

# Why are potential dangerous phthalates allowed in medical devices, and who decides if their use is warranted?



Phthalates are widely used in the medical industry to make plastics softer and therefore more comfortable and pliable to use. You can find them in a variety of medical devices such as blood bags, intravenous bags, nutrition pockets,

tubing, catheters, respiratory masks and disposable gloves.

A previous Opinion by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) showed that the presence of DEHP (di-(2-ethylhexyl) phthalate), one of the most frequently used phthalates in medical devices, may pose health risks for vulnerable groups of patients, such as neonates. According to the Medical Device Regulation (REGULATION (EU) 2017/745) using phthalates that are carcinogenic, mutagenic, toxic to reproduction (CMR) or that are identified as endocrine-disrupting chemicals (ED), is only allowed when prudent and justified, and when the benefits clearly outweigh the risks. In addition, the Medical Device Regulation requires that the risks related to the use of potentially harmful phthalates are reduced as far as possible, e.g. by minimizing the release of the substance to the patient.

## → HOW CAN IT BE DETERMINED IF BENEFITS OUTWEIGH THE RISKS?

The European Commission, through its independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), provides guidelines on how to perform the benefit-risk assessment needed for justifying the presence of CMR/ED phthalates in

medical devices, parts of medical devices or materials used to make them. The guidelines are intended to be followed by relevant stakeholders e.g. manufacturers, notified bodies and regulatory bodies.

## → HOW DO THESE GUIDELINES HELP?

The guidelines provide professionals with a step-by-step process to accurately weigh the benefits and the risks. They also provide a framework on how to assess and compare possible alternatives to the use of CMR/ED phthalates in medical devices. Besides the direct benefits to the patient being treated with a medical device containing phthalates (like blood bags) other functionalities of the phthalate within the medical device need to be considered.

In the guidelines, alternatives are defined as substances, materials, designs and medical treatments that can be used to replace the use of CMR and/or ED phthalates in medical devices. The benefit-risk assessment can help to evaluate the appropriateness of potential relevant alternatives. In this evaluation, several factors need to be included, such as the technical feasibility, device functionality, benefits and risks.

Performing any benefit-risk assessment on the use of phthalates and the development of alternatives in medical devices requires careful consideration of relevant patient subgroups regarding the use of medical devices and the resulting potential exposure.

These guidelines do not provide information on the risk benefit analysis of the use of a medical device itself. The overall analysis, when using the guidelines, will determine whether it is justified or not to use a specific CMR or ED phthalate in a medical device.

## → IN THE FUTURE

The SCHEER found that there is a considerable lack of data for the benefit-risk assessment for potential relevant alternatives for CMR/ED phthalates to be used in medical devices. Manufacturers are encouraged to collect and submit high quality data to fill this gap, and further research is encouraged on possibilities to replace these phthalates in medical devices.

The benefit-risk analysis of the CMR/ED phthalates in a medical device needs to be updated when new scientific information becomes available, new guidelines are released, or the general benefit-risk determination of that medical device is updated.

This factsheet is based on the guidelines of the independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) on “the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction or have endocrine-disrupting properties”

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These guidelines are available at:  
[https://ec.europa.eu/health/sites/health/files/scientific\\_committees/scheer/docs/scheer\\_o\\_015.pdf](https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_o_015.pdf)