

**XV ANNUAL ALL-RUSSIAN CONFERENCE  
"STATE REGULATIONS IN THE AREA OF DRUGS AND MEDICAL DEVICES  
CIRCULATION "**

**"FarmMedObraschenie 2013"**

**October 30-31, 2013, Moscow, THC "Izmailovo"**

**CONFERENCE PROGRAM**

**October 30**

**Opening ceremony**

**Plenary session (10.00-12.00, CH "Izmailovo")**

**From the quality of drugs and medical devices to high-quality health care**

- Opening address (Kagramanyan I.N. – Deputy Minister of Health of Russian Federation)
- New legislative initiatives in the healthcare sector (Kalashnikov S.V. – Chairman of the State Duma Committee on Health Services)
- Current issues of State policy in the area of Public Health (Ryazansky V. V. – Chairman of the Federation Council Committee on Social Policy)
- Assessment of Regulatory impact on the circulation of medical products and medical services in Russian Federation (Murashko M. A. – Acting Head of Roszdravnadzor)
- Guaranteeing the provisions of free medical care for compulsory health insurance program (Stadchenko N.N. – Head of Federal Compulsory Medical Insurance Fund)
- RSPP Cooperation with the Authorities on the development of domestic drugs manufacturing and improving the regulatory framework (Cherepov V.M. – Executive Vice-President of Russian Union of Entrepreneurs and Industrialists (RSPP))

**Press briefing (12.15-13.00, CH "Izmailovo")**

**Session meeting**

**Distribution of drugs for medical use, International standards and Russian Perspectives**

**(13.00-16.00, October 30 CH "Izmailovo")**

Chairman: Krupnova I.V. – Head of the Bureau of State control of drugs circulation, Roszdravnadzor

- Current issues of pharmaceutical legislation and ways to overcome them. Overview of legislative changes governing the pharmaceutical activities (Nikolaeva, N.M. – Head of Department of the legal regulations of the pharmaceutical activities, narcotic drugs and psychotropic substances circulation, Russian Ministry of Health)
- Current issues of control and supervision of pharmaceutical activities (Krupnova I.V. – Head of the organization of State control of drug circulation Roszdravnadzor, Maydykova E.E. – Head of the Department of licensing of medical and pharmaceutical activity and monitoring the quality of medical care of the Ministry of Health, Moscow region)
- Current trends in the development of wholesale distribution of medicinal products. Organizing the storage of drugs in the pharmaceutical company according to Russian legislation and the requirements of GSP (Titova J.P. – "Santens", LLC)
- Current trends in the development of the pharmacy network. Legal and ethical mechanisms of retail competition in the provision of quality medical products (Ignatieva, N.V. – Executive Director of Russian Association of Pharmacy Chains)
- Pharmacy staff: international standards and Russian Perspectives (Soloninina A.V. – Vice Principal, "Perm State Pharmaceutical Academy", Health Ministry of Russia)
- Characteristic aspects of the pharmaceutical business in questions and answers

**Session meeting**

**Russian pharmaceutical industry - focus on innovation and quality**

**(13.00-15.30; October 30 "Alfa" building, Hall # 2)**

Co-Chairs: Murashko M.A. – Acting Head of Roszdravnadzor, Tsib S.A. – Deputy Minister of Industry and Trade of Russian Federation

