



HARMFUL PLASTIC SOFTENER (DEHP) IN MEDICAL DEVICES

There is an urgent need to restrict the phthalate DEHP in medical devices made from polyvinylchloride (PVC) for vulnerable patients at risk from excessive exposure.

We urge the European Parliament to revise the Medical Devices Directive to reduce the risk from DEHP in PVC medical devices.

DEHP IS A DEVELOPMENTAL TOXICANT.

INFANTS & CHILDREN ARE AT RISK OF HIGH EXPOSURE FROM MEDICAL DEVICES.

DEHP, or di/bis(2-ethylhexyl) phthalate, is a known reproductive toxic substance, and causes birth defects and infertility in animals. Due to the common use of phthalates in many consumer products and general environmental contamination, there is widespread DEHP exposure in the general population. Human studies report that vulnerable groups, including infants, children and pregnant women, exceed the safe exposure level. Studies of infants in neonatal intensive care units show high exposure levels from medical devices containing DEHP. (Because it does not bind to the PVC matrix, DEHP leaches out of the medical device into the liquid which the device transfers to the patient's body.) These exposures occur, animal tests suggest, during development periods of heightened sensitivity.

The medical devices industry argues that the risk from DEHP has to be balanced against the anticipated benefits for the patient. This argument is misleading because safer alternatives are available for the majority of applications where PVC/DEHP plastic is used. Yet they want you and the public to believe that continued exposure to DEHP is tolerable, even for vulnerable populations, for the sake of saving lives *when these lives can be saved with DEHP-free medical devices.*

A recent study confirms the value of substituting DEHP devices by comparing infants in two neonatal intensive care units in the Harvard-affiliated Boston facilities in the USA. The studies found significantly lower DEHP levels in babies receiving care at the hospital that had switched to DEHP-free medical devices for some applications.

www.ehponline.org/docs/2005/7932/abstract.html

The medical devices industry also argues that alternative plasticisers do not guarantee lower risks than those of DEHP. Of course, the safety of other plasticizers must be rigorously examined. But some alternative polymers, such as polypropylene and polyethelene, do not require any plasticisers, and therefore cannot leach phthalates. Plasticized or soft PVC is a problem anyway, from the life-cycle perspective. It is impossible to recycle, it contributes to dioxin formation during waste combustion and it can leach plasticisers and other additives in landfills. The alternative materials used for medical devices such as polyethylene, polypropylene, polyurethane and silicon are inherently flexible, and so don't need softening with plasticizers that can leach out during medical procedures. They also don't create dioxins when incinerated.

HOSPITALS ARE ALREADY PHASING OUT PVC/DEHP.

Many healthcare institutions are responding to the growing scientific evidence and the recommendations of numerous public authorities, and substituting DEHP-softened PVC with safer DEHP-free alternatives. The Vienna Hospital and Styrian Hospital Associations in Austria, the Karolinska University Hospital and many other facilities in Sweden and Denmark, and the Na Homolce Hospital and Faculty Hospital in Olomouc, the Czech Republic are among the forerunners¹. But the alternative DEHP-free products are not labeled, which can make them difficult to find.

NATIONAL & EU INSTITUTIONS AGREE ON THE NEED TO RESTRICT DEHP GIVEN THAT SAFE ALTERNATIVES EXIST.

The EU's own Draft Risk Assessment and Risk Reduction Strategy on DEHP; two expert panels of the US National Toxicology Program (NTP); the US Food & Drug Administration (FDA); and the Health Canada Expert Panel have all reached the same conclusions: the animal studies of DEHP raise serious concerns because they are likely to predict human health impacts. Health care delivery with PVC medical products containing DEHP can be a significant source of clinical DEHP exposure, and infants receiving intensive medical care are most at risk. The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) supported the recommendation for risk reduction measures in medical equipment². The EU Scientific Committee on Medicinal Products and Medical Devices found that levels of DEHP exposure in newborns in hospitals are similar to levels that are toxic to rodents³. Some EU Member State Authorities, including the German Federal Institute for Drugs and Medical Devices (BfArM 2004), have also recommended the use of alternatives for vulnerable patient groups and encouraged manufacturers to develop new and safer DEHP-free alternatives⁴. Unfortunately, in the remaining EU member states, there are no recommendations or legal restrictions to warn or protect patients and health care providers about the potential risks from frequent and multiple DEHP exposure from medical equipment used intravenously.

