EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (SCHEER)

Request for an update of the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates, which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties

Commission Department requesting the update: Directorate-General for Heath and Food Safety – Unit D3 Medical Products and Innovation Medical Devices

1. Background

Regulation (EU) 2017/745 on medical devices (MDR) ([1]) establish a legal obligation on the Commission([2]) to provide the relevant scientific committee with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates, which belong to either of the groups of substances that are carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, or that have endocrine-disrupting properties.

The benefit-risk assessment has to take into account the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments.

The obligation to have the guidance available was set on 26 May 2020 and the document was adopted by SCHEER at plenary meeting on 18 June 2019.

The MDR sets also a legal obligation for the update of the guidance, on the basis of the latest scientific evidence. Such update can be made when appropriate and, at least, every five years.

([1]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, http://data.europa.eu/eli/reg/2017/745/2020-04-24.

([2]) MDR, Annex I, Section 10.4.3.

2. Terms of reference

The SCHEER is requested to update the guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices that was adopted by that committee at the plenary meeting on 18 June 2019.

The update has to take into consideration and be based on the latest scientific evidence.

The devices covered, or those parts thereof of those materials used therein, are those which:

- are invasive and come into direct contact with the human body;
- (re)administer medicines, body liquids or other substances, including gases, to/from the body, or;
- transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body.

The guidelines shall continue to include guidance on how, for an individual device, to:

- analyse and estimate potential patient or user exposure to the substance,
- analyse possible alternative substances, materials, designs, or medical treatments,
- justify why possible substance and/or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product, including taking into account if the intended use of such devices includes treatment of children or treatment of pregnant or breastfeeding women or treatment of other patient groups considered particularly vulnerable to such substances and/or materials.

Where the SCHEER committee will consider, during its assessment, that the current version of the guidance is still fit for purpose in the light of the latest scientific evidence, the committee will issue a new version of the document including such confirmation.

3. Deadline

The updated guidance has to be adopted by SCHEER by 18 June 2024.

4. Supporting documents

GUIDELINES on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties, SCHEER, https://health.ec.europa.eu/system/files/2020-10/scheer_o_015_0.pdf.

SCHEER approved this mandate by written procedure on 20 March 2023.