EDQM and European Pharmacopoeia: State-of-the-art Science for Tomorrow's Medicines

International Conference organised by the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe,

on the occasion of

the publication of the 10th Edition of the European Pharmacopoeia and the 25th Anniversary of the European OMCL Network and the Certification of Suitability Procedure.

19-20 June 2019, Strasbourg, France

PROGRAMME

Wednesday, 19 June 2019

08:00-08:45 Registration & Welcome Coffee (Hemicycle - Palais de l'Europe)

OPENING SESSION

08:45-09:00 **Welcome Addresses**
Ms Snežana Samardžić-Marković, Director General of Democracy, Council of Europe
Jean-Baptiste Mattéi, Ambassador, Permanent Representative of France to the Council of Europe
Dr Susanne Keitel, Director, EDQM, Council of Europe

PLENARY SESSION

Moderator: Dr Tobias Gosdschan
Outgoing Chair of the European Pharmacopoeia Commission

09:00-09:30 **Building Synergies to strengthen and support healthcare in Europe**
Dr Andrzej Rys, Director Health Systems, Medical Products and Innovation, European Commission

09:30-10:00 **Globalisation and cross-border cooperation in Europe: the perspective of a national competent authority**
Dr Dominique Martin, Director General, Agence nationale de sécurité du médicament et des produits de santé (ANSM)

10:00-10:30 **Contributions of the European OMCL Network to the protection of Public Health**
Ms Patricia Courselle, Former Chair of the OMCL Advisory Group

10:30-11:00 Coffee break and Poster session

11:00-11:30 **The Certification of Suitability Procedure - 25 years of a success story**
Dr Jean-Louis Robert, Chair of the Certification Steering Committee

11:30-12:00 **Combatting falsified medicines - the EDQM's holistic approach in support of the MEDICRIME Convention**
Dr Karl-Heinz Buchheit, EDQM, Council of Europe

12:00-12:30 **European Directorate for the Quality of Medicines & HealthCare (EDQM) & the European Pharmacopoeia (Ph. Eur.)**
Dr Susanne Keitel, Director, EDQM, Council of Europe

12:30-14:30 Lunch break (EDQM premises)

Wednesday, 19 June 2019

WORKSHOP SESSIONS

Five workshops will run in parallel with each session being repeated once, except for Biotherapeutics, Certification, 3Rs and ATMPs and OMCL Network.
Interpretation into French will not be provided during the workshop sessions.

Time & Meeting Room	EDQM Building Room 100	EDQM Building Room 550	Palais de l'Europe Meeting Room 11	Palais de l'Europe Meeting Room 10	Palais de l'Europe Meeting Room 8
14:30-17:30	**Impurities**	**Finished Product Monographs**	**Biotherapeutics**	**General Methods**	**OMCL Network**

WORKSHOP: IMPURITIES

19 June 2019, Room 100

Moderator: Prof. Torbjörn Arvidsson, Chair of the Ph. Eur. Group of Experts on Organic Chemistry (10A)

14:30-15:00 **Impurity Control in the European Pharmacopoeia (Ph. Eur.)**
Dr Gabriella Török, Chair of the Ph. Eur. Group of Experts on Organic Chemistry (10B)

15:00-16:00 **Challenges linked to the Control of Antibiotics: the EU Antibiotics Guideline and its impact on dossiers and assessments.**
Dr Jan Smeets, Centrient Pharmaceuticals Netherlands B.V, the Netherlands
Dr Uwe Lipke, Federal Institute for Drugs and Medical Devices (BfArM), Germany

16:00-16:30 Coffee break

16:30-16:50 **Experience of implementation of ICH Q3D within the Certification Procedure (CEPs)**
Dr Cristian Sampaolesi, EDQM, Council of Europe

16:50-17:10 **Control of Impurities: Challenges linked to the Establishment of Reference Standards**
Dr Jochen Pauwels, EDQM, Council of Europe

17:10-17:30 **Feedback from Users**
Panel discussion with the moderator and the speakers

17:30 Close of the first day – Reception (Palais de l'Europe)

WORKSHOP: FINISHED PRODUCT MONOGRAPHS

19 June 2019, Room 550

Moderator: Dr Tobias Gosdschan, Outgoing Chair of the European Pharmacopoeia Commission

14:30-14:50 **Experiences of The U.S. Pharmacopeial Convention (USP)**
Mr Bruk Alemayehu, U.S. Pharmacopeial Convention, United States of America

