Health Care Without Harm

GLOBAL GREEN and HEALTHY HOSPITALS

ENDOCRINE DISRUPTING CHEMICALS IN HEALTHCARE : Reducing exposures for patients

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HCWH Europe

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Introduction

We have known for decades that certain hazardous Endocrine Disrupting Chemicals (EDCs) leach out of medical devices; Bisphenol A (BPA) and phthalates (notably DEHP) are examples of hazardous substances often found in medical devices that are of particular concern due to their endocrine disrupting properties. Several concerns have been raised about patients' high risk of exposure to such chemicals during medical treatment and the detrimental long-term effects on patients' health. HCWH Europe has long campaigned to highlight and reduce these exposures for patients, especially for vulnerable populations such as newborns or pregnant/nursing women, and those receiving treatments using multiple medical devices. In response to these concerns, many healthcare facilities around the world are already switching to safer and more cost-effective medical devices that do not contain PVC, DEHP, and BPA.

The main objective of this workshop was to address the implementation of the Medical Devices Regulation (MDR), focusing on new provisions that should help phase out Carcinogenic, Mutagenic, and Reprotoxic chemicals (CMRs) and EDCs in medical devices when safer alternatives are available and technically feasible. HCWH Europe invited a range of relevant stakeholders to discuss:

- The current state of play for EDCs in medical devices (with a focus on DEHP and BPA)
- The opportunities, challenges, and barriers to substitution
- How we can increase commitment and action from all stakeholders to reduce patients' exposure to harmful chemicals, particularly for vulnerable groups

Policy makers, healthcare providers, and medical device manufacturers attended this event to join the discussion oh how we can accelerate the phase-out of harmful substances in medical devices.

This workshop also featured the launch of HCWH Europe's Non-toxic Healthcare report (second edition) providing further evidence and additional substitution case studies compared to the original report first published in 2014; this second edition also includes a new chapter exploring the use of plastics in healthcare.

Opening words

Opening the workshop **Will Clark**, Executive Director of Health Care Without Harm (HCWH) Europe, welcomed participants and introduced the organisation's goal to support the implementation of sustainable practices in the European healthcare sector.

Over the last 20 years, HCWH has advocated for healthcare providers to reduce products containing hazardous chemicals and prioritise safer alternatives. The Safer Chemicals programme aims to raise awareness of hazardous substances in medical devices and the potential risks to patients, as well as the opportunities for substitution when many alternatives are available.

Dorota Napierska, Chemicals Policy & Projects Officer, moderated the rest of the event.

EDCs in medical devices: The state of play

Carmen Freire (PhD, Senior Researcher at FIBAO - Instituto de Investigación Biosanitaria de Granada, Granada University Hospital, Spain).

Early-life exposure to EDCs and children's health: inadvertent sources of exposure

Dr. Freire first provided a summary of the current knowledge regarding endocrine disruption and effects of early-life exposure to EDCs, before focussing on results from a new study on presence of BPA and parabens (PBs) in a neonatal intensive care unit (NICU). The research group of Dr. Freire assessed the content of chemicals used in a wide array of medical products/devices used in NICU in the Granada University Hospital, as well as their (anti-)androgenic and (anti-)estrogenic activities.

She emphasised that this is the first report on the presence of BPA and PBs in materials in contact with newborns in NICUs, and

first evidence that the contents of NICU materials exert hormonal activities. Dr. Freire concluded that several materials used in NICUs may act as potential sources of exposure to BPA and PBs for extremely vulnerable neonates (newborn) patients. She added, *"there is an urgent need to eliminate or decrease the use of plastics containing BPA and other EDCs in devices and feeding equipment in NICUs."*

Prof. **Ilse Vanhorebeek** (Laboratory of Intensive Care Medicine - KU Leuven, Belgium).

The link between DEHP exposure and neurocognitive outcome of critically ill children

Prof. Vanhorebeek first provided a brief overview of the intensive care needed for critically ill children, stressing that there is a heavy reliance on indwelling (inserted in the body) plastic medical devices during provision of such care. She also emphasised that there are concerns surrounding the potential toxicity of phthalates/DEHP and that high urinary levels of DEHP metabolites recorded in premature neonates originate from indwelling medical devices.

Prof. Vanhorebeek then presented the results of a randomised controlled study, showing a link between high DEHP metabolites levels in critically ill children treated in the Paediatric Intensive Care Unit (PICU), and attention deficit disorder (measured four years after treatment). These results, she concluded, prove that DEHP is still a predominant plasticiser in indwelling medical devices and that DEHP levels exceeding the potentially harmful threshold for exposure may lead to eventual long-term neurocognitive harm. Prof. Vanhorebeek therefore concluded that medical devices with low DEHP release potential should be used whenever possible.