- Progress of the "Strategy for the development of the pharmaceutical industry up to 2020" (Tsib S.A. – Deputy Minister of Industry and Trade of Russian Federation)
- Economic measures of medicines quality (Tumusov F.S. - Deputy of the State Duma of the Russian Federation, head of the Subcommittee on circulation of medicines, the development of pharmaceutical and medical industry of the State Duma Committee on health)
- Russian pharmaceutical manufacturers - focus on innovation and quality (Dmitriev, V.A. – Director General of the Association of Russian Pharmaceutical Manufacturers)
- Presentations by domestic pharmaceutical manufacturers:
- Biopharmaceuticals: innovative solutions for emerging markets (Morozov D.V. – "Biocad", Director General)
- Creating the present, Looking to the future, (Podgorbunskich N.I. – JSC "Pharmstandard", Deputy Director General for drugs circulation)
- Creating innovative medicines through international partnerships (Ignatiev V.G. – "R-Pharm", Director General)
- Innovative development of Russian pharmaceutical company – from molecule to practical healthcare (Puchkova N.G. – NPO "Petrovax FARM", First Deputy Director General)
- Implementation of the Pharma-2020. Innovative Russian manufacturer case study (Borisov D.A. – "POLYSAN", commercial director)
- Strategy for integrated development of a full cycle company in Russian pharmaceutical market – prospects and growth drivers (Rodionov P.P. – "GEROPHARM" Group of companies, CEO)
- Possible benefits of participation in WHO medicines prequalification programs for Russian manufacturers (Polishchuk A. – Department of Health Systems and Public Health, WHO EURO)
- Track record of Russian manufactures participation in the WHO programs of medicines prequalification (Potashnikov V.A. – JSC "Biokom", Development Director)
- Medicines Compendium (Burimsky K. – Program Manager and Regional Champion, Russia and NIS, USP)

#### **Session meeting**

#### **Quality and Safety Control of Medical practice (13.00-16.00, October 30 "Alfa" Building, hall # 3)**

Chairman: Seregina I.F. – Deputy Head of Roszdravnadzor

Presentation of the "Quality Management in Health Care" magazine, Roszdravnadzor

- System approach as a basic principle in medical practice quality and safety control (Kamkin E.G. – Deputy Director of the Department of specialized medical care and rehabilitation, Russian Ministry of Health)
- The development of continuous medical education in Russian Federation. A pilot project for the introduction of CME in Russian Federation (Starodubov V.I. – the president of the Association of Medical Societies for Quality, Ulumbekova G.E. – Chairman of the Board of the Association of Medical Societies for Quality)
- Organization of State control for medical assistance procedures (Kovalev S.B. – Deputy Head of the Department of State control of the quality of public medical care, Roszdravnadzor)
- State control of compliance in medical assessments, medical examinations and medical evaluations (Veselov N.A. – Head of the Department of control of medical assessments, Roszdravnadzor)
- The limitations imposed on medical and pharmaceutical personnel in the performance of professional activities (Kupriyanov M.Y. – Head of State Department for medical care control, Roszdravnadzor)
- Limitations of the cooperation of medical and pharmaceutical communities: Russian legislation and international approach (Plieva M.R. – Director of Legal Affairs of the Association of International Pharmaceutical Manufacturers (AIPM))
- Characteristic aspects of drug promotion within the constraints imposed by Art. 74 of the Federal Law of 21.11.2011 № 323 "On the basis of health care in Russian Federation" (Chernenko I.S. – Director of Legal department, Janssen Cilag)
- Observing right to the health care (Pavlyukov D.Y. – Head of the department of quality and safety of medical activities in Moscow and Moscow region, Roszdravnadzor)
- Medical services quality. How can you manage it? (Farrachova G.R. – Deputy Director of the Educational Center of High Medical Technologies, Kazan)
- Experience and track record of departmental quality control of medical care (Danilenko I.V. – Deputy Director of the Department of Health and Pharmacy, Yaroslavl region)
- Internal control. Implementation of internal control in a medical organization (Boitchenko Y.Y. – Deputy chief physician, medical treatment, Medical Center, Russian Academy of Medical Sciences)
- Implementing the medical care compliance in the practice of health care organizations (Gertsev K.B. – Deputy Minister of Health, Moscow region)
- Main stages of the implementation of quality management system in medical institutions (Galanina E.V. – "Medicine" Ltd., chief auditor)

## **Session meeting**

### **State programs of drugs coverage at the federal and regional level (13.00-18.00, October 30 "Alfa" building, hall # 5)**

