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Position of Bundesverband Medizintechnologie concerning the revision of the CLP Regulation

Introduction

BVMed welcomes the opportunity to comment on the proposed amendments of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).
The structure and the questions in the questionnaire require comments that are more detailed. Therefore, we want to thank the European Commission for the opportunity to upload a further document.

As a trade association for medical devices, our position mainly focuses on the topics and questions that apply to medical devices.

Interlinkage of CLP and GHS

In general, we would like to stress that the introduction of new hazard classes, which are not foreseen in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), is contrary to the objectives of the GHS to which the CLP Regulation is committed.

Regulation of medical devices

Medical devices are products with a medical purpose that are intended by the manufacturer to be used, alone or in combination, for human beings. These include implants, products for injection, infusion, transfusion and dialysis, surgical instruments, etc. The main intended effect in medical devices is achieved primarily by physical means.
According to the relevant sectoral legislation (Regulation (EU) 2017/745 on medical devices; MDR), medical devices must demonstrate clinical benefit before being placed on the market. This also applies equally to the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Only devices with a positive benefit-risk balance can be placed on the market. Notably, the use of hazardous substance in medical devices is sufficiently addressed in the MDR as a fundamental requirement of Chapter II of Annex I (General Safety and Performance Requirements) of the MDR, which states that certain devices[1] shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device.

A concentration of

- *substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, or*
- *substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council, in accordance with the criteria that are relevant to human health amongst the criteria established therein*

above 0,1 % weight by weight (w/w) must be justified with regards to

[1] MDR, Annex I, Chapter II, Section 10.4.1: "Devices, or those parts thereof or those materials used therein that:

- 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, [...]"

- *an analysis and estimation of potential patient or user exposure to the substance*
- *an analysis of possible alternative substances, materials or designs*
- *argumentation as to why possible substance and/ or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality*
- *where applicable and available, the latest relevant scientific committee guidelines.*

Interlinkage of CLP and MDR

We would like to emphasize that the MDR under Annex I, Chapter II, Section 10.4 (as cited above) creates a direct linkage between the MDR and the CLP Regulation. Changes to the hazard classes in the CLP Regulation, therefore, may have an impact on the regulation of medical devices and trigger the described justifications and labelling requirements for medical devices – as articles – even if the labelling requirement under the CLP would only be applicable for substances and mixtures. An excellent example of the breakdown in logic between CLP and the MDR is Cobalt, which received classification as a CMR 1B for cobalt as a substance/mixture.-Due to the MDR linking to CLP, cobalt in articles according MDR, Annex I, Chapter II, Section 10.4.1 (including those made of alloys like stainless steel) in a concentration over 0.1% weight by weight has required justification and labelling under Annex I, Section 10.4.
We therefore urge the decision makers to take this correlation of MDR and CLP into account, when considering new hazard classes for endocrine disruptors, which might have an impact on medical devices.

Labelling exemption for substances and mixtures in medical devices

Medical devices in the form of substances and mixtures intended for the final user, especially those devices that are invasive or used in direct physical contact with the human body, are excluded in the current CLP Regulation (Art. 1. Par. 5 (d)). A revision of the exemption – if it is considered - would impact strictly regulated labelling materials. Provision of information for safe handling and use is sufficiently ensured for these devices by existing sectoral legislation, e.g. the Medical Device Regulation (MDR). This covers human health as well as environmental aspects, like advice on adequate and safe waste disposal (MDR Annex I, Chapter II, Section 14.7).

As there is already adequate legislative control in place, we **do not** see a reason why the current exemption from the hazard communication requirements under CLP for such products might be adapted/revoked. If these exemptions were nonetheless be withdrawn, sufficiently long transitional periods would be required, as any change of labelling of medicines and medical devices is strictly regulated by the MDR and requires significant efforts, time and approval.

Kind regards,

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