

**“Health as the Real Winner:
Presidency Conference on Options to Provide Better Medicines for All”**

6 March 2018, National Palace of Culture, Sofia

8.30 – 9.00 Registration of participants

9.00 – 9.30 **Opening speech:**

Ms Jeni Nacheva, Deputy Health Minister, Ministry of Health, Bulgaria

Keynote address:

Mr Martin Seychell, European Commission, Deputy Director General for Health, DG SANTE

9.30 – 10.45 First session:

- **Pharmaceutical shortages: public health or trade considerations?**

Moderator: Assoc. Prof. Assena Stoimenova, Executive Director, Bulgarian Drug Agency

Speakers:

Mr Matthew Moore, Council Legal Service: *“The Proportionality Concept”*

Ms Belén Escribano Romero, Head of Department, Pharmaceutical Inspection and Enforcement Department, Agencia Española de Medicamentos y Productos Sanitarios (AEMPS): *“Preventing Shortages Due to Parallel Export in Spain: a Proportionate Approach”*

Ms Agnès Mathieu, DG SANTE, Deputy Head of Unit “Medical products: quality, safety, innovation”: *“Legal Obligation of Continuous Supply Laid Down in the EU Legislation”*

Mr Oliver Luksic, Chief Adviser Trade and Competition, European Association of Euro-Pharmaceutical Companies: *„Limits of national Export Restrictions”*

Q&A

How can MS make sure that health comes first before commercial interests?

10.45 – 11.15 Coffee break

11.15 – 12.30 Second session:

- **European pharmaceutical industry, committed to health?**

Moderator: Prof. Dr. Nikolai Danchev, Chair of the National Council on Prices and Reimbursement of Medicinal Products

Speakers:

Ms Olga Solomon, European Commission, DG SANTE, Head of Unit “Medicines: policy, authorisation and monitoring”: *„Pharmaceutical System and the Current Developments“*

Mr Adrian van den Hoven, Director General, Medicines for Europe, *“Sustainable Competition: the Magic Formula to Align Public Health and Business Objectives for Access”*

Mr Boris Azais, Director Public Policy Europe and Canada, MSD, Representative of European Federation of Pharmaceutical Industries and Associations, *“The Research-Based Pharmaceutical Industry: Committed to Health!”*

Q&A

Business strategies, market withdrawals, affordability issues

12.30 – 13.30 Lunch

13.30 – 14.45 Third session:

- **Earlier access tools: is speed the right priority?**

Moderator: Assoc. Prof. Assena Stoimenova, Executive Director, Bulgarian Drug Agency

Speakers:

Dr Stefan Lange, Deputy Director, Institute for quality and efficiency in Health Care (IQWiG), Köln, Germany: „*Good Decisions Need Good Data*“

Ms Zaide Frias, European Medicines Agency, Head of Human Medicines Evaluation: “*Towards a 21st Century regulator’s Role: EMA Early Access Toolbox*”

Mr Yannis Natsis, Policy Manager Universal Access and Affordable Medicines, European Public Health Alliance: “*The Role of the Regulators in the European Access to Medicines Debate*”

Dr Josef Probst, Director General, Main Association of Austrian Social Security Institutions, “*Early Access or Speed Kills? A Payer’s Perspective*”

Q&A

Accelerated assessment, CMA, EMA priorities

14:45 – 15.15 Coffee break

15.15 – 16.30 Fourth session:

- **Ensuring Affordability and Access: The Solutions**

Moderator: Prof. Petko Salchev, *Professor of Social Medicine and Health Management, Director Division “Classification systems”, National Center of Public Health and Analyses*

Speakers:

Ms. Rabia Khan, Health Division, Directorate for Employment, Labour and Social Affairs, OECD: “*Maximising the Value of Pharmaceutical Spending*”

Dr Hans Kluge, Director “Division of Health Systems and Public Health”, WHO: “*Access to Medicines*”

Mr. Rainer Becker, Head of Unit “Pharma and Health Services”, DG COMP: “*Anticompetitive Practices*”

Dr Fernando Lamata, MD, PhD, Member of the Association for Fair Access to Medicines, ex-Secretary General of Health of Spain, ex-Regional Minister of Health of Castilla-La Mancha: “*What Can We Do to Ensure That Patients Have the Medicines They Need?*”

Dr Andrew Hill, Senior Visiting Research Fellow, Department of Pharmacology and Therapeutics, Liverpool University: *“How to Control the Rising Impact of Medicines on National Health Budgets”*

Q&A

Sustainability, Access, Affordability: Which Are the Solutions?

16.30 – 17.00 Conclusions