Regulatory framework: EDCs in medical devices

Petra De Sutter MEP (Member of the European Parliament, Group of the Greens/European Free Alliance, Chair

of the Committee on the nternal Market and Consumer Protection (IMCO), Prof. Reproductive Medicine, Ghent University, Belgium).

Difficulties and urgency to regulate EDCs on European level

Petra provided a brief overview of the current regulatory framework and EDC criteria and its shortcomings; she concluded that EDCs in the EU have been regulated too little and too late. Petra described the European Commission's 2018 communication as very disappointing as the framework lacks both a concrete action plan to minimise exposure to EDCs and a timeline for the next steps to move forward. In line with the precautionary principle, a hazard-based approach instead of a risk-based approach should be used.

Addressing the Medical Devices Regulation and its implementation, Petra stressed that different identification requirements for EDCs and CMRs will lead to inconsistencies across EU legislation, and that as a result the opportunity to substitute harmful chemicals (such as EDCs) with safer alternatives in medical devices might be watered down.

More positively, however, Petra acknowledged that European Commission President Ursula Von Der Leyen has mentioned EDCs as one of her priorities, as did Stella Kyriakides (European Commissioner for Health and Food Safety) and Virginijus Sinkevičius (Commissioner for Environment, Oceans and Fisheries). The European Parliament (particularly the Greens/EFA group) has been very active on EDCs according to Petra, drawing attention to a EP resolution on EDCs from April 2019. A lot of MEPs – including herself - will remain very active on this topic in this mandate, concluding that *"I hope we will finally get good regulation that bans EDCs, because we can not approve any more delays!"*

Paul Piscoi (Scientific Policy Officer - European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs).

Hazardous substances and the new Medical Devices Regulation

Paul provided a summary of the implementation process of the MDR so far, beginning with the establishment of a Medical Device Coordination Group (MDCG) and new technical Expert Groups (MDCG

subgroups). Scientific structures have also been setup comprising expert panels, expert laboratories, and reference laboratories; furthermore, nine Notified Bodies have been designated (including 2 under IVDR). A communication campaign, SCHEER's opinion on phthalates, and 31 Guidelines have also been released - covering many crucial aspects of MDR.

Paul informed participants that the European Commission's next steps are to continue designating Notified Bodies and establishing EUDAMED, work on standards, common specifications on reprocessing, establishment of UDI system. MDCG Guidance documents in crucial areas will be produced, notably on borderline and new classification rules, clinical evaluation, vigilance, and medical software/apps.

Paul also talked about hazardous substances in medical devices, addressed in Annex I on General Safety and Performance Requirements; specifically, he cited Article 5, Annex I 10.4.1-4. He also gave further explanation on SCHEER's Guidelines on phthalates in medical devices, stressing that this approach can also be used for a benefit-risk assessment, for other CMRs/EDCs present in medical devices.

The industry perspective

Oliver Bisazza (Director Regulations and Industrial Policy - MedTech Europe).

Medical Devices Regulation 745/2017: Framework for benefit-risk assessment of endocrine disruptors

Speaking on behalf of the industry association, Oliver first provided the audience with facts and figures about medical technology and MedTech industry in Europe. Focussing on the MDR, he stressed that Annex I, Section 10.4.1 lays down which substances are in scope i.e. those identified as endocrine disruptors for human health on the REACH Candidate list and substances identified in accordance with criteria in the Biocidal Products Regulation (BPR). Currently, six chemicals have been identified as endocrine disruptors for human health on the REACH Candidate list:

- Dicyclohexyl phthalate
- Bisphenol A
- Diisobutyl phthalate
- Benzyl butyl phthalate

- Bis (2-ethylhexyl)phthalate
- Dibutyl phthalate

While no EDCs have been identified yet in accordance with the criteria established under the BPR, it is expected that the list of endocrine disruptors in scope of the MDR will continue to grow.

Oliver acknowledged that for certain devices an analysis of alternatives and benefit-risk assessments would be required when CMRs and EDCs are involved. Such assessments will be part of the technical documentation for the device and subject to review by Notified Bodies. Giving the example of a multi-layered bag, a medical device that stores liquid to be (re)administered to the body, he explained that according to SCHEER guidelines, a benefit-risk assessment must consider the availability of alternative substances, materials, designs, and medical treatments, as well as benefit-risk ratio, functionality, and performance. Oliver concluded that this may result in justification for either continued use of the endocrine disruptor or its substitution.

