

Workshop | Can the Medical Devices Regulation be an engine for substitution?



DATE: Monday 6th November 2017, 08:30 - 12:00 CET
VENUE: European Parliament | Room A5E1
MODERATOR: Philippe VANDENDAELE, Health Care Without Harm (HCWH) Europe

AGENDA:

08:30 - 09:00 **Registration**

09:00 - 09:15 **Welcome and introduction**

- **MEP Michèle RIVASI**, Member of the European Parliament, Group of the Greens/European Free Alliance

Ms Rivasi will provide short introduction recalling some of the milestones that have led to the adoption of the Medical Devices Regulation that entered into force on 25th May 2017.

09:15 - 09:30

An introduction to the new regulations on medical devices and new provisions related to use of hazardous substances: Strengthening transparency and safety requirements

- **Salvatore SCALZO**, DG for Internal Market, Industry, Entrepreneurship and SMEs, Health Technology and Cosmetics – Unit GROW D.4

Mr Scalzo's presentation will provide an overview of the main novelties of the new regulations on medical devices and the state-of-play of their implementation. Special attention will be paid to developments related to new provisions on UDI database and conformity assessment procedures and their relevance to the use of hazardous substances in devices.

09:30 - 10:15

Industry perspective

Industry perspective on implementation of the Medical Devices Regulation

- **Jean-Marc ABBING**, Chair of MedTech Europe Chemicals Working Group

Sustainability for medical devices: A company's perspective

- **Blandine GAYRAL**, Environmental Policy Manager, Johnson & Johnson

Sustainability and Product stewardship: An industry perspective

- **Ivan WELVAERT**, Director of Global Product Stewardship, Becton Dickinson

MedTech Europe, the medical technology trade association and two of its member companies, will present the regulatory framework applicable to the management of chemicals in medical devices, and its perspective on the 'hazardous substances' MDR requirements in that context.

The trade association will present the key role it plays in maintaining guidance on compliance to REACH, for all its member companies, including SMEs. It will also highlight the leading role of Medtech Europe in providing support in the context of the implementation of the MDR.

Two member companies will present their best practices in terms of implementing sustainability initiatives, and improving the environmental profile of their products.

10:15 - 10:45

Coffee break

10:45 - 11:15

The role of procurement in substitution

Sustainable procurement in Flemish Hospitals

- **Tomas DELIMON**, Environmental Expert, Envicas

Mr Delimon will speak about Zorgnet-Icuro - a federation of care institutions (hospitals, mental care and elderly care) in Flanders. His focus will be on procurement policies and, in particular, he will discuss how procurement can better take account of sustainability considerations by including criteria relating to quality, safety, and the environment.

Public procurement as a tool for substitution of EDCs

- **Hanna JONSSON PhD**, Chemicals Expert, Stockholm County Council

Ms Jonsson will share some of the lessons learned phasing out hazardous substances in Sweden. She will draw on the 20-year experience of Stockholm County Council and discuss factors for successful substitution, giving concrete examples of chemical criteria applied in public procurement. She will present the third and latest phase-out list recently approved by the Stockholm County Council. This list openly defines which substances should be avoided in healthcare.

11:15 - 12:00

Panel discussion, Q&A

12:00

Closing remarks

- **Philippe VANDENDAELE**, Chemicals Policy Advisor, HCWH Europe



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