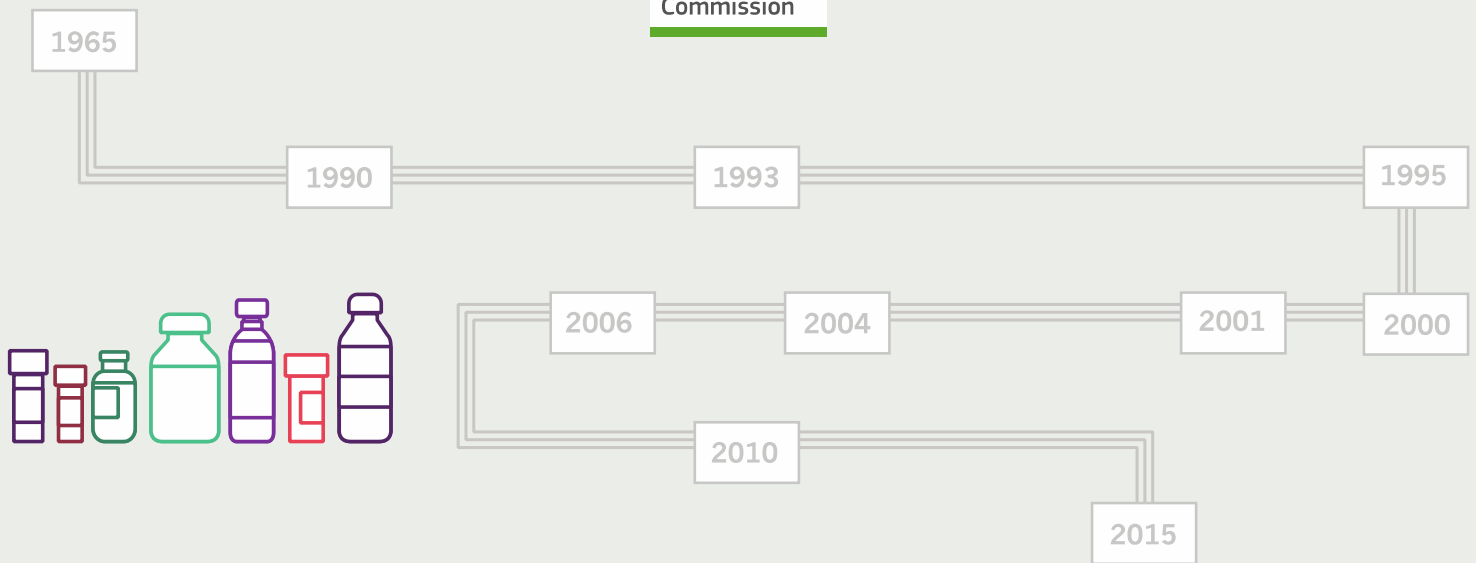




European
Commission



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*

Follow us on @EU_Health & join the conversation on #EUpharma50

Webstream available at

http://ec.europa.eu/health/human-use/events/ev_20150928_en.htm

All the presentations will be uploaded on the webpage of the conference

http://ec.europa.eu/health/human-use/events/ev_20150928_en.htm

Morning Programme

- 8.30 Registration and coffee
- 10.00 Welcome by **Dr Andrzej Rys**, Director for Health systems and products, Directorate General for Health and Food Safety, European Commission
- 10.05 Interview with **Mr Kevin Donnellon**, thalidomide survivor
- 10.15 Opening speech by **Dr Vytenis Andriukaitis**, Commissioner for Health and Food Safety, European Commission
- 10.30 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**
-