The EU Parliament has already acted and signaled its intention to limit the risks from phthalates exposure several times. 1) The Parliament has voted to ban DEHP in toys and cosmetics. 2) The Parliament in its Resolution on the Environment and Health Action Plan in 2005 called for restricting the marketing and use of dangerous substances, including DEHP, in domestic products for indoor use and **in medical devices**, specifically for vulnerable groups, particularly new-born babies, children, pregnant women, elderly persons, workers and other high-risk sections of the population.⁵ 3) The Parliament passed a Resolution on Medical Devices in 2003 calling on the Commission to explain whether soft PVC medical devices comply with the essential requirements

¹ www.noharm.org/details.cfm?type=document&id=1050

² CSTEE, January 2002, Opinion on the results of the Risk Assessment of DEHP. Doc 09012002/D(02)

³ SCMPMD, September 2002, Opinion on Medical Devices Containing DEHP Plasticised PVC.

⁴ http://www.bfarm.de/clin_042/nn_424524/DE/Medizinprodukte/riskinfo/recommend/dehp_Weichmacher_Medizinprod.html

⁵ European Parliament resolution on the European Environment & Health Action Plan 2004-2010 (2004/2132(INI)), P6_TA(2005)0045. A6-0008/2005. Texts adopted by Parliament Wednesday 23 February 2005. More at <http://www.europarl.eu.int/omk/sipade3?PUBREF=-//EP//TEXT+TA+20050223+ITEMS+DOC+XML+V0//EN&LEVEL=3&NAV=X#sdocta10>



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of that directive, and never obtained any reply.⁶ 4) The Parliament passed a Resolution in 2001 on the Commission Green Paper on environmental issues of PVC, calling for a policy to replace soft PVC, and allowing substitution policies especially for products linked directly to human health.⁷ But there are still no incentives, recommendations or legal restrictions at EU level to phase out the use of DEHP-containing medical devices. The Medical Devices Expert Group of DG Enterprise called for yet another evaluation of scientific evidence by the Scientific Committee on emerging Health risks whose opinion is due to February 2007. How long will the Parliament permit the Commission to ignore it?

DO WE WAIT UNTIL WE SEE SUBSTANTIAL HARM OR SUBSTITUTE NOW?

PVC/DEHP defenders keep pointing to the lack of definitive proof that DEHP harms humans. To obtain such proof requires accurate DEHP exposure measurements in fetuses and infants, and long-term follow-up studies as these children enter their reproductive years. The results would not be available for decades. Meanwhile, the evidence is mounting. The Swan study found a link between prenatal exposure and reproductive changes in boys; a recent Danish study found that higher concentrations of phthalates in breast milk are linked to a decrease in sex-hormone concentrations in baby boys⁸. But the need for further studies should not stop action now to protect the most vulnerable in the society – sick children. We have enough information for government authorities to act and protect vulnerable patient groups, especially newborns, from reproductive harm, *because* suitable alternatives for many medical devices exist on the market.

PLEASE support a ban on DEHP in medical devices used for high risk groups
Support amendments 46, 109 and 110 to the Ulmer Draft Report on Directive 93/42/EEC

Health Care Without Harm Europe (HCWH) is an coalition of environmental health groups and health care professionals whose goal is to make health care ecologically sustainable and no longer a source of harm to public health, without compromising patient safety or care.

The Health & Environment Alliance (formerly EPHA Environment Network) advocates protection of the environment as a means to improving the health and well-being of Europeans. Our members include NGOs specializing in public health, environment-related health conditions and associations representing health care professionals.

⁶ European Parliament resolution on the health implications of Council Directive 93/42/EEC concerning medical devices (2001/2270 (INI)) (P5_TA(2003)0232).

⁷ European Parliament resolution on the Commission Green Paper on environmental issues of PVC (COM (2000) 469 – C5-0633/2000 – 2000/2297(COS). Adopted 3 April 2001.

⁸ Main, et al. Human breast milk contamination with phthalates and alterations of endogenous reproductive hormones in three months old infants. *Environ Health Perspect* 2005; in press: doi:10.1289/ehp.8075.
And Swan, et al. Decrease in anogenital distance among male infants with prenatal phthalate exposure. *Environmental Health Perspectives* 2005; 113: 1056-1061.