Scientific Committee on Emerging and Newly Identified Health Risks

Request for a scientific opinion:

On the safety of medical devices containing DEHP (di (2-ethylhexyl) phthalate) plasticized PVC on groups possibly at risk.

1. Background

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 the Annex I of the Directive. For certain medical procedures such as blood transfusion, haemodialysis, parenteral nutrition or endotracheal tubing, the flexibility of certain parts of a medical device is essential. Various substances are used to ensure this flexibility, among which DEHP [Di-(2- EthylHexyl) Phthalate] is the most frequently used plasticizer in PVC medical devices. DEHP may migrate from the device to the human body, resulting in a certain degree of patient exposure.

Safety concerns have been expressed for high-risk patients groups, such as neonates, infants, pregnant and breast-feeding women exposed to DEHP. In September 2002, the Scientific Committee on Medicinal Products and Medical Devices adopted an opinion according to which *"there is no evidence that any of these groups do experience DEHP related adverse effects"*. However, *"a lack of evidence of causation between DEHP-PVC and any disease or adverse effect does not mean that there are no risks"*.

In February 2008, the Scientific Committee on Emerging and Newly-Identified Health Risks (Scenihr) adopted a revised opinion on "The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk". The conclusion was that *"Sofar, there is no conclusive scientific evidence that DEHP exposure via medical treatments has harmful effects in humans. However, further studies are required to confirm or reject the suggestions of adverse effects of DEHP in humans. Other patient groups with relatively high DEHP exposures, which may result in some risk, are those requiring repeated medical procedures, including male foetuses of pregnant women.*

Recently a Tolerable Daily Intake (TDI) value of DEHP has been established and published in the EU Risk Assessment Report (RAR 2006). The TDI for DEHP is 48 μg per kg body weight per day, which was based on a No Observed Adverse Effect Level for reproductive effects in rats. In view of the potential high exposure to DEHP during certain medical procedures and a very special group of patients involved, the use of TDI is not considered appropriate in these procedures".

It has been brought to our attention that a project entitled PVCfreeBloodBag, which the European Commission is funding through the LIFE+ programme, has recently issued a press release asserting that "blood bags made of DEHP-plasticised PVC pose

a significant risk to human health, due to both DEHP and PVC". This statement is based on a new life cycle Assessment (LCA) report [1].

In the light of this new study we'd like to ask to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to review and, if appropriate, update the opinion adopted in 2008.

In view of possible safety concerns linked to the use of DEHP in PVC plasticized medical devices, it is essential to review and evaluate available scientific data related to the safety of possible alternatives for patients and in particular to high risk groups.

2. Terms of reference

1. Update of the scientific opinion adopted in February 2008 on DEHP plasticized medical devices. Taking into consideration recent scientific developments, the SCENIHR is requested to review and update, if appropriate, the scientific opinion adopted in February 2008 on "The safety of medical devices containing DEHP plasticized PVC or other plasticizers on neonates and other groups possibly at risk".

In particular, the Scientific Committee is requested to evaluate:

• If DEHP in PVC plasticized medical devices is a cause for concern to neonates and children in paediatric care, in particular in relation to male fertility and tissue development,

• If there are other patient groups at risk, in particular in view of clinical procedures resulting in high exposure,

• If it is possible to establish Tolerable Intake Values of DEHP leaching from soft PVC as a basis for risk assessment for high risk patient groups, taking into account the route of exposure.

• If it is possible to propose possible alternative approaches that could reduce potential risks either by identifying alternative practices or by identifying alternatives to the use of DEHP in PVC plasticized 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

March 2013

[1] Life Cycle Assessment, LCA, of PVC Blood Bag Raul Carlson, eco2win AB 2012□03 Commissioned by Jegrelius Institute for Applied Green Chemistry, Regional Council of Jämtland, within the of EU Life+ project PVCfreeBloodBag