**PHARMACEUTICAL FORUM**

**"PHARMEXPERT 2025. eCTD and Pricing in Ukraine – A Strategic Path to Integration into the International Regulatory Space"**

**TUESDAY, JUNE 17, 2025**

**“Mercure Congress Centre”, 6, Vadym Hetman St., Kyiv**

**PROGRAM**

|  |  |
| --- | --- |
| **CET****08.00 - 08.30** | **REGISTRATION OF THE FORUM PARTICIPANTS. WELCOME COFFEE** |
|  |
| **OPENING CEREMONY OF THE FORUM** |
|  |
| **OPENING REMARKS** |
| ***Forum Moderator:* Yevhen Kunda,** CEO Proxima Research International  |
| **08.30 - 08.50** | **INTERACTIVE SURVEY** |
| **Mariia Karchevych,** Deputy Minister of Health of Ukraine for Digital Development, Digital Transformation and Digitalization  |
| **Mykhaylo Babenko,** Director of the State Expert Center of MOH of Ukraine, Associate Professor, Candidate of Pharmaceutical Sciences  |
| **Rebecca Kohler,** Chief of Party of the SAFEMed Activity at MSH**Language - English****Working language – English** |
|  |
| **BLOCK 1.****SESSION 1.****International experience.****eCTD Implementation Illustrated by Some EU Member States** |
|  |
| ***Moderator:* Yevhen Kunda,** CEO, Proxima Research International |
| **08.50 - 09.05** | ***Croatian experience in eCTD* *implementation*****Ana Borić Bilušić,** Head of Validation Department at the Agency for Medicinal Products and Medical Devices (HALMED), Croatia**Language - English****Working language – English****Online**  |
| **09.05 - 09.20** | ***the title of the presentation is pending*****Andrzej Czesławski,** Director of the Department of Monitoring Adverse Drug Reactions, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland**Language - English****Working language – English****Online**  |
| **09.20 - 09.35** | ***Implementation of the eCTD format - from an agency perspective*****Martin Clement Kristensen,** Team Leader for the team 'Check-In & Parallel Import' Danish Medicines Agency, Denmark**Language - English****Working language – English****Online**  |
| **09.35 - 09.50** | ***the title of the presentation is pending*** **Frank Dickert**, member of Regulatory Competence Center, EXTEDO GmbHSenior Business Consultant**Language - English****Working language – English****Online**  |
| **09.50 - 10.05** | ***Transition journey – lessons learned*****Agnieszka Sieliczka**, Sales Manager at Lorenz Life Science, Poland**Language - English****Working language – English****Online**  |
| **10.05 - 10.20** | ***How to launch eCTD without an IT department and why global vendors are not always ready for Ukrainian realities*****Dmytro Horilyk** , Chief Executive Officer at DrugCard |
|  |
| **10.20 - 10.50** | **COFFEE BREAK** |
|  |
| **BLOCK 1.****PANEL DISCUSSION 1.****Regulatory framework for eCTD in Ukraine** |
|  |
| ***Moderator:* Volodymyr Ignatov**, Executive Director of the Association of International Pharmaceutical Manufacturers (“AIPM Ukraine”), Candidate of Medical Sciences, MBA |
| **10.50 - 11.40** |  |
| **INTERACTIVE SURVEY** |
| **Mariia Karchevych,** Deputy Minister of Health of Ukraine for Digital Development, Digital Transformation and Digitalization  |
| **Viktoriia Hanzhelo**, Senior Associate, LA LAW FIRM (Legal Alliance) |
| **Anna Bezruk, Manager, Healthcare Committee, the European Business Association** |
| **Dmytro Lurye,** Project Manager, Medicines for Europe **Online** |
| **Volodymyr Redko,** Executive Director, Association of pharmaceutical research and development (APRaD), PhD  |
|  |
|  |
| **BLOCK 1.****PANEL DISCUSSION 2.****Practical issues of eCTD implementing. Readiness for change** |
|  |
| ***Moderator:* Alla Sorokoletova*,***  Director of Quality, Pharmacovigilance, Regulatory and International Medical Affairs Department, ACINO UKRAINE LLC, Candidate of Medical Sciences |
| **11.40 - 12.40** |  |
| **INTERACTIVE SURVEY** |
| **Presentation****Yevheniia Ishkova*,*** Deputy Director for Registration and Pharmacovigilance of the State Expert Center of MOH of Ukraine, Candidate of Pharmaceutical Sciences |
| **Presentation****Artem Klieb*,*** Head of IT Board of the State Expert Center of MOH of Ukraine |
| **Presentation****Olga Kolesova,** expert [of the Registration Materials Expert Evaluation Department](https://corp.dec.gov.ua/cart_contact/departament-ekspertizi-re%D1%94straczijnih-materialiv/) of the State Expert Center of MOH of Ukraine |
| **Kateryna** **Turlina**, Head of the Ukrainian Registration Department of PrJSC Darnytsia Pharmaceutical Company |
| **Yevhen Kudriavets,** Regulatory Affairs Manager, Roche Ukraine LLC |
| **Olena Vilchek,** Authorized Person of Bionorica SE in Ukraine, Head of the Medicines Registration Department of Bionorica LLC |
| **Tetiana Dovhenko,** Head of Regulatory Department, TAKEDA UKRAINE LLC |
|  |
| **12.40 - 13.30** | **LUNCH** |
|  |
| **BLOCK 2.****SESSION 2.****Medicines pricing policy:****international approaches and Ukrainian realities** |
|  |
| ***Forum Moderator:* Yevhen Kunda,** CEO Proxima Research International  |