Co-Chairs: Parkhomenko D.V. – Deputy Head of Roszdravnadzor, Konstantinova O.A. – Deputy Director of the Department of drug coverage and management of circulation of medical devices, Russian Ministry of Health

- The changes in the legislation governing drugs provision for persons eligible for benefits. The lists of medicines, federal and regional authorities responsibilities, procurement, monitoring performance (Gayderov A.A. – Head of Division of legal and regulatory issues of drugs coverage and drugs quality control, the Department of drug coverage and management of the circulation of medical products, Ministry of Health of Russia)
- Provision of medicines in seven highly expensive nosologies. Preliminary results of 2013 and prospects for program implementation in 2014 (Emelyanov V.Y. – Deputy Director of the Department of drugs coverage and management of the circulation of medical devices Russian Ministry of Health)
- Results of regulatory measures in subsidized drugs coverage (Fissenko V.S. – Head of the Bureau for monitoring government programs implementation, Roszdravnadzor)
- State of drugs coverage of certain categories of citizens and suggestions for improvement (Telnova E.A. – "National Institute of Public Health", Russian Academy of Medical Sciences, Leading Scientist)
- Provisions for accessibility and quality of biotech drugs: German experience (Bobro R.V. – Deputy Chairman of the Working Group on Public Health of Russian-German Chamber of Commerce ANC)
- State procurement of drugs. European and US practice (Peter Pitts – founder of the "Center of availability of medical care," former FDA public relations commissioner, USA)
- Indirect comparisons of drugs: opportunities and limitations (Kulikov A.Y. – Laboratory of Pharmacoeconomics Research I.M.Sechenov First Moscow State Medical University, Leading Scientist)
- The evolution of programs for high-cost drugs coverage: the hidden reserves and clear opportunities (Yagudina R.I. – Chair of the Department of organization of drug coverage and pharmacoeconomics, I.M.Sechenov First Moscow State Medical University,)
- Regional aspects of the subsidized drug coverage. Demand assessment, funding, procurement. Main challenges and solutions (Doroshchenko V.N. – Director of the Department of Health of the Bryansk region, Lapochkina M.V. – Head of Department of Health of the Tambov region)
- Current issues of subsidized drug coverage. Position of patient community (Zhulev Y.A – Co-chair, Russian Union of patients)

### **Training workshop on pharmacopoeia analysis methods (13.00-18.00; October 30 "Alfa" building, Hall # 8)**

Co-Chairs: Roger Williams – Director General of the United States Pharmacopoeia (USP), Kossenko V.V. – Head of the Division of the State Quality Control for medical products, Roszdravnadzor

- Pharmacopoeia analysis methods of the drugs quality control (Titova A.V. – Head of the department of drugs quality control FGBU "Information and Methodology Center for examination, recording and analysis of the circulation of Medical Products", Roszdravnadzor)
- Practical aspects and issues of peptides and recombinant proteins control (Roger Williams – Director General of the United States Pharmacopoeia (USP))
- Approaches to Organic impurities Control (Sameer Navalgund – Director Research and Development Laboratory USP-India)
- Element Impurities Control (Sameer Navalgund – Director Research and Development Laboratory USP-India)
- Enzyme preparations quality control (Sylvie Jorajuria – EDQM)
- Spectral Libraries USP (Bei Ma – Manager, Business Development, USP)
- New USP pharmacopoeia approaches and optimal bioavailability (Roger Williams – Director General of the United States Pharmacopoeia, USP)
- Pharmacopoeia unification and harmonization (Angela Long – Senior VP Global Alliances and Organizational Affairs, USP)
- "Cold chain" assurance and validation (Nigmatullin R.R. – Head of Quality Assurance of "Pharmstandard")

## **Research and Practical Symposium**

### **Orphan drugs: the international regulatory experience and national practice (13.00-15.30; October 30 "Alfa" building, hall # 9)**

