

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

INTERACTIVE SURVEY

Mariia Karchevych, Deputy Minister of Health of Ukraine for Digital
Development, Digital Transformation and Digitalization

08.30 - 08.50 **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

the title of the presentation is pending

09.05 - 09.20

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

Implementation of the eCTD format - from an agency perspective

09.20 - 09.35

Martin Clement Kristensen, Team Leader for the team 'Check-In & Parallel Import' Danish Medicines Agency, Denmark

Language - English

Working language - English

Online

the title of the presentation is pending

09.35 - 09.50

Frank Dickert, member of Regulatory Competence Center, EXTEDO GmbH Senior Business Consultant

Language - English

Working language - English

Online

Transition journey - lessons learned

09.50 - 10.05

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

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)

10.50 - 11.40

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 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

Medicines Price Regulation – risks vs. benefits (Moldova 's experience)

14.30 - 14.45

Dragoş Guţu, 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

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)

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

15.00 - 16.00

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

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)

16.00 - 17.00

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 Director CHARITY 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