14:50-15:10 **Perspective of a Regulatory Authority**
Ms Andrea Cseh-Palos, National Institute of Pharmacy and Nutrition, Hungary

15:10-15:30 **Perspective of an OMCL**
Dr Charlotte Brenier, National Agency for Medicines and Health Products Safety (ANSM), France [*Chair of the Ph. Eur. Group of Experts on Synthetic / Semi-synthetic Products (10D)*]

15:30-16:00 Coffee break

16:00-16:40 **Industry's Perspective**
From an Innovator: Dr Veronique Pinilla, UCB Pharma, Belgium
From a Generic manufacturer: Dr Manish Gangrade, Cipla Ltd., India

16:40-17:00 **Experiences of the European Pharmacopoeia**
Dr Ulrich Rose, EDQM, Council of Europe

17:00-17:30 **Feedback from Users:** Panel discussion with the moderator and the speakers

17:30 Close of the first day - Reception (Palais de l'Europe)

THE NEED FOR MONOGRAPHS ON BIOTHERAPEUTICS (ACTIVE PHARMACEUTICAL INGREDIENTS AND FINISHED PRODUCTS)

19 June 2019, Room 11

Moderator: Mr Peter MJM Jongen, Chair of the Ph. Eur. Group of Experts on P4 Biologicals

14:30-14:50 **Biotherapeutic Products in the Ph. Eur.: have all the challenges been tackled?**
Dr Mihaela Buda, EDQM, Council of Europe

14:50-15:00 Discussion

15:00-15:20 **Reference Standards for Biotherapeutic Products**
Dr Marie-Emmanuelle Behr-Gross and Dr Sylvie Jorajuria, EDQM, Council of Europe

15:20-15:30 Discussion

15:30-16:00 Coffee break

16:00-16:20 **Industry's Perspective**
Mr Lionel Randon, Merck Serono SA, Switzerland and Dr Emmanuel Rossy, Novartis, Germany

16:20-16:30 Discussion

16:30-16:50 **Perspective of a Regulatory Authority**
Dr Martijn Van der Plas, Medicines Evaluation Board (MEB), the Netherlands

16:50-17:00 Discussion

17:00-17:30 **Feedback from Users:** Panel discussion with the moderator, the speakers and Dr Joseph Albanese, Janssen J&J, USA

17:30 Close of the first day - Reception (Palais de l'Europe)

WORKSHOP: GENERAL METHODS

19 June 2019, Room 10

Moderator: Prof. Dr Michel Ulmschneider, Chair of the General Methods Working Party

14:30-14:50 **Chromatographic Separation Techniques and Challenges related to harmonisation**
Prof. Dr Jos Hoogmartens, Chair of the Ph. Eur. Group of Experts on Chromatographic Separation Techniques

14:50-15:10 **Feedback on the work of the Ph. Eur. General Methods Working Party**
Prof. Dr Michel Ulmschneider, Chair of the General Methods Working Party

15:10-15:30 **Reference Standards for Ph. Eur. Chapters**
Dr Stefan Almeling, EDQM, Council of Europe

15:30-16:00 Coffee break

16:00-16:20 **Feedback on the work of the Ph. Eur. Vibrational Spectroscopy and Analytical Data Modelling (VSADM) Working Party**
Prof. Dr Manel Alcala Bernardez, Universitat Autonoma de Barcelona, Spain

16:20-16:40 **Analytical QbD - Industry's Perspective**
Dr Graham Cook, Pfizer, United Kingdom

16:40-17:00 **Continuous manufacturing: what impact on the Pharmacopoeia**
Dr Moheb M. Nasr, Nasr Pharma Regulatory Consulting (NPRC), United States of America

17:00-17:30 **Feedback from Users:** Panel discussion with the moderator and the speakers

17:30 Close of the first day – Reception (Palais de l'Europe)

WORKSHOP: OMCL NETWORK

19 June 2019, Room 8

Moderator: Dr Maria João Portela, Infarmed, Portugal

14:30-15:00 **Official Control Authority Batch Release (OCABR): benefits, challenges and perspectives**
Dr Volker Öppling, Paul-Ehrlich-Institut (PEI), Germany

15:00-15:30 **Market Surveillance Studies: OMCL contribution to quality and safety of medicines on the market**
Dr Lone Olsen, Danish Medicines Agency (DKMA), Denmark