Co-Chairs: Maksimkina E.A. – Director of the department of drug coverage and management of medical devices circulation, Ministry of Health of Russia, Yagudina R.I. – Chair of the Department of organization of drug coverage and pharmacoeconomics, I.M.Sechenov First Moscow State Medical University,)

- Development of legislation related to orphan drugs (Maksimkina E.A. – Director of the Department for drug coverage and management of medical devices circulation, Russian Ministry of Health)

- Multiple Criteria Decision Analysis (MCDA) – a new technique for spending substantiation for treatment of rare diseases: prospects for use in Europe and Russia (dr. Xavier Badia – Professor at the University of Barcelona, member of the board of EuroQoL)
- Orphan drugs coverage issues (Mitin S.A. – "Hunter syndrome", interregional charitable public organization, President)
- Issues related to identification, assessment, treatment of rare diseases (Novikov P.V. – Head of psycho-neurology and inherited mental disorders, "Moscow Institute of Pediatrics and Pediatric Surgery", Russian Ministry of Health, Chief Medical Genetics Specialist, Russian Ministry of Health)
- Creating a CTEPH patients database - diagnosis and management strategy (Shostak N.A. – Department Chair of Intermediate Level Therapy, Pirogov Russian National Research Medical University, Russian Ministry of Health)

## **Round table**

### **National aspects of pharmaceutical market regulation (16.00-18.30, October 30 "Alfa" building, Hall # 2)**

Chair: Murashko M.A. - Acting Head of Roszdravnadzor

Featuring representatives of foreign regulatory authorities:

- Ukraine (Solovyov A.S. – Chairman of Ukrainian State drugs Service, Gurak D.D. - Director of GMP / GDP Center)
- Republic of Belarus (Reutskaya L.A. – Head of the Pharmaceutical Inspection and Drugs Coverage, Ministry of Health of Belarus)
- Kazakhstan (Tulegenova A.U. – Head of the pharmaceutical expertise Division of the National Center of Expertise of drugs, medical devices and medical equipment)
- Georgia (Djikia T. – Deputy Director of the Department of Pharmaceuticals)
- Serbia (Yakovych S. – Acting Head of the Agency for Medicinal Products and Medical Devices)
- India (Dr. Singh – Head of the Central Organization for Control of compliance with the standards of drugs)
- France, etc.

## **Research and Practical Symposium**

### **Interdisciplinary observational programs and inclusion of results in the prophylactic activities as a basis for the development of modern treatment strategies for obesity (16.00-18.00; October 30 "Alfa" building, the hall # 7)**

Chairman: Ametov A.S. – President of "International Diabetes program", Department Chair of Endocrinology and Diabetology, Russian Medical Academy of Post-Graduate Education, Roszdrav; Antsiferov M.B. – chief endocrinologist of the Moscow Department of Healthcare

- Interdisciplinary observational programs as a way to develop programs for periodic health examination, diabetes screening and an effective and safe treatment of obesity (Ametov A.S. – President of the "International Diabetes program", Department Chair of Endocrinology and Diabetology, Russian Medical Academy of Post-Graduate Education, Roszdrav)
- "Primavera" Observational Program as an effective tool for managing cardiovascular risk in obesity pharmacotherapy (Zhuravleva M.V. – leading scientist, clinical pharmacologist of the Moscow Department of Health)
- Overview of consumption and regulation of circulation of drugs used in obesity pharmacotherapy (Mashutin A.B. – Director of Strategic Development "PROMOMED")

## **Session meeting**

### **Requirements of current legislation to control and circulation of narcotic drugs and psychotropic substances and their precursors, cultivation of narcotics-containing crops in Russian Federation (16.30-18.30, October 30 CH "Izmailovo")**

Chairman: Krupnova I.V. – Head of Bureau of State control of drugs circulation, Roszdravnadzor

