



UNIVERSITY OF CATANIA

MASTER IN DRUG
REGULATORY AFFAIRS



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

PROGRAM

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|--------------------|---|
| 10:30-10:45 | Welcome address
Filippo Drago - SIF and University Authorities |
| 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 Quality Omega (France) |
| 12:30-13:00 | Innovation in drug development: do we need a common parameter?
Francis Megerlin - EUCOR, University of Strasbourg (France) |
| 13:00-13:30 | The comparator in clinical trials: the German model
Jan Geldmacher - AKDAE, Berlin (Germany) |
| 13:30-14:30 | Lunch break |
| 14:30-15:00 | Early access procedures: is it always an advantage? Do we need a harmonization?
Patrizia Popoli - President, Scientific Committee, Italian Agency for Medicines (Italy) |
| 15:00-15:30 | Early access programs in Italy: pros and cons
Claudio Jommi - SDA Bocconi School of Management, Milan (Italy) |
| 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) |
| 17:00-17:15 | Concluding remarks
Filippo Drago |



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