Eurasian Economic Union until 2035? Are domestic pharmaceutical manufacturers ready for the requirements that the EAEU is introducing to establish the proper quality of medicines?

Moderator:

- **Vadim Kukava**, Executive Director, The Association of Pharmaceutical Companies «Innovative Pharma»

Panellists:

- **Vladislav Davankov**, Deputy of the old State Duma of the Federal Assembly of the Russian Federation
- **Marina Durmanova**, President, Association for the Support and Development of Pharmaceutical Activities of the Republic of Kazakhstan **(online)**
- **Victor Fisenko**, First Deputy Minister of Health of the Russian Federation
- **Mikhail Grubman**, Biotech Sales and Export Director, NPO Petrovax Pharm
- **Aleksey Kedrin**, Chairman of the Board, Association of Pharmaceutical Manufacturers of the Eurasian Economic Union (EAEU)
- **Viktor Nazarenko**, Member of the Board, Minister in charge of Technical Regulation, Eurasian Economic Commission

Front row participants:

- **Anna Belova**, General Director, Pharmprobeg
- **Vladimir Shipkov**, Executive Director, Association of International Pharmaceutical Manufacturers (AIPM)

10:00–11:30

Pavilion G
conference hall G6

'Ensuring Drug Security' Russian Pharmaceutical Forum

Regulation 2.0: Stress Test of the System from the Pandemic to New Challenges

The drug circulation regulatory system faced new, unprecedented challenges in 2022, such as the risk of a significant increase in the cost of medicines and the protection of the national market against shortages of vital drugs both due to the curtailed supply of original imported drugs as well as logistics disruptions in the supply of raw pharmaceutical materials. The experience Russia has gained from the COVID-19 pandemic has strengthened its regulatory system and prompted the government to make quick and effective decisions that have proven that the development, registration, and commercial release of drugs can be significantly accelerated without compromising safety and quality. This experience should be adopted today and continued. How are shortages of raw pharmaceutical materials and logistics problems affecting the cost of finished products? What government measures to regulate and control costs can protect the interests of pharmaceutical manufacturers, pharmacy

chains, and end consumers? Is the model of state procurements for the production of vital and essential drugs and new dosage forms with the guaranteed procurement of drugs for several years applicable in the current realities that Russia is facing? Will the compulsory licensing system be able to insure the Russian market in the event the supply of imported drugs decreases or their prices significantly increase? How might potential measures to speed up the registration process affect the quality of products? What is the best way to maintain effective control and oversight activities and ensure the quality of medicines in the face of the new challenges? What is the social significance of pharmacovigilance?

Moderator:

- **Alla Samoylova**, Head, Federal Service for Surveillance in Healthcare (Roszdravnadzor)

Panellists:

- **Sergey Glagolev**, Deputy Minister of Health of the Russian Federation
- **Chinara Mambetaliyeva**, Deputy Director, Department of Technical Regulation and Accreditation, Eurasian Economic Commission
- **Irina Maysak**, Deputy Director, State Pharmaceutical Supervision in the Sphere of Circulation of Medicines "Gospharmnadzor" **(online)**
- **Timofey Nizhegorodtsev**, Deputy Head, Federal Antimonopoly Service of the Russian Federation
- **Vitaliy Omelyanovskiy**, General Director, Center for Healthcare Quality Assessment and Control of the Ministry of Health of the Russian Federation
- **Aleksandr Petrov**, Chairman of the Subcommittee on Medicines, Development of the Pharmaceutical and Medical Industry of the State Duma of the Federal Assembly of the Russian Federation for Health Protection
- **Dmitry Zemskov**, Executive Director, Biochemist

Front row participant:

- **Dmitry Sychev**, Rector, Russian Medical Academy of Continuous Professional Education of the Ministry of Health of the Russian Federation

