



Brussels, 11th November 2015

Dear Mrs Glenis Willmott,

The undersigned European and international environmental and health organisations would like to bring to your attention to an amendment (AM 355) adopted by the European Parliament plenary session in April 2014, during the first reading of the European Commission (EC) Regulation Proposal on Medical Devices (COM 2012/542)¹. The amendment calls for the phase-out of toxic chemicals contained in medical devices when safer alternatives are available and technically feasible².

We call on you, as the European Parliament Rapporteur for the EC Medical Device Regulation proposal, to strongly support Amendment 355 in the upcoming trialogue negotiations between the European Parliament (EP), the Luxembourg and the Dutch Presidencies of the European Council, and the European Commission.

EP Amendment 355 to the EC Medical Device Regulation Proposal

Amendment 355 states that chemicals that are carcinogenic, mutagenic, or reprotoxic (CMRs), such as certain phthalates and metals, or that have endocrine disrupting properties (EDCs), such as phthalates and Bisphenol A (BPA), and which are contained in medical devices that are invasive or come into contact with the body of patients or are used to administer, transport or store medicines, bodily fluids or other substances (including gases in concentrations above 0.1% by weight), shall be banned. The amendment still allows the use of CMRs and EDCs in medical devices for up to four years through a derogation process. Manufacturers may ask for an exemption in cases where the elimination or substitution of these substances is technically impracticable, the reliability of the substitute

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012PC0542>

² <http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2013-0324&language=EN>

substance is not ensured, or if the negative impact caused by substitution outweighs the benefits to the patient's health and safety. Given the flexibility and length of the derogation period, this amendment enables the medical device industry to substitute CMRs and EDCs with safer alternatives, because any constraints that manufacturers might face in the substitution process are well taken into consideration.

SCENIHR final opinions on the safety of DEHP and BPA contained in Medical Devices

In June of this year the EC Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published a final opinion on the safety of medical devices containing the Di(2-ethylhexyl) phthalate, (DEHP)-plasticised PVC, or other plasticisers for neonates and other groups possibly at risk³. 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 represent the most vulnerable population, both in terms of the levels 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 developmental and reproductive toxicity.

Moreover, in January of this year SCENIHR published a final opinion on the safety of the use of BPA in medical devices⁴, concluding that there may be some risk of adverse effects caused by BPA use, especially for neonates in intensive care units, infants undergoing prolonged medical procedures, and for dialysis patients.

Finally, there is growing scientific evidence generally that BPA and many phthalates may present a hazard to human health and the environment, aside from the studies directly involving medical patients. Evidence of hazard to human health comes from clinical and epidemiological studies, animal studies, and *in vitro* studies, encompassing both prenatal and postnatal exposures - providing a much fuller understanding of the effects of EDCs on the endocrine system, including non-monotonic dose-responses, low-dose effects, and developmental vulnerability⁵. In addition, data collected from wildlife studies, laboratory experiments, and *in vitro* studies have shown adverse effects on the environment, particularly to invertebrates and vertebrates classes and aquatic organisms⁶.

Safer alternatives and best practices

Safer alternatives for almost all medical devices are available on the market and are already used by many healthcare institutions in Europe⁷. The only exception is blood bags, although a recent EU-funded project has successfully produced a blood bag prototype that does not contain PVC and is currently being tested at the Karolinska University Hospital in Sweden⁸. Because safer alternatives are available on the market, many hospitals in Europe have already started implementing a PVC-free policy. For example, Vienna Hospitals have phased out PVC in their neonatal units since 2000 and Stockholm County Council (SLL) started phasing out PVC and phthalates from its healthcare facilities in 1997. Moreover, the paediatric unit of Westfriesgasthuis Hospital in the Netherlands is PVC- and phthalates-free, and the Hospital of Southern Jutland in Denmark has also followed the Dutch example.

The way forward

Given the recent SCENIHR opinions acknowledging the adverse effects of DEHP, BPA, and other phthalates contained in medical equipment; the growing scientific evidence and concern about the harm from these chemicals; the safer alternatives on the market; and the examples of healthcare systems successfully using these alternatives, we call on you, Mrs Willmott, to champion the EP amendment for a phase out of CMRs and EDCs in medical devices, whenever safer alternatives are available and technically feasible.

³ http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

⁴ http://ec.europa.eu/health/scientific_committees/emerging/opinions/index_en.htm

⁵ Gore, A. C. et al, 2015, *EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals*, Endocrine Reviews - <http://press.endocrine.org/doi/10.1210/er.2015-1010>

⁶ <https://noharm-europe.org/edcs-report>

⁷ www.safermedicaldevices.org

⁸ <http://www.pvcfreebloodbag.eu/>

This phase-out, which has gained overwhelming support in the European Parliament, will not translate into EU law without your strong support in the triologue negotiations, particularly vis-a-vis the European Council. The existing requirement to label CMRs has not prevented patients from being exposed to these toxic chemicals; therefore, the Council's amendment, which supports nothing more than the labelling of medical devices that contain CMRs and EDCs, will not bring about any change.

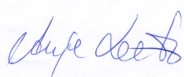
As you may be aware, DEHP is already on the candidate list under REACH to undergo authorisation. But because REACH exempts medical devices for health considerations from the authorisation process, industry will continue to use DEHP in the production of applications for the medical field, unless this loophole is closed in the new medical device regulation.

The goal of healthcare is to "first, do no harm" to people and the environment. Strong scientific evidence shows the toxicity of medical devices containing BPA and phthalates. Today you have the opportunity to lead the change and make a major contribution to the phase-out of CMRs and EDCs in medical devices when safer alternatives are available and technically feasible. We look to you to represent the interests of people and the environment by enabling European healthcare to become safer.

Many thanks for your consideration.

Yours sincerely,

Representatives of European and international environmental and health organisations as detailed below:



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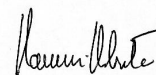
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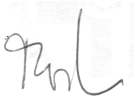
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