SCENIHR Final Opinion on The safety of the use of bisphenol A in medical devices

Today, the European Commission and its non-food Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have published the final opinion on “The safety of the use of bisphenol A in medical devices”.

Concern for the safety of vulnerable groups such as infants, pregnant and breast-feeding women when exposed to bisphenol A (BPA) through medical devices have recently been raised. Such medical devices include include implants, catheters, and most dental devices.

This opinion aims to assess whether the use of bisphenol A in these devices could give reasons for safety concerns, to provide indications on limit values for BPA release from medical devices and to identify any patient group, e.g. infants, pregnant and breastfeeding women who would be particularly at risk.

When drafting the final opinion the SCENIHR considered the temporary oral TDI (t-TDI) of 4 µg/kg b.w./day derived by EFSA as a solid base for carrying out the risk assessment for the use of BPA in medical devices. Several exposure scenarios have been evaluated taking into account the material used, information related to BPA leaching, the duration of a single treatment and the frequency of treatments, giving rise to toxicologically relevant acute, short and long term exposure. However, the information available is very limited and in many cases due to the lack of experimental data, only estimations were used.

Concerning exposure via the oral route, it can be concluded that the long term exposure to BPA via dental material is far below the recently derived t-TDI and poses negligible risk for human health associated to BPA exposure.

Some risk for adverse effects may exist, when the BPA is directly available for systemic exposure after non-oral exposure routes, especially for neonates in intensive care units, for infants undergoing prolonged medical procedures and for dialysis patients.

In spite of this, it should be considered also the benefit of medical devices: the survival of neonates, for example, often depends on the availability of the medical devices which causes a relatively high BPA exposure. The possibility to replace BPA in these products should be considered against their efficiency in the treatment, as well as the toxicological profile of the alternative materials, when available.

However, better data on exposure would be beneficial for the refinement of the present risk assessment, to be carried out when new data on exposure via medical devices will be available.