- Legal regulation of circulation of narcotic drugs and psychotropic substances and their precursors, the cultivation of narcotic-containing crops, harmonization of regulatory legal acts of Russian Federation with the generally recognized principles and norms of international law in combating illicit trafficking in drugs and precursors (Nikolaeva, N.M. – Head of legal regulation of pharmaceutical activities, circulation of narcotic drugs and psychotropic substances, Russian Ministry of Health)
- Details of prevention and investigation of crimes committed in legal circulation of narcotic drugs and psychotropic substances and their precursors (Maslovskaya E.V. – Head of the Bureau for the Prevention of Crime in legal circulation of narcotic drugs, psychotropic substances and their precursors, Operational Investigative Department of Drug Control Service of Russia)
- Current issues of control and supervision in the area of narcotic drugs and psychotropic substances circulation (Orihivskaya E.N. – Head of the Department of Licensing and Accreditation Department of Health of Moscow)
- Distribution of the "potent drugs" in the pharmacy in view of new legislation, the challenges and the solutions (Nevolina E.V. – Executive Director of non-profit partnership to promote pharmaceutical industry "Pharmacy Guild")

- Discussion (answers to the questions of the session meeting)

### **Session meeting**

#### **The role of patient organizations in the decision-making system of modern health care (16.30-18.30; October 30 "Alfa" building, hall #9)**

The Chairman : Vlasov Y.V. – Chairman of the Public Council for the Protection of Patients' Rights, Roszdravnadzor

- Universal approach to drug coverage of patients with orphan diseases (Myasnikova I.V. – Executive Director of Russian Society of Rare (Orphan) Diseases)
- The contribution of Russian Union of Patients to the improvement of the legal system to protect patients' rights in Russian Federation (Zhulev Y.U. – Co-Chair, Russian Union of Patients)
- Participation of patient movements in optimizing decision-making system at Russian Federation constituent entity level (Dronov N.P. – Chairman of the Executive Committee, member of the Coordinating Council of the "Movement Against Cancer", member of the Council for the protection of patients' rights under the Ministry of Health of Russian Federation, a member of the Council for the Protection of Patients' Rights of Roszdravnadzor)
- Developing system of civil control of healthcare at the present stage (Vlasov Y.V. – Chairman of the Public Council for the Protection of Patients' Rights, Roszdravnadzor)
- Public Council under the territorial Roszdravnadzor bodies in 2012-2013. Region readiness for the regionalization of the "Seven Nosologies" program from the viewpoint of the Board members:

Head of the Public Council for the Protection of Patients' Rights, Nizhny Novgorod territorial Roszdravnadzor (Kuznetsov K.V. – Chairman of the regional branch of the Public Council)

Head of the Public Council for the Protection of Patients' Rights Orenburg territorial Roszdravnadzor (Dolgushin N.N. – Chairman of the regional branch of the Public Council)

Head of the Public Council for the Protection of Patients' Rights Rostov territorial Roszdravnadzor (Edigarova G.N. – Chairman of the regional branch of the Public Council)

Head of the Public Council for the Protection of Patients' Rights, St. Petersburg territorial Roszdravnadzor (Olshansky A.I. – the chairman of the regional branch of the public council)

Head of the Public Council for the Protection of Patients' Rights Ulyanovsk Territorial Roszdravnadzor (Abdulov R.A. – Chairman of the regional branch of the Public Council)

**October 31**

**Section meeting**

**State quality control of medicines**

**(9.00-12.00; October 31 "Alfa" building, Hall # 2)**

Chairman : Kosenko V.V. – Head of the organization of State control of quality medical products, Roszdravnadzor