Stefan Kolb (Vice President European Governmental Affairs, Fresenius Kabi Division Transfusion and Cell Technologies – Fresenius, Germany).

Progress and challenges in replacing DEHP in a broad portfolio

Stefan opened his presentation by introducing the Fresenius Health Care Group and the company's broad medical care product portfolio including examples of DEHP- and plasticiser-free products. (all Fresenius dialysers are made of completely DEHP-free material for example).

In his presentation, Stefan also discussed regulatory challenges within the Blood Transfusion Industry. All manufacturers have already studied alternatives for Red Blood Cell storage (DINCH, DEHT etc.) and even partially launched them, however, elevated free haemoglobin levels were observed in all cases – which can result in severe health risks to patient. He strongly emphasised that piling up regulatory challenges could negatively impact the availability of blood supply within the EU.

Stefan concluded that whilst Fresenius is on track to phase out DEHP wherever feasible, challenges still remain for blood transfusion products where no viable alternatives currently exist.

Substitution of EDCs in medical devices

Arianna Gamba (Procurement Policy & Projects Officer - HCWH Europe).

Public procurement as a tool for chemical substitution

Arianna explained the concept of sustainable public procurement and its relevance for the healthcare sector, she added that there is no doubt that informed procurement is an effective tool to achieve the substitution of harmful chemicals.

Arianna explained that to implement sustainable public procurement in healthcare, you must first have a sustainable procurement policy in place and leadership support. Conducting a baseline assessment is important to collect data that will help you prioritise products e.g. those used to treat potentially vulnerable patient groups. She stressed the importance of both engaging with suppliers while searching for alternatives and collaboration with other hospitals to exchange experience. As primary users of these products, health professionals as well as procurement staff should be informed about the health impacts of hazardous substances. Arianna added that some provisions within the Public Procurement Directive and the Medical Device Regulation allow the introduction of sustainability criteria when preparing tenders thus setting a demand for safer products. The final step she concluded, is that once the contract has been granted it is important to monitor its correct implementation.

To put this process into context Arianna provided some best practice examples from HCWH Europe members and others across the European healthcare sector:

- Vienna Hospital Association (Austria)
- Stockholm County Council (Sweden)
- University Hospital of Olomouc (Czechia)
- Ostrava University Hospital (Czechia)
- Kosice Saca Hospital

Arianna also highlighted a case study from Stockholm City Council showing that the prices of alternatives are not necessary higher than those of PVC-based medical devices containing DEHP.

Dorota Napierska (Chemicals Policy & Projects Officer - HCWH Europe).

Launch of the 2nd edition of Non-toxic report Healthcare report

Dorota closed this session by launching the 2nd edition of Health Care Without Harm Europe's report Non-toxic Healthcare.

She explained the motivation to publish this update was to further raise awareness and accelerate the shift towards substitution of harmful substances within the European healthcare sector, supported by research, evidence, and collaboration. This report contains new evidence of DEHP and BPA hazards for human health and exposure through medical devices, an update on the European legal framework for hazardous chemicals in medical devices, and a new chapter on the health impact of plastics in healthcare. One of the report conclusions is that a consistent technical implementation of Annex I.II.10.4 of the MDR must be ensured, particularly to protect the most vulnerable patient groups.

Discussion:

How can we increase commitment and action from all stakeholders to reduce patients' exposure to EDCs, particularly for vulnerable groups?

The key issues raised during this discussion were:

- The lack of health professionals' awareness on the presence of harmful chemicals in medical devices – this means the demand for PVC- and DEHP-free medical devices from hospitals is too small for industry to scale-up production.

- To raise such awareness, successful examples of European healthcare facilities that have switched to alternatives are important in showing that phasing out PVC and/or phthalates is not only possible but in many cases already a reality.
- The need for healthcare procurers from different regions and countries to collaborate and properly consider environmental criteria and show the industry an increased demand for phthalates-free medical devices.
- It is important to demonstrate that substitution does not have to be too costly.
- The healthcare sector should incorporate the concept of circular economy.

Dorota Napierska closed the workshop by expressing her satisfaction at the range and engagement of participants to this workshop. On behalf of HCWH Europe, she expressed her gratitude to all participants present at the event, and noted that the workshop had been an ideal forum to learn and discuss some of the challenges regarding substitution to safer chemicals. This HCWH Europe workshop allowed for open discussions and exchanges and was helpful in identifying outstanding issues.

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Health Care Without Harm (HCWH) Europe is the European arm of a global not for profit NGO whose mission is to transform healthcare worldwide 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. HCWH's vision is that healthcare mobilises its ethical, economical, and political influence to create an ecologically sustainable, equitable, and healthy world.

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