

## THE PROBLEMS WITH DEHP SHOULD BE SOLVED UP STREAMS!

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**Health Care Without Harm (HCWH) is an International Coalition of Hospitals and Health Care Systems, Medical and Nursing Professionals, Community Groups, Health Affected Constituencies, Labour Unions, Environmental Health, Environmental and Religious Organisations. Its mission is to transform the health care industry so it is no longer a source of environmental harm by eliminating pollution in health care practices without compromising safety or care. To follow the development of HCWH and its progress towards the goals, please visit [www.noharm.org](http://www.noharm.org).**



### Life begins in water

To have the best possible start the foetus is surrounded with warm and nice water, protected by a mother who eats and drinks as healthy as possible. The placenta protects against toxic substances. This safety concept has been developed by evolution because the earliest life stages are the most vulnerable, when all diversity of cells is structured in order to build different organs with very complex interactions. The natural way for protecting the developing child is to deny all foreign substances, known toxics as well as unknown ones. This is the precautionary principle expressed by Mother Nature herself. The placenta is, however, not adapted to manage many of the existing human-made chemicals.

Even if we as adults take great risks sometimes, we expect the Health Care Sector to not take the same risks with public health. As Hippocrates words teach physicians to First Do No Harm, we believe that health care implies following the natural safety concept. We also expect our policy makers to have stricter chemical regulations for protecting children and patients.

### **BUT this is unfortunately not the case:**

Phthalates are a group of chemicals commonly used to make polyvinyl chloride (PVC) plastic flexible. 90% of phthalates production is used to soften PVC. Naturally rigid, PVC requires softening agents like phthalates to make it flexible. Since phthalates are not bound to the plastic, they leak from the plastic, their rate

of release depending on the conditions of use. The result is large-scale environmental pollution, including contamination of breast milk.

### **The amounts of flexible PVC are significant within the health care sector.**

Using PVC medical devices puts specific patient groups at significant health risk because of the exposure to DEHP (di-2-ethylhexyl phthalate). DEHP is the most widely used softening agent in PVC medical devices. It has been included on the list of reprotoxic, mutagenic and carcinogenic substances issued by the European Commission. The European Union has banned the use of dangerous substances in cosmetics, paints, glues and other products. Several scientific studies have characterized DEHP as potentially harmful for neonates, toddlers, pregnant women and chronically ill patients because of its effects on testes, kidneys, fertility and development. However, DEHP has not been banned in medical devices yet!

### **Yet PVC and phthalate use are slowly approaching stricter legislation. This is not surprising, since PVC is founded upon unsustainable chemistry:**

Chlorine is a highly reactive halogen. Chlorine therefore easily forms persistent and bioaccumulative substances in processes where organic substances are present. And PVC plastic typically contains 40% chlorine by weight. The result is that during the manufacture of PVC by-products form that include both persistent and bioaccumulative compounds. The pulp and paper industry, for example, radically reduced its emission of persistent organic pollutants (POPs) by eliminating chlorine gas for bleaching purposes.

In the health care sector, infectious waste incineration is a source of dioxins release to the environment. Dioxin emerges when waste that contains chlorine is burned. PVC plastic is a major source of the chlorine in medical waste. The primary medical use of PVC is in intravenous (IV)

bags, tubing and gloves. Dioxin is a human carcinogen, which has been linked to birth defects, decreased fertility, immune system suppression, neuro-developmental effects, endometriosis and other hormonal dysfunction.

The amounts of softened PVC are significant within the health care sector. It is however important to see the forest and not just the single trees: By focusing on single issues as getting rid of DEHP without considering a strategy for phasing out other phthalates, additives or the system of PVC, the path to sustainability may be very extended.

Risk Assessments (RA) are often very limited and not conclusive as safety declarations. One important reason is that RAs do not consider aggregate exposure of different phthalates that already occurs in real life and therefore will pose a completely underestimated different risk scenario.

There are about 6 different common used phthalates, but at least 10 more that might be developed and used by industry. Bearing in mind the long term discussions of DEHP and that the normal action time for political bans are 30 years for substances as DDT and PCB, we would not be on the safe side on several 100 years if the single substance policy should continue.

The approach must be to solve problems up stream and use a reverse burden of proof in combination with the precautionary principle: When a smaller amount of chemicals, within a great class of similar chemicals, show dangerous properties, we have to assume that the whole class is dangerous, until the opposite situation can be proved. Going from DEHP to another phthalate could be a smart step in some cases, as a cost effective step for a short period, depending on the circumstances. In the same way it could be wise to substitute phthalates for other additives, but an additive free solution must be the ultimate goal for all medical devices. Bearing in mind that PVC can never be a sustainable solution, we have to look for solutions without PVC anyway.

### Specific experience internationally

Through European and international cooperation we encourage medical devices manufacturers to offer environmentally friendly products in all of the countries where they sell their products. Persuading them to avoid double standards for environmentally friendly products should result in a universal offer of non-PVC alternatives not only in the environment-conscious countries such as Sweden, Germany, Austria or Netherlands but also in US and Canada, in Central and Eastern European countries and Russia.

### Conclusions and recommendations for green purchasing:

We bring together medical devices manufacturers and hospitals purchasing managers to pursue the environment saving strategies and transition to PVC-free medical devices. By first persuading specific hospital units such as neonatal care units to substitute for non-PVC alternatives, we can shift the market away from PVC. However, the substitution to safer materials is not a process that manufacturers will complete themselves. An obvious example is Baxter, which continues to defend the use of DEHP in medical devices and continues to claim that "DEHP does not pose human health risks as a result of exposure from medical products."

Although the manufacturers are tough to convince, the experience in US shows that a market strategy is more successful than lobbying for legislative change on EU or national level where the PVC industry has very strong influence among the legislators. The important strategy is to attract people directly involved in health care institutions. Labour unions, nurses associations and key medical experts proved to be influential allies in our campaign.

