

Consensus Panel Series
Pharmaceutical Legislation: The need for pragmatism – and how to make it happen

Tuesday, March 15th, 2022

08.30 – 17.30 CET

Background

The dramatic improvement in the health of the citizens of Europe over the last two centuries has transformed the continent and the lives of the people living in it. But is Europe able to seize the new benefits that science, technology and forward-thinking public-policy decisions could confer on current and future generations of Europeans – or is it losing the will and capacity to grasp the fruits of progress?

With the upcoming revision of EU pharmaceuticals legislation, and drawing lessons from the COVID-19 pandemic, EAPM is organising a series of consensus panels regarding this topic on Tuesday, March 15th, 2022

Sessions will include:

- Consensus Panel I: Familiar challenges and new complications
- Consensus Panel II: Market Authorization, Access & Incentives
- Consensus Panel III: Predictable and sustainable access to quality medicines
- Consensus Panel IV: Unmet medical need
- Consensus Panel V: Formalize existing pathways for innovative medicines & Ensure expedited assessment pathway
- Consensus Panel VI: Shortages of medicines and vulnerabilities in the pharmaceutical supply chain

Expected outcomes

The main outcome will feed into activity that will support our engagement at the EU level and national level.

- foster innovation, including in areas of unmet medical need
- ensure access to affordable medicines
- improve security of supply
- adapt to new scientific and technological developments
- reduce red tape.

Participants

Attendees will be drawn from key stakeholders whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. These participants will include public health decision makers, representatives from the European Commission, Members of the Parliament, patient organisations, and umbrella organisations representing interest groups and associations actively engaged in the field. Each session will comprise panel discussions as well



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08:30 -10:00 Consensus Panel I: Familiar challenges and new complications

Chair: Denis HORGAN, European Alliance for Personalised Medicine

08:35 -08:45

Need for Action to ensure Access

Sara Cerdas, MEP, European Parliament

Stanimir Hasardzhiev, Secretary-General - Patient Access Partnership (PACT) (Confirmed)

08:45 -08:55

Improving Access at the Global Level

Sarah Garner, Acting Program Manager - Access to Medicines and Health Products, WHO EURO (Confirmed)

08:55 -09:05

Keeping the person in personalised medicine

Kathi Apostolidis, Vice President, European Cancer Patient Coalition (confirmed)

09:05 -09:15

Adapt to new scientific and technological developments

Bettina Ryll, Member of the first EU Cancer Mission board (confirmed)

09:15– 09:25

Regulatory Framework

Ralf Herold MD PhD, Senior scientific officer, Task Force Regulatory Science and Innovation, Research and Innovation, European Medicine Agency. (Confirmed)

09:25 – 09:35

Social Insurance Perspective

Yannis Natsis, Director, European Social Insurance Platform (Confirmed)

09:35 – 09:45

Stakeholder Perspective

09:45 -10:00

Panel Discussion: What do we want from you? How Can This be Supported

10:00-11.30 Consensus Panel II: Market Authorization, Access & Incentives

Chair: Denis HORGAN, European Alliance for Personalised Medicine



- 10:05 -10:15 **Perspective from European Commission**
Olga Solomon, *Head of Unit for Medicines: Policy, Authorisation and Monitoring - Directorate General for Health and Food Safety (SANTE), European Commission. (Confirmed)*
- 10:15 -10:25 **Economic Perspective**
Pedro Barros, *Professor of Economics at the Nova School of Business & Economics, Portugal*
- 10:25 - 10:35. **Perspective from EUnetHTA**
Dr Alric Ruether, *Co-Chair of the EUnetHTA 21 Consortium Executive Board and Head of the International Affairs Unit at IQWiG (Confirmed)*
- 10:35 -10:45 **Perspective from Romania**
Stefan Staicu, *Health attaché, Romania, EU/Brussels*
- 10.45– 10.55 **Perspective from a Member State, Luxembourg**
Anna Chioti, *Head of Division Pharmacy and Medicines at the Directorate of Health, Luxembourg (Confirmed)*
- 10.55 – 11.05 **Perspective from a Member State, Malta**
Stephen Mifsud, *Legal and Health Attache, Malta (Confirmed)*
- 11:05 -11:30 *Panel Discussion: What do we want from you? How Can This be Supported*

11.30 -13:00	Consensus Panel III: Predictable and sustainable access to quality medicines
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Chair: Denis HORGAN, European Alliance for Personalised Medicine

