"The lifecycle of plastics and human rights" Mandate of the Special Rapporteur on toxics and human rights

Health Care Without Harm (HCWH) Europe welcomes this call for submission - a rights-based approach to the production, use, and disposal of plastic is needed. Plastics are a serious burden and threat to both human health and the environment; we would like to take this opportunity to add the important issue of plastics used in the healthcare sector to this discussion.

Modern healthcare makes use of a wide range of plastic-based medical products to provide high quality and effective treatment to patients. High volumes of plastic single-use products and complex plastic composites are routinely used by the health sector and it is becoming increasingly important to understand the impact these materials have on human health.

Hazardous substances leach from medical devices into patients

We have known for decades that certain plastic medical devices may contain hazardous substances in their composition, and evidence shows that these substances can leach from the device and enter patients' bodies during use, thus compromising patient safety.[i] [ii] [iii]

Concerns regarding hazardous chemical exposure through medical devices are particularly relevant to vulnerable patients that undergo multiple medical interventions or are exposed chronically over extended periods, including infants in neonatal care and dialysis patients.

Unborn children and neonates are exposed to hazardous chemicals from medical devices at a highly vulnerable moment of their development, with potential lifelong consequences. The unborn and young are not able to metabolise chemical substances in the same way as adults, and lower body weight is also risk factor – this risk is especially high for premature babies, who often need many medical interventions – another risk factor. Ensuring that these vulnerable groups of patients are, whenever possible, not exposed to hazardous chemicals is of utmost importance.

Phthalates and Bisphenol A (BPA) are substances of particular concern that are often found in medical devices. Phthalates (DEHP in particular), are commonly used as plastic softeners in PVC-based medical devices, whilst BPA is used to produce certain plastics such as polycarbonates and epoxy resins that have applications in the medical device industry. A major concern surrounding these substances is that they are known endocrine disrupting chemicals (EDCs).

HCWH Europe has recently published the report *Non-toxic healthcare: Alternatives to hazardous chemicals in medical devices: Phthalates and Bisphenol A*, with more information on EDCs used in medical devices and their effects on human health, particularly in women and children. The report also promotes the substitution of harmful substances by demonstrating that many alternatives with safer toxicological profiles are available on the market.

Progressive manufacturers, governments, health systems, hospitals, and health practitioners are starting to come together to lead this change; many European healthcare providers have already moved to eliminate PVC, DEHP, and BPA from healthcare practice – particularly in maternity and neonatal wards to protect the most vulnerable.

Importantly, substituting EDCs within the healthcare sector needs to be further encouraged through strong political and regulatory action, supported by research, evidence, collaboration, and greater awareness.

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[i] Su, PH. et al. (2012) *Exposure to di(2-ethylhexyl) phthalate in premature neonates in a neonatal intensive care unit in Taiwan.* Pediatric Critical Care Medicine, Volume 13, Issue 6. https://journals.lww.com/pccmjournal/Abstract/2012/11000/Exposure_to_di_2_ethylhexyl__phthalate_in.9.aspx

[ii] Mallow, EB. et al. (2014) *Phthalates and critically ill neonates: device-related exposures and non-endocrine toxic risks.* Journal of Perinatology, Volume 34. https://www.nature.com/articles/jp2014157

[iii] SCENIHR (Scientific Committee on Emerging and Newly-Identified Health Risks). (2015) *Scientific Opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other groups possibly at risk.* https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_047.pdf