UNIVERSITÀ degli STUDI di CATANIA

MASTER IN DRUG REGULATORY AFFAIRS

CERD CENTRO PER LA RICERCA E LA CONSULTAZIONE IN DISCIPLINE REGOLATORIE DEL FARMACO

CENTRE FOR RESEARCH IN REGULATORY AFFAIRS AND HTA

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"

SCIENTIFIC PROGRAM

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 Strasburg (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*

Chairman **Olivier Wong** - *Chief Medical Officer, Medi Qualité Omega (France)*

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 Strasburg (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 Solá - *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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