Industry perspective on hazardous substances requirements in the Medical Devices sector

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(Chair Chemicals Working Group, MedTech Europe)

MedTech Europe

from diagnosis to cure

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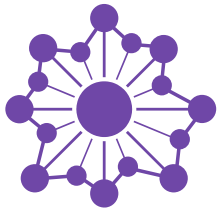
The European trade association
for medical technology industries
including medical devices, diagnostics and digital health.

OUR MEMBERS

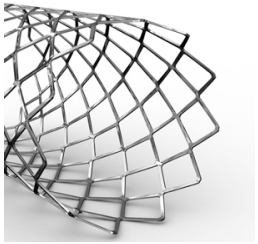
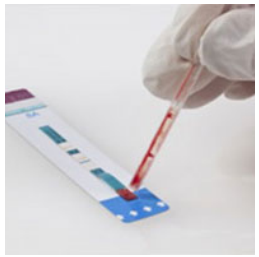
95+ multinational corporations

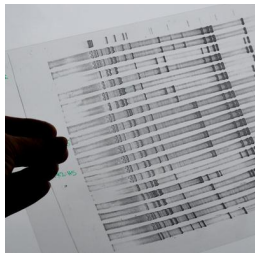


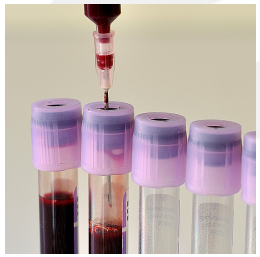
45+ medical technology associations

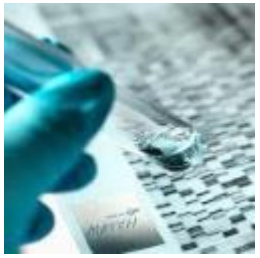
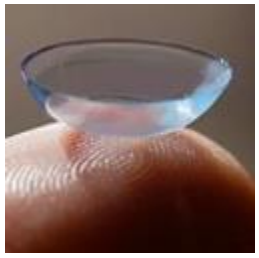
MEDICAL TECHNOLOGY

is any technology used to **save** and **improve** lives of individuals suffering from a wide range of conditions.











There are more than **500,000 products, services and solutions** currently available.

THE MEDTECH INDUSTRY IN EUROPE

€ 110 billion market

500,000+ medical devices

50,000+ *In vitro* diagnostics test

26,000+ companies of which 95% are SMEs

625,000+ employees

#1
In filing patent applications. 20% more than computer industries and double the pharma industry

Medical Devices (MD)

What are medical devices?

- Innovative technologies available to hospitals, physicians and patients that save lives, replace & restore body functions, prevent diseases development, monitor patients conditions and equip health institutions and home.

Why are they useful?

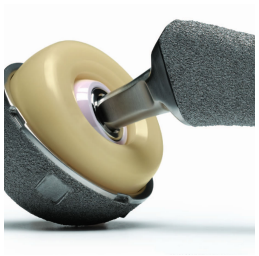
- Offer increasingly integrated health care services and solutions to improve hospitals, physicians and health care systems efficiencies.

Examples of medical devices

- Hospital beds, matrasses, sheets
- Surgical tools, gloves, tables
- Bandages
- Wheelchairs
- Surgical robots
- AIMDs: Pacemakers, defibrillators
- Stents
- Artificial hip, knee, legs
- Eye lenses
- Hearing aids






Regulatory aspects in a nutshell

Harmonised Directives 1990s:

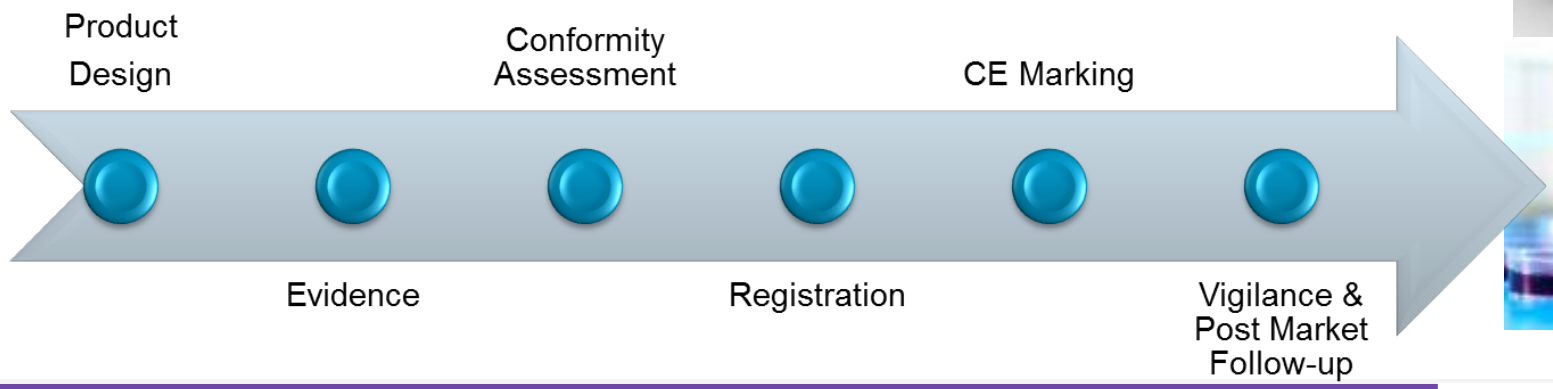
MDD – Medical Devices Directive
AIMD – Active Implantable Medical Devices Directive