- The system of State control of quality of medicines in Russian Federation. Results, Issues and Prospects (Kosenko V.V. – The Head of the organization of State control of quality medical products, Roszdravnadzor)
- Federal laboratory facilities and their importance in ensuring medicines quality (Ryzhkov E.A. – Deputy Director General of State Organization "Information and Methodology Center for examination, recording and analysis of the circulation of Medical Products", Roszdravnadzor . Titova A.V. - Head of the department of drugs quality control of the "Information and Methodology Center for examination, recording and analysis of the treatment of Medical Products", Roszdravnadzor)
- Quality of pharmaceutical substances for manufacturing of medicines in EU. EDQM (video presentation, Susanne Keitel – EDQM Director)
- Regulation of circulation of medical products in China. The quality control system (Zhang Wei – General Secretary of the Chinese Pharmacopoeia Commission)
- Express-Analysis methods. USP General Guidelines and programs (Bei Ma – Manager, Business Development, USP)
- Stepping up countermeasures to combat circulation of counterfeit medicines (Wilfrid Roge – Director of the International Institute of research against counterfeit medicines)
- Combating illicit traffic of medicinal products - mission of the Department of French national OCLAESP (Nicolas Duvinage – Deputy Director of the Central Bureau against damage to the environment and public health (OCLAESP), General Directorate of the National Gendarmerie Ministry of Internal Affairs of France)
- Current issues of pharmacovigilance in Russian Federation (Glagolev S.V. – deputy Head of the Bureau of the State quality control of medical products, Head of Department of monitoring the effectiveness and safety of medicines of the Bureau of State control of medical products quality, Roszdravnadzor)
- Planning and conducting clinical trials by Russian company – emphasis on quality (Putilovskiy M.A. – Deputy Director General, Head of Clinical Research "Materia Medica Holding")

**Section meeting**

**Regulation of circulation of medical devices. Issues and Prospects**

**(9.00-13.00; October 31 "Alfa" building, hall # 5)**

Co-Chairs: Borzik I.K. – Deputy Head of Roszdravnadzor, Migeeva M.A. – Acting Chief of Bureau of State Control and Registration of medical devices, Roszdravnadzor, Monogarova I.I. – Head of Department of regulation of medical products circulation of Department of drug coverage and management of the circulation of medical devices of Ministry of Health of Russia, Antonov V.S. – Deputy Director General of "Center for Monitoring and Clinical and Economic Evaluation", Roszdravnadzor

- Registration Procedure for medical devices. Registration paperwork. Medical device dossier requirements for State registration (Sukhanov M.M. – Deputy Head of the Bureau of State control and registration of medical devices, Head of the Department of registration of medical devices, Roszdravnadzor)
- Current issues and specifics of the carrying out an expert examination of quality, effectiveness and safety of medical devices (Antonov V.S. – Deputy Director General of "Center for Monitoring and Clinical and Economic Evaluation", Roszdravnadzor)
- The globalization of regulation in the area of health care products, trends, opportunities and challenges (Tretyakov A.M. – Executive Director, IMEDA)
- State control over the circulation of medical devices in Russian Federation (Migeeva M.A. – Acting Head of the Bureau of State control and registration of medical devices, Roszdravnadzor)
- Regulation of circulation of medical devices in China (Zhong Lu – Deputy Director of Center for Medical Device Evaluation)
- State control over the circulation of medical devices. World experience (video presentation by Kimberly A. Trautman – Associate Director of Center for Devices and Radiological Health, FDA)
- Current issues of monitoring safety of medical devices in Russian Federation (Glagolev S.V. – Deputy Head of the Bureau of the State quality control of medical products, Head of Department of monitoring the effectiveness and safety of medicines of the Bureau of State control of medical products quality, Roszdravnadzor)
- Topical issues of safety monitoring of medical devices (Kamaldinova Yu. -senior coordinator of the Department of quality assurance of medical devices, LLC Johnson &Johnson)

### **Session meeting**

#### **Drugs coverage of health facilities. Role of pharmaceutical organizations**

**(9.00-12.00; October 31 "Alfa" building, Hall # 8)**

Co-Chairs: Krupnova I.V. – Head of the Bureau of State control of drug circulation, Roszdravnadzor, Galagush L.L. – Head of the Novosibirsk region Roszdravnadzor., Yagudina R.I. – Chairman of the NGO "Moscow Pharmaceutical Society"

