



HAZARDOUS CHEMICALS IN MEDICAL DEVICES: PHTHALATES



Continued exposure to hazardous chemicals is not tolerable, especially for vulnerable groups of the population. When alternatives to medical devices containing phthalates are available, they should be made mandatory. Many European manufacturers have among their range of products phthalate-free medical devices while several hospitals have moved or compromised to move away from phthalates and towards a non-toxic healthcare system.

Phthalates are a group of chemical substances, primarily used as plasticisers (softeners) in plastics. They are abundant in PVC based medical devices such as blood bags, tubing, catheters and disposable gloves, where they can account to up to 40% of the final product. Phthalates are not chemically bound to plastic materials so they can easily be released, transferred or leached into the air, water or body fluids during their production, use and discard. Since the 1990's, phthalates have been the subject of great scientific and public concern due to their effects on the environment and human health. Numerous phthalates are classified as toxic to reproduction, which may impair fertility and cause harm to unborn children (e.g. DEHP, DBP, DIBP and BBP), and are documented or suspected endocrine disrupting chemicals

Human bio-monitoring studies have detected phthalates in almost every individual analysed¹, with children presenting higher levels than adults. Phthalates act by inhibiting the production of testosterone in testis². Exposure to phthalates in humans has been related with developmental disorders including testicular cancer, diminished sperm quality, reduced reproductive and thyroid hormone levels, insulin resistance leading to obesity and attention-deficit disorders^{1,3,4,5}. In women, elevated concentrations of DEHP and its main metabolite (MEHP) have been associated with premature births, endometriosis in infertile women and premature breast development^{6,7,8}.



In December 2012, France passed a law that for the first time bans the use of tubes containing DEHP in paediatrics, neonatology and maternity wards in hospitals. The ban will be in place from July 2015, and foresees the possibility, in the near future, to also prohibit the use of DBP and BBP in all medical devices.



Unborn children and infants are especially vulnerable to phthalate exposure as they are not able to process chemical substances as adults⁹. Different scientific studies have found links between levels of DEHP metabolites in urine and the number of DEHP-containing medical devices used in intensive care units^{9,10}. Furthermore, researchers found that neonates receiving lipid-base infusates at 32 or 37 °C (temperature in incubators) through a PVC infusion line, received a DEHP dose exceeding the lower limit of the total daily intake (TDI) within 6 hours, and potentially much more if leaching persisted beyond the sixth hour of infusion¹¹. Effects on genital development in male children of pregnant women exposed to phthalates were also found at levels below those commonly found in 25% of women in the United States¹².

Phthalates are allowed in medical devices in the EU and the current European Commission proposal for a Regulation on Medical Devices COM(2012)542 only requires the device to be labeled if it contains specific phthalates (DEHP, DBP, DIBP and BBP) which are classified as carcinogenic, mutagenic or toxic to reproduction according to REACH (CMR substances Category 1a and 1b) and are used to administer and/or remove medicine, body fluids or other substances to or from the body, or intended for transport and storage of these body fluids or substances. If the device is intended for use in the treatment of children, pregnant women or breastfeeding women, the manufacturer must indicate a reason for using these substances in technical documentation. There is however, no obligation to phase them out or develop safer alternatives.

DEHP is the most common phthalate found in medical devices. In the European phthalate market, DiNP and DiDP/DPHP have substituted DEHP as the most common phthalate. However, it is not clear whether this overall trend is mirrored in the medical sector. Besides being classified as a reproductive toxicant, DEHP is also identified as a Substance of Very High Concern (SVHC) according to REACH. It is well established that medical procedures are a source of DEHP exposure for patients, particularly infants undergoing intensive care, dialysis patients and blood donors¹. DEHP leaches out of medical devices into the solution the devices are carrying into the patient's body. DEHP leaches in particular into fatty solutions, such as feeding formulations and is of great concern for neonates, whose small body size and occasionally intensive medical treatment result in extremely high exposures.



Safer alternatives exist for the majority of applications where phthalates are used (PVC plastic), including for example propylene and silicone that do not require plasticisers^{13,14}. These alternatives are safer than others using different plasticisers¹³. When plasticisers are not used, leaching does not occur and the lifespan of devices is improved¹⁵. Furthermore, since the alternatives are not made from PVC, they can be more easily recycled, eliminating the problems associated with disposal of PVC medical equipment.

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