Development of the substitution principle: the case of phthalates in medical devices.

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The presence on the market of products that may endanger our health is no longer acceptable, above all because there are alternatives which are less toxic and, in the case of biomaterials, fully biocompatible (1). Di-(2-ethyl-hexyl)-phthalate (DEHP) is the most widely used plasticizer in PVC medical devices. However, DEHP is not chemically bound to PVC and, with time and use, migrates from medical devices to the human body. The potential for DEHP to produce adverse effects in humans has been the subject of considerable discussion and debate in the scientific community. In particular, premature newborns are at higher risk, because of their small body size and the multiple exposure to medical device-related to the DEHP (2). Experimental studies and some epidemiological data indicate that developmental exposures to DEHP may seriously impact on reproductive and metabolic development (3,4).

A model for the possible replacement of EDs – in this case phthalates – is the result of the research project BRITE (Biocompatible flexible polymer alloys based on polyesters from renewable resources for mass-consumer applications involving contact with human fluids and tissues, 2000-4). Notwithstanding the success of the project, that has delivered a new plasticizer biocompatible and devoid of significant toxicity, there is still a lack of regulatory decisions towards the presence of phthalates in medical devices. The Scientific Committee of the European Commission on Emerging and Newly-Identified Health Risks (SCENIHR) – DG SANCO has assessed on 2008 the use of DEHP as plasticizer in medical devices (3). The SCENIHR recognized that DEHP exposure in premature newborns raises potential concerns; moreover, the Committee has given attention to eight possible alternative plasticizers that show lower toxicity in laboratory animals as compared to DEHP. On such potential alternatives SCENIHR recommends further studies on migration from devices as well as on actual usefulness. However, the attention by policy-makers towards a possible replacement of DEHP would greatly ease the production of new data recommended by SCENIHR. Unfortunately, alternative solution will be placed on the market at a price higher compared to the replaced product; but it is equally clear that calculation of the relevant costs and benefits will have to include the expense, for families as well as communities, associated to the long-term and trans-generational effects health risks of the use of “old” compounds identified as EDs.

References