- Rational drugs prescription during hospital stay (Kuznetsov M.R. – Professor of Surgery, N.I. Pirogov Russian National Research Medical University)
- Overview of the current State of MPI pharmacy facilities: issues to be addressed (Abramov A.Y. – First Deputy Head of the Department of Health of Moscow, Kondratieva B.B. – Department of organization of drug coverage and pharmacoeconomics, I.M.Sechenov First Moscow State Medical University, Russian Ministry of Health)
- A multi-disciplinary approach to pharmacotherapy in "complex" MPI patients: International experience (Yagudina R.I. – Chairman of the NGO "Moscow Pharmaceutical Society")
- Modern technological solutions as the main driver of the development of quality of pharmaceutical care (Umarov S.Z. – St. Petersburg State Chemical-Pharmaceutical Academy, Russian Ministry of Health)

### **Session meeting**

#### **Creating "road map" in oncology – Issues of drug coverage**

**(9.00-12.00; October 31 "Alfa" building, hall # 9)**

Chairman: Lichinitser M.R. – Deputy Director of the "N.N. Blokhin Russian Cancer Research Center" RAMS

- Vital and essential drugs, new possibilities of practical oncology (Lichinitser M.R. – Deputy Director of the "N.N. Blokhin Russian Cancer Research Center" RAMS)
- Evidence-based medicine and clinical and economic study in oncology (Kucheryavenko O.A. – graduate student at the London School of Hygiene and Tropical Medicine, an expert of the American branch of Cochrane network of medical services consumers and of the "Right to Health" project of the international "Oxfam Great Britain" fund)
- Legal and institutional framework for providing cancer care to Russian population: Patients Community view (Dronov N.P. – Chairman of the Executive Committee, member of the Coordinating Council of "Movement Against Cancer", a member of Council of public organizations for protection of patients' rights under the Ministry of Health of Russian Federation)
- Presentation of the "Road Map" project (Melik-Guseinov D.V. – a member of the Coordinating Council on drug circulation at Ministry of Health of Russian Federation, Director of "Center for Social Economy")
- Performance evaluation and economic aspects of Target Therapy of hepatocellular carcinoma (Kulikov A.Y. – Leading Scientist, Laboratory of Pharmacoeconomic studies of the I.M.Sechenov First Moscow State Medical University, Russian Ministry of Health)

### **Session meeting**

#### **State registration of drugs. Assessment of drugs for State registration**

**(13.00-17.00; October 31 "Alfa" building, Hall # 2)**

Co-Chairs: Tsyndymeev. A.G. – Director of Department of State regulation of circulation of drugs, Russian Ministry of Health, Mironov A.N. – CEO "Scientific Center for Expertise of Means of Medical Application», Russian Ministry of Health

- State regulation of drug circulation (Tsyndymeev A.G. – Director of the Department of State regulation of drug circulation, Russian Ministry of Health)
- Registration of drugs in the system of State regulation of the drug circulation: current situation and expected changes (Rumyantsev D.A. – Head of Drug Registration of Department of State regulation of drug circulation, Russian Ministry of Health)
- Research and expert support of the electronic version of the State Register of Medicinal Products (Belova E.V. – Deputy Director General of State Organization "Center for Assessment and Quality Control of Medical Products", Russian Ministry of Health)
- Management of "Scientific Center for Assessment of Medical Products», Russian Ministry of Health (Mironov A.N. – Director General, Scientific Center of Assessment of Medical Products, Russian Ministry of Health)
- Perspectives for research in improvement of the drugs assessment (Merkulov V.A. – First Deputy Director General, Scientific Center of Assessment of Medical Products, Russian Ministry of Health)
- Improving assessment in "Scientific Center of Assessment of Medical Products", Russian Ministry of Health (Sakaeva I.V. – Deputy Director General for assessment "Scientific Center of Assessment of Medical Products", Russian Ministry of Health)
- Current status of State pharmacopoeia and development prospects (Sakanyan E.I. – Director of pharmacopoeia and international cooperation, "Scientific Center for Assessment of Medical Products", Russian Ministry of Health)
- Role of research, innovations and methodology development of "Scientific Center for Assessment of Medical Products", Russian Ministry of Health in the improvement of the system of the assessment of quality, effectiveness and safety of drugs in Russian Federation (Bunyatyan N.D. – Deputy Director General for Research, "Scientific Center for Assessment of Medical Products" Russian Ministry of Health)

