CONFERENCE ON
50 YEARS OF EU PHARMA LEGISLATION:
ACHIEVEMENTS AND FUTURE PERSPECTIVES

Brussels, 28 September 2015

PROGRAMME
Charlemagne Conference Centre - Room De Gasperi
170, rue de la Loi (1040 Brussels)

Conference organised by the European Commission under the Chairmanship of Commissioner for Health and Food Safety, Dr Vytenis Andriukaitis
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Webstream available at

All the presentations will be uploaded on the webpage of the conference
Registration and coffee

Welcome by Dr Andrzej Rys, Director for Health systems and products, Directorate General for Health and Food Safety, European Commission

Interview with Mr Kevin Donnellon, thalidomide survivor

Opening speech by Dr Vytenis Andriukaitis, Commissioner for Health and Food Safety, European Commission

Introduction of the panel discussion by Mr Carlos Jimenez Renjifo, United Nations

SESSION 1
Risk regulation – What is the appropriate level?

Moderator: Mr Patrick Deboyser, Minister-Counsellor, European External Action Service

10.35 Introductory statement by Prof. Tamara Hervey, Head of School of Law, Jean Monnet Professor of European Law, University of Sheffield

10.45 Panel discussion:
Patients want early access, society wants safe medicines: Does one exclude the other?
Is the regulator risk averse? Have we gone too far?
Can pharmacovigilance and observational studies replace clinical trials?
Are affordable medicines and high safety standards compatible?

Panel members:
Ms Dolores Montero, Head of Division Pharmacoepidemiology and Pharmacovigilance, Agencia Española de Medicamentos y Productos Sanitarios
Ms Susan Forda, Vice President, Global Regulatory Affairs International at Eli Lilly & Company
Mr Yann Le Cam, Chief Executive Officer, European Organisation for Rare Diseases
Mr Adrian van den Hoven, Director General of the European Generic Medicines Association
Mr Hubertus Cranz, Director General of the Association of the European Self-Medication Industry

11.30 Coffee break

SESSION 2
Friends or foe – Regulators and industry

Moderator: Dr Sabine Jülicher, Head of Unit Medicinal Products Authorisation, European Medicines Agency, Directorate General Health and Food Safety, European Commission

11.50 Introductory statement by Mr Peter O'Donnell, Associate editor at Politico

12.00 Panel discussion:
Trust and transparency?
Can regulators be gatekeepers and partners at the same time?
Is legislation shaping business or is business shaping legislation?

Panel members:
Dr Christa Wirthumer-Hoche, Head of Austrian Medicines and Medical Devices Agency
Mr Stefano Marino, Head of Legal Service, European Medicines Agency
Mr Richard Bergström, Director General, European Federation of Pharmaceutical Industries and Associations
Dr Mary Baker, Immediate Past President of the European Brain Council and President of the ‘Year of the Brain’ project.
Mr Carlo Pettinelli, Director for Consumers, Environment and Health Technologies, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission

12.45 Lunch buffet
Afternoon Programme

14.10 Welcome by Mr Xavier Prats Monné, Director General for Health and Food Safety, European Commission

14.15 Keynote address by Dr Elisabeth Heisbourg, Director of Health (acting), Ministry of Health, Grand-Duchy of Luxembourg

14.30 Communicating Science - a glimpse into the future

Communicating science to a lay audience is a growing priority for researchers worldwide. By doing so, they not only change the common stereotype of the scientist, but also justify funding for their research, and inspire the next generation of scientists and engineers.

FameLab® is an exciting competition to find the new faces of science across the world and brings together people from all over the world to share their passion for science. FameLab is open to anyone working in/studying science, technology, engineering, medicine or maths. The competition format is similar to talent shows on TV. Contestants have just three minutes to charm the audience and jury with clear scientific content. Presentations are judged according to FameLab's golden rule of the three C's: Content, Clarity and Charisma. The 10 national finalists selected through heats held across the country, compete in the International Final which takes place in the UK during the Cheltenham Science Festival each June.

To mark the importance of research in our everyday lives FameLab brings young scientists from across the EU to Brussels in an exciting competition to give us a glimpse into the future.

SESSION 3

Pharmaceutical developments in the 21st century - perspectives, challenges and innovation

Moderator: Ms Giulia Del Brenna, Deputy Head of Cabinet of Mr Carlos Moedas, Commissioner for Research, Science and Innovation, European Commission

15.20 Introductory statement by Prof. Michel Goldman, Professor at the Université Libre de Bruxelles and former Executive Director of the Innovative Medicines Initiative

15.30 Panel discussion:
Current trends, future perspectives. What's next?
Is regulation enabling innovation or does innovation happen anyhow?
Personalised medicine(s): The end of one size fits all?
Innovation, at what cost?

Panel members:
Ms Françoise Grossetête, Member of the European Parliament
Mr Martin Seychell, Deputy Director General for Health, Directorate General Health and Food Safety, European Commission
Prof. Guido Rasi, Principal Adviser in charge of Strategy, European Medicines Agency
Prof. Dr Chas Bountra, Professor of Translational Medicines in the Nuffield Department of Clinical Medicine and Associate Member of the Department of Pharmacology at the University of Oxford
Prof. Dr Klaus Cichutek, President of the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany. Chairman of the Heads of Medicines Agencies’ Management Group
Dr Pierre Meulien, Executive Director of the Innovative Medicines Initiative

16.15 Closing of the conference: Mr Xavier Prats Monné, Director General for Health and Food Safety

16.30 End of the Conference