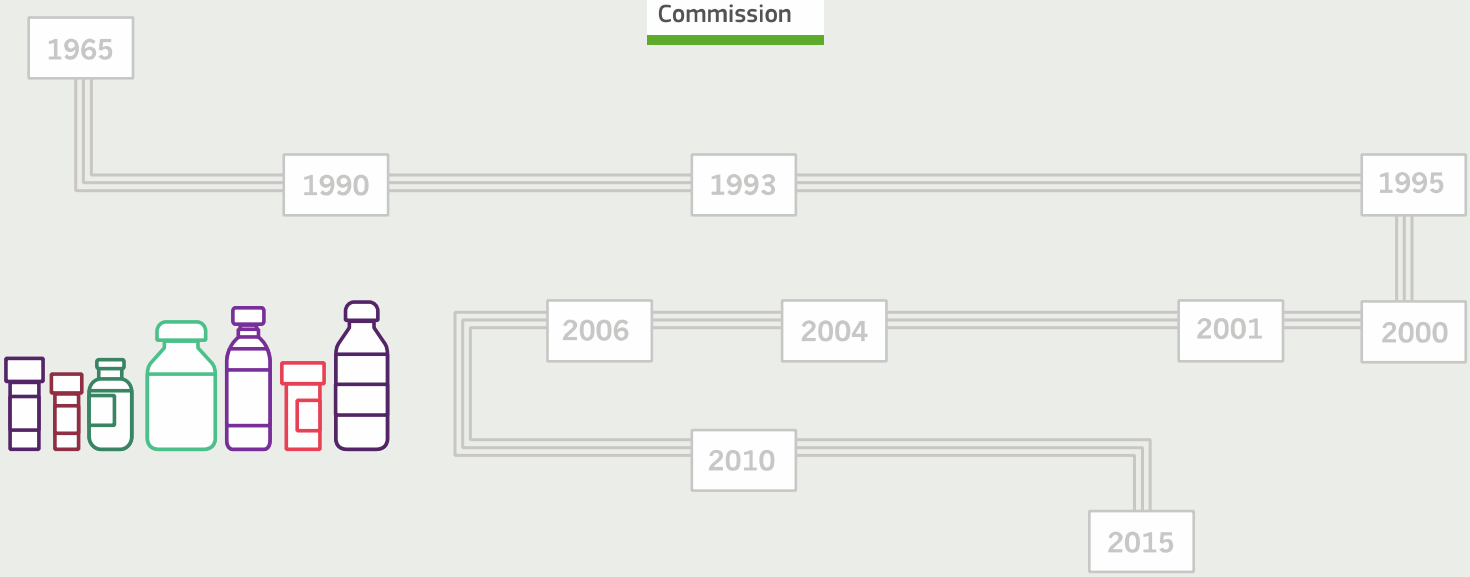
European Commission



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

Brussels, 28 September 2015

Draft 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

Health

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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

28 September 2015 – Brussels

Programme

Morning Programme

9.00 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 a Thalidomide victim**

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

10.30 Introduction of the panel discussion by the facilitator **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 **Professor Alberto Alemanno**, Jean Monnet Professor of Law and Risk Regulation, École des Hautes Etudes Commerciales de Paris

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

Panel members:
Member of the European Parliament [tbc]
Ms Dolores Montero, Head of the Division of 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

11.30 Coffee break

SESSION 2
Friends or foe – Regulators and industry

Moderator: **Dr Patrick O'Mahony**, Chief Executive of the Health Products Regulatory Authority, Ireland

11.50 Introductory statement by **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:
Ms Sabine Jülicher, Head of Unit Medicinal Products Authorisation, European Medicines Agency, Directorate General Health and Food Safety, European Commission
Mr Stefano Marino, Head of Legal Service, European Medicines Agency
Mr Richard Bergström, Director general, European Federation of Pharmaceutical Industries and Associations
Dr Mary Backer, 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 Technoligies, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission [tbc]

12.50 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**, Directeur de la Santé (acting), Ministry of Health, Grand-Duchy of Luxembourg [tbc]

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 **bring 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: European Commission [tbc]

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

15.15 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:
Mr Martin Seychell, Deputy Director General for Health, Directorate General Health and Food Safety, European Commission
Dr Guido Rasi, Principal Adviser in charge of Strategy, European Medicines Agency
Prof. Dr Chas Bountra, Professor of Transatlantic 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
Mr Pierre Meulien, Executive Director of the Innovative Medicines Initiative

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

16.30 End of the Conference