Workshop Report

Can the Medical Devices Regulation be an Engine for Substitution?

European Parliament | Monday 6th November 2017

Health Care Without Harm

The Greens | EFA in the European Parliament

On the 6th of November 2017, HCWH Europe organised a workshop *Can the medical devices regulation be an engine for substitution?* This event was kindly hosted by MEP Michèle Rivasi, the shadow rapporteur on the Medical Devices Regulartion (MDR) for the group of the Greens at the European Parliament.

The main objective of the workshop was to consider how provisions within the MDR can be used to substitute medical devices containing harmful chemicals with safer alternatives. These provisions mirror the REACH requirement for progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Annex I.II.10.4.1 of the MDR includes a 0.1% concentration limit for category 1A and 1B carcinogenic, mutagenic, and reprotoxic (CMR) substances and endocrine disrupting chemicals (EDCs) in devices that are invasive and come into direct contact with the body.

Medical devices will only be permitted to contain such substances at a level above this limit if a justification is provided to the Notified Body (NB) - which is overseen by the national competent authority.

To address this provision and its potential for substitution, HCWH Europe invited a range of relevant stakeholders, mainly manufacturers and procurers, asking whether they were fully aware of this potential and how they were going to avail of them.

OPENING WORDS

Opening the Workshop, Philippe Lamberts MEP, Co-President of the Greens/EFA said that it should come as no surprise that the European Parliament (EP) was keen to host this event; the EP, he recalled, has been very active over the years as co-legislator on the MDR.

He indicated that the EP's motivation *then* was to deliver a good piece of legislation and that *today* its motivation was to ensure that all parties involved implement this instrument to improve the quality, safety, and reliability of medical devices.

Looking back, he recalled that the reform efforts leading to the adoption of the MDR were triggered by the *Poly Implant Prothèse* (PIP) breast implant scandal that made the headlines in 2012 - Breast implants made of industrial silicone

had been marketed as medical devices and received a European Conformity (CE) certificate from a renowned notified body.

Commenting on this, Lamberts deplored that the elaboration of the MDR had taken so long and that its effective entry into force, May 2020, would take place almost a decade after the event. Though critical, his closing words were of encouragement and he acknowledged the need for collaborative thinking amongst relevant actors for a successful implementation process.

INTRODUCTION TO THE NEW REGULATIONS ON MEDICAL DEVICES AND NEW PROVISIONS RELATED TO USE OF HAZARDOUS SUBSTANCES: STRENGTHENING TRANSPARENCY AND SAFETY REQUIREMENTS

Salvatore Scalzo (Unit D4 - Health Technology and Cosmetics DG Internal Market, Industry, Entrepreneurship and SMEs, European Commission) set the scene with an informative presentation that first provided a summary of the process leading to the adoption of the MDR before focussing on the main points of this new regulatory framework applicable to medical devices.

Having done so, Scalzo then moved on to address the specific issue of substitution, discussing the way the Regulation will deal with hazardous substances in medical devices according to Annex I.II.10.4.1 of the MDR. He helpfully clarified that the presence of hazardous substances (subject to justification according to Annex I.II.10.4.1) would need to be indicated on the label of the device. This information, he stressed, will feature in the mandatory Unique Device Identification data elements to be provided by the manufacturer to the EUDAMED Database - the EU's database where all medical devices placed on the market have to be entered.

Still discussing these technical but helpful aspects, he informed participants that the European Commission was working hard on the future EU medical device nomenclature to enhance database search functions. This was a key point, given access to the new and revamped EUDAMED will be extended to include not only the National Competent Authorities (NCAs) and the European Commission, but also the Medical Devices Coordination Group (MDCG), Notified Bodies (NBs), Economic Operators (EOs - manufacturers, authorised representatives, importers, sponsors), experts, and the public, including medical institutions.

Scalzo closed his presentation by giving participants a timeline of the key next steps including the:

- Publication of CAMD/COM roadmap – next few weeks
- Adoption Implementing Act on Notified Bodies codes: by 26th November 2017
- Applications for designation of notified bodies: as from 27th November
- Setting–up and first meeting of the MDCG: 28th November 2017
- Launch of the procedure for a corrigendum to the two Regulations: December 2017

Click here to view Salvatore Scalzo's presentation

INDUSTRY PERSPECTIVE ON IMPLEMENTATION OF THE MEDICAL DEVICES REGULATION

With the following presentation, delivered by Jean-Marc Abbing (Chair Chemicals Working Group, MedTech Europe), participants were given the manufacturers' perspective of the issue. Speaking on behalf of the industry association, he provided us first with facts and figures about what the industry represents in terms of products captured by the MDR but also in terms of the industry's economic weight and the people it employs as a sector.

