



## Tackling harmful chemicals in medical devices

26/05/2021

# Regulation (EU) 2017/745 on Medical Devices



- 1993: Council Directive 93/42/EEC on medical devices (AIMDD)
- 1990: Council Directive 90/269/EEC on the approximation of the laws, regulations, administrative provisions and directives of the Member States relating to the minimum health and safety requirements for the use of work equipment



Devices (AIMDD)

## Stricter requirements on the use of hazardous substances:

Manufacturers of medical devices are required to provide **adequate justification** to the Notified Body **for the presence of CMRs 1A and 1B and/or endocrine disruptors** that are:

Contained in certain invasive medical devices

Above a certain concentration (0.1% weight by weight (w/w))

# Exposure to harmful chemicals in healthcare

- Exchange transfusion of blood in neonates
- Extracorporeal membrane oxygenation (ECMO) treatment of neonates and of adults
- Total Parenteral Nutrition (TPN) in neonates
- Multiple procedures in sick neonates
- Haemodialysis
- Enteral nutrition in neonates and adults
- Heart transplantation or coronary artery bypass graft surgery
- Massive blood transfusion of red blood cells and plasma
- Peritoneal dialysis



Premature neonates in neonatal intensive care units, infants subjected to repeated medical treatment using medical devices, and dialysis patients **are at risk of DEHP- and BPA-induced effects**

# Speakers



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# About HCWH Europe



We are a non-profit European network of hospitals, healthcare systems, healthcare professional bodies, local authorities, research/academic institutions, and environmental and health organisations.

Health Care Without Harm is a global movement:

- Three regional HCWH offices (Europe, USA, South East Asia) and virtual team in Latin America
- Partners around the world (Australia, China, India, South Africa)

# First, do no harm



**Vision:** Healthcare mobilises its ethical, economic and political influence to create an ecologically sustainable, equitable and healthy world.

**Mission:** Transform healthcare so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice.

# Global Green and Healthy Hospitals



GGHH is an international network of:

- Hospitals
- Healthcare facilities
- Health systems
- Health organisations

This worldwide community comprises **1,450 members** in **72 countries**, representing the interests of over **43,000 hospitals/health centres**.



# Exposure to harmful chemicals in healthcare

## MEDICAL TEXTILES

Phthalates (plasticizers)

Polybrominated Biphenyl Ethers (flame retardants)

## CLEANING PRODUCTS

Glycol Ethers (surfactant)

Cyclosiloxanes (spreading agent)

Ethanolamines (emulsifier)

## FLOORING

PVC



## INTRAVENOUS TUBING & BAGS

Phthalates (plasticizers)

## MEDICAL DEVICES

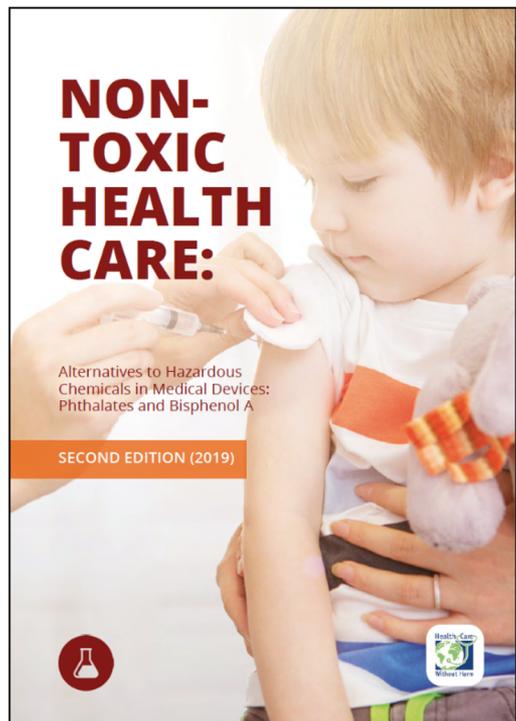
Phthalates, BPA (plasticisers)

## MEDICAL GLOVES

Phthalates (plasticisers)



# Safer Medical Devices



[https://noharm-europe.org/sites/default/files/documents-files/6154/2019-12-03\\_HCWH\\_Non\\_Toxic\\_Healthcare\\_2\\_WEB.pdf](https://noharm-europe.org/sites/default/files/documents-files/6154/2019-12-03_HCWH_Non_Toxic_Healthcare_2_WEB.pdf)



[https://noharm-europe.org/sites/default/files/documents-files/6203/2020-01-22\\_EDCs\\_workshop\\_report.pdf](https://noharm-europe.org/sites/default/files/documents-files/6203/2020-01-22_EDCs_workshop_report.pdf)

Health Care



Without Harm

# Q&A



# Thank you for participating!



Please send any further questions to:

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