SCIENTIFIC COMMITTEE ON
EMERGING AND NEWLY IDENTIFIED HEALTH RISKS
(SCENIHR)

Request for an opinion on the safety of medical devices containing DEHP-plasticized PVC or other plasticizers on neonates and other 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 on "Medical Devices containing DEHP plasticized PVC; Neonates and Other Groups Possibly at Risk from DEHP toxicity" 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"*.

According to published data on reproduction toxicity, neonates and prepubertal males may suffer adverse effects from DEHP exposure in medical devices. According to a recent risk evaluation of DEHP on human health carried out in the context of the "existing" chemicals substances legal framework, it is now possible to determine a Tolerable Daily Intake (TDI) of DEHP, when present in the environment.

It is therefore necessary for the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to review and possibly update the opinion adopted in 2002.

Since alternative DEHP-free medical devices have been recently introduced in the market, the long term effect of these alternative plasticizers or alternative materials, when used in medical devices, are not well known. 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 these alternatives for patients and in particular to high risk groups.

2. Terms of reference

2.1 Update of the scientific opinion adopted in September 2002 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 September 2002 on "Medical Devices containing DEHP Plasticized PVC; neonates and other groups possibly at risk from DEHP toxicity".

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.

2.2 Medical devices containing alternative plasticizers: possible risk for certain uses or to certain patient groups. Since alternative DEHP free medical devices have been developed and are used to treat patients, the Scientific Committee is requested to evaluate the potential risks of currently available alternatives in relation to patient health, when used in medical devices.

3. Deadline

February 2007