Moving on to the regulatory challenges faced by the industry, Abbing placed the adoption and implementation of the MDR against the backdrop of equally challenging regulatory instruments that the industry has had to comply with over the past decade including the Classification, Labelling and Packaging (CLP) Regulation, REACH, and Restriction of Hazardous Substances (RoHS) Directive.

Focussing on the MDR, Abbing stressed that these new rules were indeed challenging as they also include specific provisions concerning product design, waste disposal, and specific requirements regarding chemical, physical, and biological properties of substances used in medical devices. He acknowledged that for certain devices, an analysis of alternatives and risk-benefit assessment would be required when CMRs and EDCs are involved.

For this reason, Abbing stated that MedTech will continue to work with the relevant parties to ensure that no grey areas remain post-implementation. He supported this statement by indicating that MedTech would actively engage as a stakeholder with the scientific committee of the European Commission (SCHEER) – who have been tasked by the MDR to prepare guidelines on a benefit-risk assessment of the presence of phthalates and CMRs in medical devices.

Click here to view Jean-Marc Abbing's presentation

SUSTAINABILITY FOR MEDICAL DEVICES: A COMPANY'S PERSPECTIVE

Blandine Gayral, Environmental Policy Manager with Johnson & Johnson – a member of MedTech – followed with a presentation designed to illustrate how a major market player was actually seeking to anticipate the requirements of the MDR. She opened by introducing Johnson & Johnson (J&J), focussing on the company's approach to sustainability in general and then moving on to increasingly concrete and tangible initiatives adopted by the company to foster its sustainability agenda.

Gayral mentioned the second pillar of the J&J *2020 Health for Humanity Goals* which includes concrete measures such as promoting fully integrated sustainable design solutions into their product innovation processes and targets to reduce impacts on climate and water resources.

Gayral dwelled on their *Top Sustainability Focus Areas*, which include measures to address chemicals of concern in products. Illustrating their current approach she mentioned the EARTHWARDS™ initiative whose objectives are to support the development of more sustainable products, provide tools and resources to enable sustainable innovation, and to enable meaningful and credible claims.

Click here to view Blandine Gayral's presentation

SUSTAINABILITY AND PRODUCT STEWARDSHIP: AN INDUSTRY PERSPECTIVE

Ivan Welvaert, Director - Global Product Stewardship Office of Global Sustainability, Becton Dickinson (BD) closed this section showcasing the industry perspective. Having introduced BD, he then outlined its approach to sustainability and was very concrete in the approach taken by Becton Dickinson. Detailing their 2020 Sustainability goals for product stewardship, he mentioned that their approach sought to:

- Improve the life cycle impacts of products
- Eliminate priority materials of concern, (intentionally added), in each of the following product categories:
  - » Devices: PVC and phthalates
  - » Instruments: phthalates, brominated flame retardants (BFRs), and heavy metals
  - » Packaging: PVC and expanded polystyrene

These very specific measures are hopefully indicative of a trend that emanates from the market, where some players are clearly trying to anticipate the requirements of the MDR.

Click here to view Ivan Welvaert's presentation

SUSTAINABLE PROCUREMENT IN FLEMISH HOSPITALS

In the latter part of the workshop we heard from procurers and their practices. The first speaker was Tomas Delimon, Environmental Expert, Envicas, speaking on behalf of Zorgnet-Icuro, a HCWH Europe member.

Zorgnet-Icuro is a network consisting of healthcare organisations, specifically general hospitals, residential and ambulatory initiatives from mental healthcare, and facilities of the care of the elderly. There are over 775 recognised healthcare organisations that are members of Zorgnet-Icuro, employing a combined total of approximately 129,000 staff.

Delimon first explained the approach of Zorgnet-Icuro to sustainability issues; he then focussed on procurement policies and, in particular, he discussed how procurement can better take account of sustainability considerations by including criteria relating to quality, safety, and the environment.