12:15–13:45

Pavilion G
conference hall G2

'Ensuring Drug Security' Russian Pharmaceutical Forum

Pharmaceutical Industry in Russia – Reset 2030: On the Path to Independence

"According to IQVIA, Russia is home to more than 900 manufacturers (92 companies with revenue of more than USD 15 million in 2021). RNC Pharma found that 76.7% of raw materials imported to Russia in 2021 came from India and China and 19.7% came from EU countries. Russia imported a total of 15,800 tonnes of pharmaceutical substances worth RUB 195.4 billion last year". The country's import substitution agenda has taken on increased importance due to the challenges of 2022. Russia must become independent of imported medicines, medical devices, and equipment. Long-term solutions need to found as soon as possible in order to build logistics tracks, replace imported raw materials in manufacturing, and prevent a shortage of high-quality components and vital medical products. To saturate the Russian market, it is essential to accelerate the introduction of domestic developments, provide financial support, and establish technological chains at all stages of production, from the procurement of raw materials to the production of a final product that is competitive compared with world analogues. What state support measures for key enterprises in the pharmaceutical and medical industries, product distributors, and pharmacy chains envisage the development of the Russian pharmaceutical industry? Can Russian production facilities provide high-precision equipment to the market? What measures to support small and medium-sized pharmaceutical businesses could contribute to the development of the pharmaceutical market? What risks exist after the timeframe for the state registration and expert examination of the quality of medicines is shortened?

Moderator:

- **Aleksey Kedrin**, Chairman of the Board, Association of Pharmaceutical Manufacturers of the Eurasian Economic Union (EAEU)

Panellists:

- **Sergey Glagolev**, Deputy Minister of Health of the Russian Federation
- **Mikhail Grubman**, Biotech Sales and Export Director, NPO Petrovax Pharm
- **Vasily Osmakov**, First Deputy Minister of Industry and Trade of the Russian Federation
- **Petr Rodionov**, General Director, Geropharm LLC
- **Aleksandr Semenov**, President, Active Component
- **Vladimir Shipkov**, Executive Director, Association of International Pharmaceutical Manufacturers (AIPM)

12:15–13:45

Pavilion G
conference hall G3

'Ensuring Drug Security' Russian Pharmaceutical Forum

The Economics of Drug Supply: How to Balance Supply and Demand

The economic approach to the drug supply system means choosing from a set of alternative management decisions that can achieve the maximum result given limited resources while simultaneously increasing demand for modern drugs. The proper choice of the right alternative, in turn, depends on the ability to select and analyse the primary factors of influence to achieve a balance of demand for drugs and supply. The institutional environment of the modern pharmaceutical market in Russia has an impact on both the state and its commercial segment. One of the key aspects of achieving a balance and optimizing the economics of drug supply is an effective public drug procurement system that is built both taking into account the current market realities and all the innovative models that exist in world practice. How flexible should the legal regulation of the pharmaceutical industry be? How should pricing be managed when people's personal funds account for 64% of the demand for drugs? What economic factors dictate the choice of a procurement system? What are the economic consequences of changing drug therapy and should this be taken into account when choosing treatment tactics? How should preferences work for the domestic pharmaceutical industry?

Moderator:

- **Elena Maksimkina**, Director, "Federal Center for Planning and Regulation Of Medical Supply Circulation" of the Ministry of Health of the Russian Federation

Panellists:

- **Victor Fisenko**, First Deputy Minister of Health of the Russian Federation
- **Dmitriy Galkin**, Director of Department of Pharmaceutical and Medical Industry Development, Ministry of Industry and Trade of the Russian Federation
- **Igor Narkevich**, Rector, St. Petersburg State Chemical-Pharmaceutical Academy
- **Timofey Nizhegorodtsev**, Deputy Head, Federal Antimonopoly Service of the Russian Federation
- **Filipp Romanov**, Deputy Chairman of the Board, Association of Pharmaceutical Manufacturers of the Eurasian Economic Union (EAEU)

Front row participants:

- **Roman Ivanov**, Director of the Scientific Center for Translational Medicine, Vice-Rector for Scientific and Technological Development, Sirius University of Science and Technology
- **Alexey Kolbin**, Professor, Head of the Department of Clinical Pharmacology and Evidence-Based Medicine, First St. Petersburg State Medical University named after Academician I.P. Pavlova

- **Galina Shemanaeva**, Acting Deputy Head of Administration of the Tambov Region
- **Vadim Tarasov**, Director, Institute of Translational Medicine and Biotechnology Institute of Translational Medicine and Biotechnology, First Moscow State Medical University named after I.M. Sechenov