- International and local clinical development. Expert Assessment practices (Vasilyev A.N. – Director of Assessment and Control of FPP, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Special aspects in assessment of immunological drugs for State Registration (Bondarev V.P. – Director of expertise and control of Medical Immunobiological Drugs, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Trials of immunological drugs (Movsesyants A.A. – Head of the Testing Center of Medical Immunobiological Drugs Quality Assessment, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- International practices and domestic experience in confirming Compliance for Immunobiological drugs (Yakimov Y.M. – Director of Certification Center for Medical Immunobiological Drugs, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Amendments to the registration dossier, requirements and recommendations for paperwork (Rychihina E.M. – Head of the Control and Organization Department, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Drugs Quality Assessment during State registration. Frequently Asked Questions (Lutseva A.I. – Deputy Head of Testing Center for Drugs Quality Assessment “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health), Kovaleva E.L. – Deputy Director of Assessment and Control of FPP, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Expert assessment of drug safety in clinical trials in Russian Federation (Lepakhin V.K. – Director of Drugs Safety Assessment, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health), Romanov B.K. – Deputy Director of Drugs Safety Assessment, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Modern approach to the therapeutic equivalence in the expert evaluation of drugs (Kukes V.G. – Director of the Clinical Pharmacology Center, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health, Prokofiev A.B. – Deputy Director of the Clinical Pharmacology Center, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- Current issues of scientific planning of expert evaluation and protection of intellectual property (Borisevich I.V. – Director of Planning and R&D coordination, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)
- “Scientific Center for Assessment of Medical Products” Academic Programs (Yagudina R.I. – Director of Academic Programs, “Scientific Center for Assessment of Medical Products”, Russian Ministry of Health)

#### **Session meeting**

##### **Health technologies assessment: the transition to a system-level solution implementation**

**(13.00-17.00; October 31 "Alfa" building, hall # 7)**

Co-Chairs: Kagramanyan I.N. – Deputy Minister of Health of Russian Federation, Khabriev R.U. – Director of the National Institute of Public Health, RAMS, Rumyantsev A.G. – Director of the D.Rogachev Federal Research Center of Pediatric Oncology, Hematology and Immunology.

- Possible HTA models: Expert community strengths (Khabriev R.U. – Director of the National Institute of Public Health Sciences)
- Primary objective of HTA: a clinician outlook (Rumyantsev A.G. – Director of the D.Rogachev Federal Research Center of Pediatric Oncology, Hematology and Immunology.
- Drugs in the HTA: Real-life cases (Arinina E.E. – expert of the Moscow Pharmaceutical Society)
- Economic assessment of medical devices. How it benefits Russian healthcare? (Kulikov A.Y. – Leading Scientist, Laboratory of Pharmacoeconomics Research, I.M.Sechenov First Moscow State Medical University Russian Ministry of Health)

#### **Round table**

##### **Circulation of drugs in the framework of the Customs Union**

**(15.00-17.30; October 31 "Alfa" building, hall #8)**

Co-Chairs: Zhogova I.T. – Deputy Director of the Department of Technical Regulation and accreditation of Eurasian Economic Commission, Shchekin D.A. – Head of the Department of Technical Regulation and accreditation of Eurasian Economic Commission

- Development of common principles for the circulation of drugs and medical products within the territories of the Member States of the Customs Union
- Preparation of the Agreement on common principles and rules of the drug circulation within the territories of the Member States of the Customs Union and Common Economic Space

**Please note that the Organizing Committee reserves the right to make changes to the program and speakers list**