



Anja Leetz,
Health Care Without Harm Europe,
1 Rue de la Pépinière,
B1000 Brussels,
Belgium
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Department of Health

Department of Environment, Food, and Rural Affairs
Nobel House, 17 Smith Square
London
SW1P 3JR
United Kingdom

Dear Minister Truss ,

I am writing to you on behalf of the above organisations and HCWH Europe. HCWH Europe's objective is to help the EU healthcare sector improve patient safety and care, whilst reducing the sector's environmental footprint. As part of this broad mission, we have been very active in tackling the issues raised by endocrine disrupting chemicals (EDCS) in medical devices.

Status of the Triologue

It is our understanding that this month your Brussels *attachés* are and will be discussing the proposed Medical Devices Regulation in successive meetings of the Council Working Party on Pharmaceuticals and Medical Devices. These discussions, which are part of the Triologue, should iron out the remaining differences between the positions of the Council and the European Parliament (EP) with a view to reaching an agreement by 30th June, still under the auspices of the Dutch Presidency.

One of the outstanding issues, where an agreement must be reached with the EP, appears to be the provision on the phasing-out of Carcinogenic, Mutagenic and Reprotoxic substances (CMRs) and Endocrine Disrupting Chemicals (EDCs) contained in medical devices.

Last call

We would like to draw your attention to amendment 355 to the proposed Medical Devices Regulation that was adopted by the European Parliament in April 2014. This amendment seeks to phase out CMRs and EDCs contained in medical devices when safer alternatives are available, technically feasible, and do not compromise the safety of patients. To us, the proposed amendment has a clear merit: it meets the substitution objectives of REACH in ensuring that toxic substances are replaced by safer alternatives. It additionally provides for a derogation period that would allow the medical device industry to substitute CMRs and EDCs with safer alternatives.



Since this is probably our last chance, for a long time, to address this issue at EU level, we would like to reiterate our call to the Council in particular to rise to the occasion in reaching an agreement that complies with the objectives of REACH, thus ensuring that in the future toxic substances are indeed replaced by safer alternatives.

It is worth pointing out that DEHP, an EDC, will be phased out under REACH and it would therefore seem inconsistent and confusing to allow continued exposure to DEHP through medical devices.

Mounting scientific evidence on the hazard of EDCs

We sincerely hope the final decision on this issue will be informed by science. As you know, there is a growing scientific consensus about the harmful effects of these hazardous chemicals on human health. In 2015, we released a comprehensive report ([Non-Toxic Healthcare: Alternatives to Phthalates and Bisphenol A in Medical Devices](#)) about the risks associated with exposure to phthalates and Bisphenol A (BPA). We have also released an [infographic on this issue](#).

We are not the only ones to recognise these hazards. Because of the mounting scientific evidence, SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), the European Commission's very own scientific committee, concluded in its [final opinion](#) published in January 2015, there may be some risk of adverse effects caused by Bisphenol A (BPA), an EDC, on human health.

In June 2015, SCENIHR also published a [final opinion](#) on the safety of medical devices containing DI (2-ethylhexyl) phthalate, (DEHP)-plasticised PVC, or other plasticisers for neonates and other groups possibly at risk. After revision of the scientific literature, SCENIHR concluded that chronic patients (such as adult patients undergoing haemodialysis), premature neonates in neonatal intensive care units, and infants subject to repeated medical treatment with medical devices, have the highest exposure to DEHP and other plasticisers/phthalates. SCENIHR further stated that neonates and infants are the most vulnerable section of the population, both in terms of the level of DEHP exposure they face, and because organ development occurs during the early stages of life. For these reasons, SCENIHR considers the above-mentioned vulnerable populations particularly at risk to the developmental and reproductive toxicity caused by these plasticisers.

More recently, in 2016, the Dutch National Institute for Public Health and the Environment issued a report, [Bisphenol A Recommendations for Risk Management](#), highlighting the varying levels of risks associated with BPA in medical devices, stressing in particular the concerns about the effects of BPA on the immune system of foetuses and young children.

Still as part of that growing awareness, in April 2016 EFSA (the European Food Safety Authority) announced that it was setting up a working group of international experts to evaluate new scientific evidence on the potential effects of BPA on the immune system. EFSA is conducting this review following publication of the Dutch report mentioned above.



Even more recently and more alarmingly, scientists at the Technical University of Denmark have published [a study](#) evidencing that low doses of BPA cause cell proliferation in rat breast tissue, lower sperm counts, masculinisation of female rat brains and an increase in body weight in older female rats.

You still have the opportunity to make a major contribution to the phase-out of CMRs and EDCs in medical devices. Agreeing with EP amendment 355 would help meet the EU's very own objectives as set out in REACH and would help the EU regain credibility with civil society and EU citizens at large.

Absent such an agreement, we would respectfully invite you to push for a national strategy on EDCs in medical devices. For example, as a result of the increasing scientific evidence and growing public awareness, the Netherlands recently decided to launch a national initiative. Other Member States, such as Denmark¹ and Germany², have also acknowledged the risks associated with EDCs in medical devices and have issued guidelines as part of their national strategies. If and when required, we would be most grateful if you could find the time to meet with us, perhaps through your Brussels *attachés*, or in your own country, to discuss such possible strategies going forward.

As a final comment, we would like to point out that in today's climate the EU is often regarded as ineffectual and too responsive to private corporate interests. Such scepticism would be further fuelled if, as a result of horse-trading, adequate provisions to address this issue were peremptorily dismissed.

We trust that you will give this letter the attention it deserves.

Yours sincerely,

Anja Leetz,
Executive Director, HCWH Europe on behalf of:

Lynn Ladbrook: Chief Executive, Breast Cancer UK
Dr Michael Warhurst: Executive Director, CHEM Trust (UK)
Alliance for Cancer Prevention (UK)

¹ <http://www2.mst.dk/Udgiv/publications/2013/06/978-87-93026-22-3.pdf>

² DEHP als Weichmacher in Medizinprodukten aus PVC. Bonn, Deutschland: The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM), 2006 9211/0506.