12:15–13:45

Pavilion G
conference hall G6

'Ensuring Drug Security' Russian Pharmaceutical Forum

Made in Russia Brand: The Time of Trust

Localized drugs accounted for 44.5% of total sales in 2021. Of the 808 items on the list of vital and essential drugs, up to 80% are produced by Russian pharmaceutical manufacturers, more than a third of which have full-cycle production. Russian-produced drugs made up 61.2% of total package drug sales in 2021. Given the current geopolitical sanctions and the policy of import substitution, people's trust in Russian medicines is crucial since people should be motivated to buy domestically produced drugs because they are confident in the quality and effectiveness of the range being offered instead of not having any other choice. According to a survey conducted in 2020 by the Russian Public Opinion Research Centre, 12% and 54% of respondents said they 'fully trust' and 'likely trust' Russian-made drugs, respectively. A positive reputation for the Made in Russia brand and strategies for shaping a particular opinion in society should be based on targeted information work, while observing the principle of openness and transparency. What factors influence the image of domestic medicinal products and how can they be managed? To what extent can publications in reputable sources on the efficacy, safety, and quality of Russian medicines influence public opinion? What strategies should the state, the medical expert community, and manufacturers employ to bolster people's trust?

Moderator:

- **Aleksandr Petrov**, Chairman of the Subcommittee on Medicines, Development of the Pharmaceutical and Medical Industry of the State Duma of the Federal Assembly of the Russian Federation for Health Protection

Panellists:

- **Airat Farrakhov**, Member of the Committee of the State Duma of the Federal Assembly of the Russian Federation on Budget and Taxes
- **Alexey Kuznetsov**, Assistant to the Minister of Health of the Russian Federation
- **Natalia Prokopieva**, Chairman of the Board of Directors, Evalar
- **Kirill Rodin**, Director for Government Relations, Russian Public Opinion Research Center
- **Oleg Yanushevich**, Rector, A.I. Yevdokimov Moscow State University of Medicine and Dentistry of the Ministry of Health of the Russian Federation; President, Association of Russian Doctors

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12:15–13:45

Pavilion G
conference hall G7

'Ensuring Drug Security' Russian Pharmaceutical Forum

Value-Based Approaches to Healthcare: How to Ensure High-Quality Medical Care and Efficient Funding

The government is increasing investment in developing the healthcare system and expenditures on providing medical services under Mandatory Health Insurance (OMS) are rising by the year. Even so, the current life expectancy is still well below target set in the Russian Federation National Development Goals up to 2030. This means that the need is more acute than ever for Russia to develop value-oriented healthcare based on value as the outcome of the entire process by which medical care is provided not only the eyes of the doctor and the healthcare system, but also those of the patient. Implementation of a value-oriented approach makes possible a maximally effective distribution of available financial resources and formation of a patient-centric healthcare system in which control is exercise not over the processes and scope of medical care but the outcomes vital to the patient achieved by the joint efforts of various medical specialists and information collaboration between medical services. What is of value to the healthcare system, the doctor and the patient? Is Russia ready to make the transition to a value-oriented healthcare model? How should the process be arranged for introducing value-oriented approaches to the system for exercising quality control over medical care? What changes would the OMS system require to transfer to payment for medical care depending on treatment outcomes?

Moderator:

- **Vitaliy Omelyanovskiy**, General Director, Center for Healthcare Quality Assessment and Control of the Ministry of Health of the Russian Federation

Panellists:

- **Ilya Balanin**, Chairman, Federal Mandatory Medical Insurance Fund (FOMS) **(online)**
- **Anatoly Fesyun**, Acting Director, "National Medical Research Center for Rehabilitation and Balneology" of the Ministry of Health of the Russian Federation
- **Dmitry Maystrenko**, Director, Russian Scientific Center for Radiology and Surgical Technologies named after Academician A.M. Granov" of the Ministry of Health of Russia
- **Alla Samoylova**, Head, Federal Service for Surveillance in Healthcare (Roszdravnadzor)
- **Evgeny Shlyakhto**, Director General, Almazov National Medical Research Centre; President, All-Russian Non-Governmental Organization "Russian Society of Cardiology"
- **Vladimir Zelensky**, First Deputy Minister of Health of the Russian Federation **(online)**
- **Yuriy Zhulev**, Co-Chairman, All-Russian Union of Patients

Front row participants:

