"Regulation on Medical Devices (MDs) and In Vitro Diagnostic Medical Devices (IVDMDs)"

Tuesday, 26 February 2012 from 12.30 to 18.00
European Parliament, Room ASP 1G2 Brussels

The event is open to the public. Interpretation will be provided in EN-FR-DE.

Part 1. Improving the regulatory framework for medical devices in the EU: new challenges ahead

12.30 - 12.35 **Welcome and opening by the Chair MEP Dagmar Roth-Behrendt**

First panel: The system of approval of medical devices
12.35 - 14:05

- **Ms. Paola Testori-Coggi** - DG SANCO, Director-General
- **Mr. Serge Bernasconi** - MedTech Europe, EDMA & Eucomed, CEO
- **Prof. Werner Siebert** - Vitos Orthopedic Clinic Kassel, Medical Director
- **Prof. Panos Vardas** - European Society of Cardiology (ESC) - President
- **Ms. Monique Goyens** - The European Consumers' Organisation (BEUC), Director-General
- **Mr. Hubertus Cranz** - Association of the European Self-Medication Industry (AESGP), Director-General
- **Mr. Richard Bergström** - European Federation of Pharmaceutical Industries and Associations (EFPIA), Director-General
- **Mr. Guido Rasi** - European Medicines Agency (EMA), Executive Director

Second Panel: Definition of single-use devices and reprocessing
14.05 - 15:05

- **Mr. Peter Schroeer** - Global Surgery Group, Johnson & Johnson, Group Director EMEA Regulatory Affairs
- **Ms. Katrin Fjeldsted** - Standing Committee of European Doctors (CPME), President
- **Ms. Nicola Bedlington** - European Patient's Forum (EPF), Executive Director
- **Mr. Marc Schreiner** - European Hospital and Healthcare Federation (HOPE), Governor
- **Mr. Robert Schroedel** - European Association for Medical Device Reprocessing (EAMDR), President

Third Panel: Are the expertise and structure of notified bodies sufficient for ensuring the necessary safety of medical devices and fulfilling their obligations?

15.05 - 16:05

- **Ms. Deborah Cohen**, British Medical Journal (BMJ), Investigations Editor
- **Mr. Gert Bos -** The European Association for Medical devices of Notified Bodies (Team-NB), President
- **Mr. Rainer Edelhäuser -** Notified Body Operations Group (NBOG), Chair
- **Prof. João Nabais** - International Diabetes Federation European Region (IDF Europe), President
- **Mr. Franz Terwey,** European Social Insurance Platform (ESIP), President

16.05 - 16.10 **Conclusions by the Chair**

Part 2. The specific needs related to In vitro diagnostic medical devices

16.10 - 16.15 **Opening by the Chair MEP Peter Liese**

1. - The COM proposal on IVDMDs

16.15 - 16.25 **Specifics of the IVDMDs proposal**
Ms, Sabine Lecrenier*, Head of Unit "Health Technology & Cosmetics", DG SANCO, European Commission*

16.25 - 16.35 **IVDMD manufacturers' point of view**
Mr Serge Bernasconi*, European Diagnostic Manufacturers Association (EDMA), CEO*

16.35 - 16.45 **Self-testing devices: consumers' needs and expectations**
Mrs Sine Jensen, *Danish Consumer Council, Senior Health Adviser*

16.45 - 17.00 Questions & Answers

2. - Special aspects of DNA testing

17.00 - 17.10 **Informed consent: a bioethical issue**
Dr. Laurence Lwoff, *Committee on Bioethics (DH-BIO), Bioethics Department of the Council of Europe, Secretary*

17.10 - 17.20 **Legal aspects related to the DNA testing**
Prof. Dr. Hans-Georg Kamann, *Centre of European Law, University of Passau*

17.20 -17.30 **Perspective of patients and disabled people**
Dr. Katrin Grüber, *Mensch, Ethik und Wissenschaft*

17.30 - 17.40 **DNA testing: Current and future regulatory challenges**
Prof. David Barton, *The European Society of Human Genetics*

17.40 - 17.55 Questions & Answers

17.55 - 18.00 ***Conclusions by the Chair***