

# EU Guidelines Address New Benefit-Risk Justification for Medical Devices Containing Certain Phthalates and Other Hazardous Substances

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The European Commission (Commission) recently published the final version of its guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices, covering phthalates that are carcinogenic, mutagenic, toxic to reproduction (CMR), or have endocrine-disrupting (ED) properties (the Guidelines). Importantly, the Guidelines mention that the approach set forth can also be relied upon when conducting the benefit-risk assessment of other CMR and ED substances present in medical devices as required by the Medical Device Regulation (MDR).

At the request of the Commission, the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) prepared the Guidelines to address the new justification requirement set out in the MDR. Companies placing medical devices containing MDR/ED phthalates (or other CMR/ED substances) on the EU market under the MDR should consider how the justification requirement for the use of CMR/ED phthalates could affect their products and operations. The Guidelines may well trigger significant additional work for these companies, including the adoption of measures to avoid supply interruptions.

## **MDR Restriction of Phthalates**

Phthalates are widely used in the medical devices industry as plasticizers of polymers helping to make plastic flexible and tougher. When used as plasticizers, phthalates may comprise a substantial part of the medical device. The [MDR](#) restricts the use of CMR substances of category 1A and 1B, and ED substances for which there is scientific evidence of probable serious effects to human health (CMR/ED phthalates) in certain medical devices if the concentration of CMR/ED phthalates is above 0.1 percent weight by weight (w/w), as these substances may be released from medical devices into the environment or into the human body. The phthalate restriction applies to medical devices (including parts and materials used) which

- (i) are invasive and come into direct contact with the human body;
- (ii) (re)administer medicines, body liquids or other substances, including gases, to or from the

human body;

- (iii) transport or store such medicines, body fluids or substances, including gases, to be
- (re)administered to the human body (collectively referred to as “medical devices in scope”).

For medical devices in scope, the use of CMR/ED phthalates above 0.1 percent w/w is permitted only with a proper justification.

The justification requirement does not apply to medical devices in scope containing CMR/ED phthalates *below* 0.1 percent w/w. However, these devices shall comply with the general requirement that medical devices must be designed and manufactured in such a way as to reduce, as far as possible, the risks posed by substances or particles that may be released from the device.

### **Guidelines on Benefit-Risk Assessment**

As part of the required justification related to inappropriate alternatives, not only the risk of the CMR/ED phthalates by themselves shall be evaluated but also the impact of the possible alternatives on the functionality, performance and the overall benefit-risk ratio of the medical device.

Therefore, before CMR/ED phthalates can be used above 0.1 percent w/w, manufacturers must demonstrate on the basis of a proper scientific justification that possible alternatives are not appropriate to maintain the functionality, performance and benefit-risk ratios of the medical device.

The Guidelines set out detailed requirements as to how to conduct such a benefit-risk assessment for the justification of the presence of CMR/ED phthalates above 0.1 percent w/w in medical devices. They explain, *inter alia*, that such an evaluation should be performed by a “multidisciplinary team” including among others, for example, a material scientist, medical device specialist, toxicologist and clinician.

The Guidelines also describe the evaluation of possible alternatives for CMR/ED phthalates, setting out 10 steps in the assessment of presence of CMR/ED phthalates in medical devices in scope. The term “alternatives” is defined as substances, materials, designs and medical treatments that can be used to replace the use of CMR and/or ED substances in medical devices. Consequently, alternatives are not limited to substances or materials but could also be new device designs (e.g., production processes), medical treatments (e.g., procedures) or a combination of these. The Guidelines indicate that the functionality and performance of any possible alternative should be comparable to the CMR/ED phthalates they intend to replace, to the extent that there would be no clinically relevant difference foreseen in the performance of the medical device, or in the outcome of the alternative medical procedure.

The stepwise approach set out in the Guidelines can be summarized as follows:

- Assessment of the **presence** of phthalates in a medical device (Steps 1-3)
- Assessment of **possible alternative** substances, materials, designs or medical treatments (Steps 4-7)
- Assessment of **potential relevant alternative** substances, materials, designs or medical treatments **versus CMR/ED phthalates** (Steps 8-10)

The Guidelines are addressed to stakeholders such as manufacturers, notified bodies and regulatory bodies. The MDR requires that the Guidelines be updated when deemed appropriate on the basis of the latest scientific evidence, but at least every five years.

The Guidelines have been drafted and adopted in light of the MDR, which will apply as from May 26, 2020. Companies placing or intending to place medical devices containing phthalates (or other CMR/ED substances) on the EU market may wish to consider how the new requirements will affect their operations and whether updates to documentation are necessary. These new requirements could potentially represent significant additional work for medical device manufacturers to ensure a smooth transition to the new rules and avoid supply interruptions.

## CONTACTS

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

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