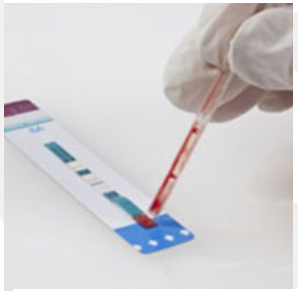
Revision 2017:

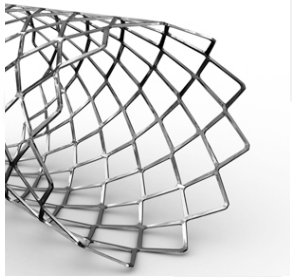
MD Regulation (EU) 2017/745

The new MD Regulation:
Provisions on chemical substances in Annex I

High-level overview of the regulatory process:





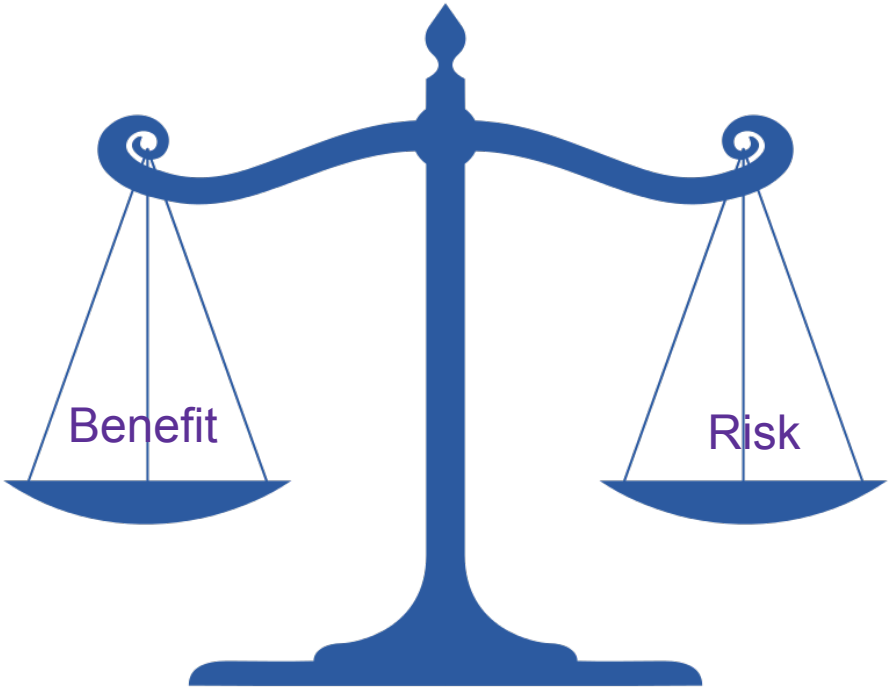


Chemicals in medical devices: regulatory framework

CLP	REACH	RoHS	MDR
→ Hazard identification → *tool for next step in risk management* → *does not consider the context of use*	→*Horizontal legislation for all chemicals management* → *dynamic tool for risk management options* → *primary tool for driving safe management and substitution of chemicals*	→ *Restriction – with exemptions to address risk at the waste stage* → *Waste legislation / limited scope (EEE / substances targeted)*	→ *Benefit – risk to patient assessment* → *Reduce the risk from leakage*

MDR risk-benefit assessment

Medical Devices Regulation



- Benefit – risk ***to patient*** assessment in support of Annex I on substances, including justification subject to scrutiny by notified body
- Guidelines to be developed by SCHEER (for targeted substances and medical devices)

MedTech Europe Chemical Working Group: historical overview

ROHS Directive (Restriction of Hazardous Substances in EEE):

- ROHS I (2002) – Medical Devices (MDs) not included in the scope
- Commission study (2005/2006) to assess how to include MDs in ROHS II
- Result: a stepwise phase-in of MDs (2014) in the updated ROHS
- First experience with mandatory substitution of chemicals in MDs

REACH :

- Eucomed (ex-MedTech Europe) guidance on REACH in 2007
- Focus on the impact from a downstream user perspective (registration of substances and their use in the supply chain)
- Impact of authorisation requirements was not clear then

MedTech Europe Chemical Working Group: work anno 2017

REACH:

- Understanding, clarifying and monitoring REACH processes
- Life Sciences Roundtable on REACH on 26 September with ECHA, the European Commission and the European Medicines Agency
- Advice: Industry should engage early in REACH processes and work with the regulators to ensure a workable outcome

MDR: Annex I requirements regarding substances:

- Work on clarification of the text: no grey areas!
- Stakeholder in the development of guidelines (SCHEER)

Practical implementation issues & sharing best practices:

- Workshop on full material declaration (FMD) and systems applied
- Share policies: Corporate members => SME via the National Associations:
  - Johnson & Johnson
  - Becton Dickinson

Thank you for your time

For more information, please contact the MedTech Europe Secretariat:

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