The safety of the use of bisphenol A in medical devices

EFSA Meeting in Parma 29-30 October 2012

Arne Hensten, lic. & dr. odont.
Member of SCENIHR
DG SANCO
Health and consumer safety
Non-food committees

Scientific Committees

- on consumer safety
- on emerging and newly identified health risks
- on health and environmental risks
BPA in medical devices

About 3% of total polycarbonate production is used for the manufacture of medical devices.
Background 1

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. autotransfusion 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.
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’.*
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.
The SCENIHR is asked

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).
The SCENIHR is asked

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.
The SCENIHR is asked

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.
SCENIHR

**SCENIHR started working on assessing the safety of the use of bisphenol A in medical devices in April 2012.**
MEDICAL DEVICES, 93/42/EEC

The devices must 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.
Risk assessment and exposure from medical devices

Oral; dental devices

Non-oral

- Dermal
- Mucosal
- Inhalation
- Parenteral
- Implantation
DG SANCO
Health and consumer safety
Non-food committees

Scientific Committees
- on consumer safety
- on emerging and newly identified health risks
- on health and environmental risks
Public Consultation on the Discussion Paper addressing the New Challenges for Risk Assessment

Ecological risk assessment

Human health risk assessment
Submission of comments:
The preliminary opinion can be found at:

http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_037.pdf (971 KB)

All interested parties are invited to submit their comments and proposals on the preliminary opinion to the following website:


The deadline for submission of comments is 30 November 2012