- **Vadim Kukava**, Executive Director, The Association of Pharmaceutical Companies «Innovative Pharma»
- **Olga Tyulkina**, Director, Public Health Center; Chief Freelance Prevention Specialist of the Leningrad Region

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14:30–16:00

Pavilion G
conference hall G2

'Ensuring Drug Security' Russian Pharmaceutical Forum

Women in Pharmaceutical and Biotechnology Industry

Given the current global challenges, there is a growing demand to create a new mindset concerning healthcare. Improving the availability and efficiency of drug supply is one of the key tasks of the national healthcare industry. Women are actively involved in the scientific development of modern medicines and ensure the smooth operation of enterprises that produce modern medicines. What are the priority focuses for the development of pharmaceuticals in the current conditions? How can the manufacturing of domestic drugs be expanded to meet the demand for high-quality and affordable drugs in Russia? What resources do companies need to develop the production of affordable drugs? What improvements can be made to the training and retraining of staff at modern pharmaceutical enterprises? What new health protection technologies are most effective in preventing serious diseases and building a healthy society?

Moderator:

- **Tatyana Yakovleva**, First Deputy Head, Federal Medical-Biological Agency of the Russian Federation

Panellists:

- **Elena Baranova**, Founder, Baranova Monaco; President, EU Institute of Personalized Prevention and Health
- **Oksana Drapkina**, Director, National Medical Research Center for Preventive Medicine of the Ministry of Health of the Russian Federation
- **Galina Karelova**, Deputy Chairman of the Federation Council of the Federal Assembly of the Russian Federation
- **Elena Maksimkina**, Director, "Federal Center for Planning and Regulation Of Medical Supply Circulation" of the Ministry of Health of the Russian Federation
- **Lyudmila Scherbakova**, Co-Founder, Chairman of the Board of Directors, Velpharm LLC
- **Tatyana Semenova**, Deputy Minister of Health of the Russian Federation
- **Anastasia Stolkova**, Director of "Women for a Healthy Society"

Front row participant:

- **Lyalya Gabbasova**, Deputy Director for General Affairs, Medical Research and Education Center, Lomonosov Moscow State University

14:30–16:00

Pavilion G
conference hall G3

'Ensuring Drug Security' Russian Pharmaceutical Forum

Digitalization in Drug Supply: Accessibility, Transparency, and Authenticity

The federal project 'Creation of a Unified Digital Network in Healthcare Based on the Unified State Healthcare Information System' regulates issues concerning digitalization in the healthcare system. The project aims to introduce a system of electronic prescriptions and the automated management of subsidized drug supply throughout Russia by 2024. The system used to monitor the movement of drugs can control the supply of medicines and track a drug's path from the manufacturer to the pharmacy, while guaranteeing the authenticity of drugs. In 2021, changes were made to the rules for issuing drug prescriptions, which can be provided both in hard copy and electronic form. Given the ongoing problem with the sale of banned or restricted drugs online, digitalization will ensure transparency and security for both prescription and over-the-counter drugs. What are the benefits of developing a unified digital network for all parties involved in the drug supply industry? Will the creation of a unified digital network improve control over the availability of medicines at medical organizations and pharmacy chains? What risks could arise from fully transitioning to an electronic prescription

system? What prospects exist for the home delivery of prescription drugs as the country transitions to electronic prescriptions?

Moderator:

- **Alla Samoylova**, Head, Federal Service for Surveillance in Healthcare (Roszdravnadzor)

Panellists:

- **Dmitry Alkhazov**, Chief Executive Officer, Advanced Technologies Development Center (ATDC)
- **Alexey Martynov**, President, Association of Biomedical Cellular Products Manufacturers
- **Pavel Pugachev**, Deputy Minister of Health of the Russian Federation **(online)**
- **Lorenzo Redalie**, Head of Humanitarian Affairs Department, Regional Delegation of the International Committee of the Red Cross for the Russian Federation and the Republic of Belarus
- **Dmitry Somov**, Acting General Director, Information and Methodological Center for Expertise, Accounting and Analysis of the Circulation of Medical Products
- **Vladimir Vinogradov**, Head of Business Pharma, Russian Post

Front row participants:

- **Evgeny Miroshnikov**, First Deputy Governor – Minister of Digital Development of the Belgorod Region
- **Artem Sokolov**, President, The Association of Internet Trade Companies
- **Yan Vlasov**, Co-Chairman, Russian Patient Association