As part of this discussion Delimon dwelled on the accreditation systems used by Flemish hospitals - 60% of Flemish hospitals are accredited by the Dutch Institute for Accreditation in Health Care (NIAZ). He explained that NIAZ develops quality standards, tests healthcare institutions and assesses whether hospitals maintain acceptable quality level of care. The other 40% of hospitals in Flanders are members of The Joint Commission International (JCI) who identifies, measures, and shares best practices in quality and patient safety.

Click here to view Tomas Delimon's presentation

PUBLIC PROCUREMENT AS A TOOL FOR SUBSTITUTION OF EDCS

Hanna Jonsson PhD, Chemicals Expert - Stockholm County Council (SCC). The County Council is responsible for all publicly-financed healthcare and public transport in Stockholm County. In terms of healthcare, Stockholm County Council is one of Europe's largest healthcare providers.

Jonsson addressed the issue of the potential of the MDR for substitution head on. As a chemical expert she is working on the substitution list used by the SCC - the result of a political decision: *Stockholm County Council will decrease its environmental impact caused by hazardous chemicals*.

Jonsson explained that SCC would encourage the use of "nice" chemical products, which she defined as those that do not cause allergies or are hazardous to aquatic life. Going forward, the idea would be to prioritise "nice" articles and consumables to ensure that no foreign substances reach patients or employees. That approach, she clarified, is part of a broader desire to contribute to a toxic free circular economy.

For Jonsson, there is no doubt that the most effective tool to achieve substitution of harmful chemicals is through informed procurement. She gave some details about the SCC applying their procurement policy, stressing that this has allowed them to go beyond the minimum requirements that are set out in legal instruments.

Click here to view Hanna Jonsson's presentation

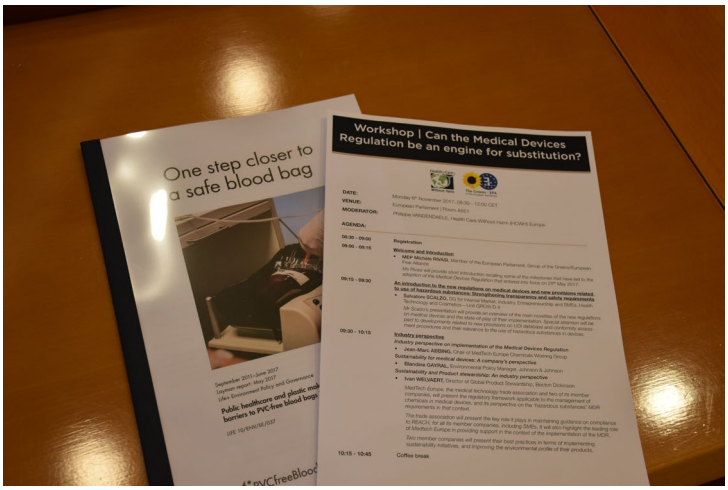
INNOVATION FOR SUSTAINABLE HEALTHCARE PRODUCTS: OUTCOMES OF THE EUROPEAN PVC-FREE BLOOD BAG PROJECT

Lena Stigh, Project Manager - Region Jämtland Härjedalen, was the last speaker to present and provided participants with an update on the PVCfreeBloodBag project, funded by the European Commission.

This project is a concrete example of what can be achieved in terms of innovation and substitution - The PVCfreeBloodBag project has demonstrated that is possible to produce a blood bag without EDCs or CMRs by selecting a safer plastic.

Having provided a short description of the milestones to date, Stigh then clarified what the next step of The PVCfreeBloodBag project would be, i.e. market introduction. So it is easy to understand that for this and other similar projects, the proper implementation of the MDR is key.

Click here to view Lena Stigh's presentation



CLOSING REMARKS

Philippe Vandendaele, Chemicals Policy Advisor for HCWH Europe, closed the session by expressing his satisfaction at the range of participants to this workshop. He commented that all those who contributed to this workshop were in some way or another profoundly affected by the changes brought about by the medical devices regulation.

Vandendaele thanked the speakers for sharing what their respective challenges were and noted that the workshop had been an ideal forum to clarify some of these challenges, recognising and identifying them being a first step. This HCWH Europe workshop allowed for open discussions and exchanges and was helpful in identifying outstanding issues.

On behalf of HCWH Europe, Vandendaele expressed his gratitude to the participants for having made this heavy and technical piece of legislation come to life through their experience.

Click here to find HCWH Europe resources relating to EDCs and medical devices

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