| **13.30 - 13.45** | **Presentation****Mykhaylo Babenko,** Director of the State Expert Center of MOH of Ukraine, Associate Professor, Candidate of Pharmaceutical Sciences  |
| **13.45 - 14.00** | ***Pharmaceutical market of Ukraine. Regulations vs development*****Serhii Ishchenko,** CPO Proxima Research International |
| **14.00 - 14.15** | **Medicines price regulation in the context of a patient-centred healthcare model****Stanislav Kniazkov,** Technical Officer, WHO Regional Office for Europe**Online** |
| **14.15 - 14.30** | ***Pharmaceutical Pricing: International Trends and Options for Ukraine*****Dr Panos Kanavos**, Associate Professor of International Health Policy in the Department of Health Policy at the London School of Economics and Political Science, Deputy Director at LSE Health and Program Director of the Medical Technology Research Group (MTRG)**Language - English****Working language – English****Online** |
| **14.30 - 14.45** | ***Medicines Price Regulation – risks vs. benefits (Moldova ' s​ experience)*****Dragoș Guțu**, Director General of the Agency for Medicines and Medical Devices of the Republic of **Moldova****Language - English****Working language – English****Online** |
| **14.45 - 15.00** | ***Pricing Regulation – The Portuguese Experience*****Sofia Mello,** pricing expert INFARMED, Portugal**Language - English****Working language – English****Online** |
|  |
|  |
| **BLOCK 2.****PANEL DISCUSSION 3.****Mechanisms and tools for implementing state policy and control in the field of pricing: challenges and new opportunities**  |
|  |
| ***Moderator:* Lidiia Sanzharovska**, associate partner, LA LAW FIRM (Legal Alliance) |
| **15.00 - 16.00**  | **INTERACTIVE SURVEY** |
| **Oleksandr Hrytsenko**, Acting Head of the Department — head of department with issues of quality and availability of medicines, their rational use of the Pharmaceutical Department of the Ministry of Health of Ukraine |
| **Roman Isayenko,** Head of the State Service of Ukraine on Medicines and Drugs Control |
| **Oresta Pinyazhko,** Director of the Department of Medical Technology Assessment of the State Expert Center of the Ministry of Health of Ukraine, Candidate of Pharmaceutical Sciences |
| **Kostyantyn Kosyachenko,** Director of the Department of Standards in the Field of Healthcare of the State Expert Center of the Ministry of Health of Ukraine, Head of the Department of Organization and Economics of Pharmacy of the National Medical University named after O.O. Bogomolets, Doctor of Pharmaceutical Sciences, Professor, Honored Worker of Pharmacy |
| **Tetyana Kotliar**, Head of the Public Union “All-Ukrainian Pharmaceutical Association “PHARMUKRAINE”  |
| **Kostiantyn Vashchenko**, Government Relations Director PrJSC Darnytsia Pharmaceutical Company |
| **Vitaliy Gordienko,** Chairman of the Board, Association of pharmaceutical research and development (APRaD) |
| Representative of the State Service of Ukraine on food safety and Consumer Protection  |
| **Volodymyr Liakhovskyi**, Co-Chairman of the Healthcare Committee of the Executive Board. Project Management Manager of the Corporate Communications Department of JSC Farmak |
|  |
| **BLOCK 2.****PANEL DISCUSSION 4.** **Patient’s perspective on the price of medicines: affordability, transparency, trust**  |
|  |
| ***Moderator:* Olena Filiniuk**, MD, PhD, Senior Technical Advisor on Pharmaceutical Governance and Financing, SAFEMed / USAID project |
|  | **INTERACTIVE SURVEY**  |
| **16.00 - 17.00**  | **Natalia Husak**, Head of the National Health Service of Ukraine |
| **Oleg Klots**, General manager at the State Enterprise "Medical Procurement of Ukraine" |
| **Viktor Serdyuk**, President of the CHARITY ORGANIZATION "ALL-UKRAINIAN COUNCIL FOR THE PROTECTION OF PATIENTS' RIGHTS AND SAFETY" |
| **Representative** **Public Union "Pharmacy Professional Association of Ukraine" (APAU)**  |
| **Oleksandr Chumak**, Association of Drug Manufacturers of Ukraine (ADMU) |
| **Mykhailo Renskyi,** Deputy Director General for Development of Cooperation with International Organizations and Development of New Drugs, JSC Lekhim |
| **Tetyana Kulesha**, Head of the Council of the Public Association "Orphan Diseases of Ukraine" **Online** / **online** |
| **Inna Ivanenko,** Executive DirectorCHARITY ORGANIZATION "CHARITABLE FUND "PATIENTS OF UKRAINE" |
| **Oleg Vivsiannyk,** Director of the Department of Civil Protection and Public Health of the Rivne Regional State Administration, Candidate of Public Administration. |
|  |
| **RESOLUTION ADOPTION** |
|  |
| **17.00** **-** **17.15** | **Oleksandr Gudzenko,** Doctor of Pharmaceutical Sciences, Professor, Honored Healthcare Worker of Ukraine, Head of the Agency for Methodological and Scientific and Practical Work of the State Expert Center of MOH of Ukraine, Organizing Committee Co-Chairman |
| **FORUM CLOSING. BUFFET*****Forum Moderator:* Yevhen Kunda,** CEO Proxima Research International  |