14:30–16:00

Pavilion G
conference hall G6

'Ensuring Drug Security' Russian Pharmaceutical Forum

From Innovations to Generics: New Prospects

Generic drugs make up about 80% of the market in Russia. On average, there are about 10 generics per original drug in addition to around 30–50 generics for antibiotics and painkillers. Given the decrease in the supply of finished dosage forms from European countries, generics are becoming the main alternative drug on the Russian market, while the risks of drug defects due to sanctions are protected by the law on the compulsory licensing of medicines. However, the main keys to strengthening the Russian pharmaceutical market should not only be independence from imports, but also the development of the country's own innovations. Russia needs to create a cluster of enterprises that are capable of synthesizing active pharmaceutical ingredients, and conditions should be created to develop an innovative pharmaceutical industry. What regulatory policy and quality control solutions are needed to create competitive generics in Russia? Do domestic pharmaceutical manufacturers have enough capacity and technology to develop generics for drugs that are covered by the law on compulsory licensing? What state support instruments for R&D will help stimulate the development of the innovative pharmaceutical industry in Russia? What new models of cooperation do business and scientific development institutions need to develop and introduce to stimulate innovation in the pharmaceutical and biotechnology market?

Moderator:

- **Evelina Zakamskaya**, Editor-in-Chief, Doctor Channel; Anchor, Russia 24

Panellists:

- **Sergey Glagolev**, Deputy Minister of Health of the Russian Federation
- **Vadim Kukava**, Executive Director, The Association of Pharmaceutical Companies «Innovative Pharma»

- **Natalia Mokrysheva**, Director, National Medical Research Center for Endocrinology Ministry of Health of the Russian Federation **(online)**
- **Vasily Osmakov**, First Deputy Minister of Industry and Trade of the Russian Federation
- **Sergei Saiganov**, Rector, North-Western State Medical University named after I.I. Mechnikov
- **Kira Zaslavskaya**, New Products Director, "Promomed" Group of Companies

16:45–18:45

Congress Centre
conference hall D1

'Ensuring Drug Security' Russian Pharmaceutical Forum

Plenary session

Drug Security: Humanity at the Heart of Collaboration

For Russia, drug security is currently a top priority in the healthcare sector and a precondition for the country to reach an entirely new level given the realities of the current challenges. The government's immediate agenda includes maintaining the availability of medicines, ensuring the financial stability and technological independence of pharmaceutical industries, and fulfilling state guarantees for the provision of drugs to society. In a country with stable drug security, each citizen must be sure that his/her life and health are reliably protected. Such confidence is primarily manifested in the trust of society and people's approval of the actions of state institutions. Today, it is not only crucial to unite the key regulators, the expert community, and society and establish the openness and transparency of various processes, but also to build a space for understanding and cooperation. People's health and lives are a primary focus of the laws of humanism and go beyond political boundaries. What solutions will get the healthcare and medical supply industry out from the pressure of sanctions? What strategies for the import independence of the pharmaceutical industry are protecting the government's interests? How can the state and society build a dialogue towards trust and cooperation? What is the best way to ensure national drug security and guarantee that Russian citizens regularly have high-quality and effective drugs available to them?

Moderator:

- **Sergey Brilev**, President, The Global Energy Association

Panellists:

- **Ikhtiyar Aslanov**, Head of Regional Delegation for the Russian Federation and the Republic of Belarus, International Committee of the Red Cross
- **Mariangela Batista Galvao Simao**, Assistant Director-General, Access to Medicines and Health Products, World Health Organization **(online)**
- **Mikhail Murashko**, Minister of Health of the Russian Federation
- **Aleksandr Petrov**, Chairman of the Subcommittee on Medicines, Development of the Pharmaceutical and Medical Industry of the State Duma of the Federal Assembly of the Russian Federation for Health Protection
- **Alla Samoylova**, Head, Federal Service for Surveillance in Healthcare (Roszdravnadzor)
- **Tadzio Schilling**, Chief Executive Officer, Association of European Businesses (AEB)
- **Evgeny Shlyakhto**, Director General, Almazov National Medical Research Centre; President, All-Russian Non-Governmental Organization "Russian Society of Cardiology"
- **Veronika Skvortsova**, Head, Federal Medical-Biological Agency of the Russian Federation