- 11:35 -11:45 **Access, Access, Access**
Kateřina Konečná MEP, *GUE/NGL, European Parliament*
- 11:45 -11.55 **Perspective from the Oncology Area as well as Italy**
Prof. Giuseppe Curigliano *Department of Oncology and Hemato-Oncology, University of Milan (Confirmed)*
- 11:55 -12:05 **Perspective from the Respiratory area as well as Poland**
Joanna Chorostowska-Wynimko, *Secretary General, European Respiratory Society (Confirmed)*
- 12:05 -12:15 **HTA Perspective**
Hans-Peter Dauben, *Secretary General, EuroScan (Confirmed)*
- 12.15 – 12.25 **Perspective from the Rare Disease area**
Simone Boselli, *Public Affairs Director, European and International Advocacy, Eurordis (confirmed)*
- 12.25 – 12.35 **Access, Access, Access**
Orla Glavin, *Executive Director, European Federation of Neurological Associations (Confirmed)*



12:35 -13:00 *Panel Discussion: What do we want from you? How Can This be Supported*

13.00 – 13.45 Lunch

13:45 -15:15 Consensus Panel IV: Unmet medical need

Chair: Denis HORGAN, European Alliance for Personalised Medicine

13:50 -13:55. **Welcome: Sirpa Pietikäinen, Member of the European Parliament**

13:50 -14:00 **Framing the Discussion**
Nikos Dedes, President, European AIDS Treatment Group, Chair of “Positive Voice”

14:55 -14.05 **Polish/Lung perspective**
Rafal Dziadziuszko Deputy Head, Professor, Department of Oncology and Radiotherapy of the Medical University of Gdansk, Poland (Confirmed)

14:05 -14:15 **Perspective from the Rare Disease Area**
Gilles Vassal, Professor of Oncology in University Paris-Sud and head of Clinical Research at Gustave Roussy, SIOPE Board Member (Confirmed)

14:15 -14:25 **Unmet Medical Need**
Dr. Christine Mayer-Nicolai, VP, Head Global Regulatory and Scientific Policy (GRASP), Merck. (Confirmed)

14.25 – 14.35 **Perspective from the Breast Cancer Community**
Tanja Spanic, President of ED Slovenia, Europa Donna – European coalition, president. (Confirmed)

12:35 -15:00 *Panel Discussion: What do we want from you? How Can This be Supported*

15:00 -16.15 Consensus Panel V: Formalize existing pathways for innovative medicines & Ensure expedited assessment pathway

Chair: D. Horgan, EAPM Executive Director

15:05 -15:05 **Introductory Remarks:**
Andrey Kovatchev, Group of the European People's Party, European Parliament (Confirmed)

15:05 -15:15 **Framing the Discussion**
Richard Sullivan, Professor, Cancer & Global Health at Kings College London (KCL) and founding director of the Institute of Cancer Policy.



- 15:15 -15:25 **Economic Perspective**
Bengt Jönsson, *Professor Emeritus, Department of Economics, Stockholm School of Economics (SSE)*
(Confirmed)
- 15:25 -15:35 **Health Technology Assessment**
Iñaki Gutierrez-Ibarluze, *Past President Director of Innovation of the Basque Foundation for Health Innovation and Research (BIOEF)* (Confirmed)
- 15:35 -15:45 **Innovation, Innovation, Innovation**
Thomas Kuhler, *Head of Regulatory & Policy EU, Global Regulatory Science and Policy, Sanofi* (Confirmed)
- 15.45 – 15.55 **Patient Perspective**
Stephen McMahon, *President, Irish Patient Association*
- 15.55 -16:15 *Panel Discussion: What do we want from you? How Can This be Supported*

16:15 – 17.30	Consensus Panel VI: Shortages of medicines and vulnerabilities in the pharmaceutical supply chain
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Chair: D. Horgan, EAPM Executive Director

- 16:15 -16:25 **Framing the Discussion**
Cristian Busoi, *EPP, Member of the European Parliament*
- 16:25 -16.35 **Regulatory Perspective, Ireland**
Darren Scully, *Senior Assessor – Shortages, Health Products Regulatory Authority (HPRA), Ireland* (Confirmed)
- 16:35 -16:45 **OECD Perspective**
Ruth Lopert, *Senior Health Policy Analyst, Health Division, Directorate for Employment, Labour and Social Affairs, Organisation for Economic Co-operation and Development* (Confirmed)
- 16.45 – 16.55 **"Recommendations from the Cancer Mission Board Horizon Europe"**
Christine Chomienne, *Vice-Chair of the Mission Board Cancer at the European Commission & Professor of Cellular Biology at the Université de Paris, France.* (Confirmed)
- 16.55 -17:30 *Panel Discussion: What do we want from you? How Can This be Supported*