15:30-16:00 Coffee break

16:00-16:40 **API Testing: how OMCLs can support the control of APIs**
Dr Eric Deconinck, Sciensano, Belgium and Mr Yvan Grange, National Agency for Medicines and Health Products Safety (ANSM), France

16:40-17:00 **The contributions of OMCLs in the fight against Falsified and Illegal Medicines**
Mr Stephen Young, Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

17:00-17:30 **Feedback from Users:** Panel discussion with the moderator and the speakers

17:30 Close of the first day – Reception (Palais de l'Europe)

Thursday, 20 June 2019

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11:30-12:00 **Feedback from Users**
Panel discussion with the moderator and the speakers

12:00-14:00 Lunch break (EDQM premises)

WORKSHOP: THE 3Rs AND ATMPs

20 June 2019, Room 11

Moderator: Dr Lukas Bruckner, Chair of the Biological Standardisation Programme Steering Committee

09:00-09:20 **Achievements of the Biological Standardisation Programme and the Ph. Eur. in the field of the 3Rs**
Dr Catherine Milne and Dr Gwenael Cirefice, EDQM, Council of Europe

09:20-09:40 **The 3Rs: perspectives for the future**
Dr Lukas Bruckner, Chair of the Biological Standardisation Programme Steering Committee
Mr Arnoud Akkermans, National Institute for Public Health and Environment (RIVM), the Netherlands

09:40-10:00 **Vet Vaccines perspective**
Dr Elizabeth Kamphuis, Boehringer Ingelheim Vetmedica GmbH, Germany

10:00-10:15 **Feedback from Users**
Panel discussion with the moderator and the speakers

10:15-10:45 Coffee break

10:45-11:15 **ATMPs: how can Ph. Eur. fulfil its role for tomorrow's medicines? Viewpoint of OMCL/ Regulator**
Dr Marie-Cristina Galli, Istituto Superiore di Sanità (ISS), Italy

11:15-11:45 **Viewpoint of Industry**
Dr Mehrshid Alai-Safar, Kite Pharma, United States of America

11:45-12:00 **Feedback from Users**
Panel discussion with the moderator and the speakers.

12:00-14:00 Lunch break (EDQM premises)

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Panel discussion with the moderator and the speakers

12:00-14:00 Lunch break (EDQM premises)

WORKSHOP: CERTIFICATION

20 June 2019, Room 8

Moderator: Dr Jean-Louis Robert, Chair of the Certification Steering Committee

09:00-09:30 **EU Active Substance Master File (ASMF) work-sharing: Viewpoint of a Regulator**
Ms Nienke Rodenhuis, Medicines Evaluation Board (MEB), the Netherlands

09:30-10:00 **EU ASMF work-sharing and CEPs: Viewpoint of Industry**
Dr Martijn Klop, Synthon BV, the Netherlands

10:00-10:30 Coffee break

10:30-11:00 **The International Pharmaceutical Regulators Programme (IPRP) and its Quality Working Group for Generics**
Mr Gary Condran, Health Canada, Canada

11:00-11:20 **What's new in Certification**
Ms Hélène Bruguera, EDQM, Council of Europe

11:20-11:40 **Update on quality guidelines for the control of active substances**
Dr Olaf Ludek, Icelandic Medicines Agency (IMA), Iceland

11:40-12:00 **Feedback from Users**
Panel discussion with the moderator and the speakers

12:00-14:00 *Lunch break (EDQM premises)*

Thursday, 20 June 2019

Hemicycle - Palais de l'Europe

CLOSING PLENARY SESSION

Moderator:
Prof. Torbjörn Arvidsson, Incoming Chair of the European Pharmacopoeia Commission

14:00-14:30 **International Developments**
Dr Petra Dörr, Swissmedic, Switzerland

14:30-15:00 **The Role of the EDQM in International Harmonisation Initiatives**
Ms Cathie Vielle, EDQM, Council of Europe

15:00-15:30 Coffee break and Poster session

15:30-16:30 **Reports from the Workshop Sessions & Discussions**

16:30-16:45 **Final Conclusions & Closing Remarks**
Prof. Torbjörn Arvidsson, Incoming Chair of the European Pharmacopoeia Commission
Dr Susanne Keitel, Director, EDQM, Council of Europe

16:45 Close of the conference

More information is available at:
www.edqm.eu

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