Coordinator: Filippo Drago

EUROPEAN REGULATORY CONFERENCE
Forum of European Regulatory Experts
for the minimization of interstate discrepancies

Towards a European Pharmaceutical Harmonization:
Clinical evidence versus clinical benefit

“Adaptation processes in the regulatory world are too long: we cannot wait that a change is made through an adaptation process, we have to anticipate the adaptation”. (Francis Megerlin)

Catania, February 21st, 2020
Biological Tower, Via S. Sofia, 97
Aula Magna “Umberto Scapagnini”

S C I E N T I F I C  P R O G R A M

09:30-10:30 Registration

10:30-10:45 Welcome address
Filippo Drago - Coordinator Master in Drug Regulatory Affairs, Catania
Francesco Priolo - University Rector
Alessandro Mugelli - Past-President SIF
Chairman Francis Megerlin - EUCOR, University of Strasbourg (France)

10:45-11:30 Introductory lecture
Facing old and new difficulties towards a European Pharmaceutical Union
Guido Rasi - Executive Director, European Medicines Agency, Amsterdam (The Netherlands)

11:30-12:00 Value-based pricing of drugs in the UK
Kenneth Paterson - Professor emeritus, University of Glasgow (UK)

12:00-12:30 How clinical effectiveness is used in France to triage innovative drugs?
Olivier Wong - Chief Medical Officer, Medi Qualité Omega (France)

12:30-13:00 The comparator in clinical trials: the German model
Jan Geldmacher - AKDAE, Berlin (Germany)

13:00-13:30 Early access procedures: is it always an advantage? Do we need a harmonization?
Patrizia Popoli - President, Scientific Committee, Italian Agency for Medicines (Italy)

13:30-14:30 Lunch break

14:30-15:00 Early access programs in Italy: pros and cons
Claudio Jommi - SDA Bocconi School of Management, Milan (Italy)

15:00-15:30 Innovation in drug development: do we need a common parameter?
Francis Megerlin - EUCOR, University of Strasbourg (France)

15:30-16:00 The issues around a harmonized HTA approach in Europe from a German system’s perspective
Frank-Ulrich Fricke - University of Nurnberg (Germany)

16:00-16:30 Funding orphan medicinal products beyond price
Oriol Morales Sola - Chief Executive Officer, Health Innovation Technology Transfer (Spain)

16:30-17:00 Influence of Europe-Japan interactions on the European drugs regulatory and reimbursement systems
Isao Kamae - University of Tokyo (Japan)

17:00-17:30 Concluding remarks
Filippo Drago

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