Scientific Committee on Emerging and Newly Identified Health Risks

Request for a scientific opinion on

the safety of the use of Bisphenol A in medical devices

1. Background

Bisphenol A (BPA) is an intermediate that is mainly used in combination with other chemicals to manufacture plastics and resins. For example, BPA is used in polycarbonate, a high performance transparent, rigid plastic used to make food containers, such as returnable beverage bottles, tableware (plates and mugs) and storage containers. Residues of BPA are also present in epoxy resins used to make protective coatings and linings for food and beverage cans and vats. BPA can migrate in small amounts into food and beverages stored in materials containing the substance.

BPA is a weak oestrogen, as demonstrated by *in vitro* studies. Many *in vivo* studies have been performed to examine its potential effects on reproduction and development. The safety o BPA in food contact materials has already been evaluated by the US Food and Drug Administration[1] and by the European Food Safety Authority[2]. Although these evaluations did not identify outright reasons for concern, a number of uncertainties in the current scientific knowledge concerning the safe use of BPA remain. Considering these remaining uncertainties, especially with regard to the potential adverse health effects of BPA exposure to infants through polycarbonate baby bottles, the European Commission decided on the basis of the precautionary principle that all baby bottles on the EU market containing BPA should be replaced by the middle of 2011.

Recently, safety concerns have been expressed for vulnerable groups such as infants, pregnant and breast-feeding women exposed to BPA through other products.

Medical devices are a particular product category in which BPA is often found. Examples include implants, catheters, and most dental devices. Some BPA-containing medical devices may have direct and/or indirect contact with the patients (e.g. auto-transfusion apparatus, filters, bypasses, tubing, pumps, instruments, surgical equipment, blood pathway circuits and respiratory tubing circuits). These products are used on all types of patients e.g. adults, children etc.

Due to the common use of polycarbonate plastic and epoxy resins in such a wide range of products, low level human exposure to BPA occurs, but the health significance of the exposure levels has been controversial.

According to Council Directive 93/42/EEC, medical devices may only be placed on the market if they meet the essential requirements laid down in its Annex I. The devices must

[1] http://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm

[2] http://www.efsa.europa.eu/en/topics/topic/bisphenol.htm

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be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

2. Terms of reference

In the light of the above considerations, on the basis of the available scientific evidence and taking into account the previous safety evaluations of BPA, the Scientific Committee on Emerging and Newly Identified Health Risks is requested to provide a scientific opinion on 'The safety of the use of bisphenol A in medical devices'.

In particular, the SCENIHR is asked:

1. To determine whether levels of exposure to BPA from the use of the various medical devices containing BPA could give reasons for concern from the health point of view and, if possible, to provide indications on limit values for BPA release from medical devices.
2. To identify whether any particular medical devices containing BPA could result in human exposures which will give reasons for concern under their normal use patterns or other foreseeable circumstances (e.g. high release of BPA due to the nature of the material of the medical device or to particular contact conditions).
3. To identify, any patient group e.g. infants, pregnant and breastfeeding women who would be particularly at risk in light of the answer to the above questions.
4. In case reasons for concern related to BPA are identified, to propose possible alternative approaches that could reduce potential risks either by identifying alternative practices or by identifying alternatives to the use of BPA in medical devices. If no clear answer can be provided on this point the SCENIHR is asked to formulate recommendations for research that could help provide scientific evidence to that end.

3. Deadline

July 2012 (for public consultation)