# Position Paper on Medical devices regulation's wording on carcinogens, mutagens and reprotoxic substances

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MedPharmPlast Europe, a sector group of the European Plastics Converters, represents companies involved in the whole value chain of plastic medical devices and pharmaceutical packaging in Europe.

MedPharmPlast Europe welcomes the political agreement by the Council of the European and the European Parliament on the comprehensive regulatory framework for medical devices and strongly advocates evidence-based policymaking.

MedPharmPlast Europe shares the ambition to strengthen the regulatory framework on medical devices and their safe use. Therefore, and supporting the need to provide effective ways of eliminating or reducing exposure to materials which may cause harm to patients, we acknowledge the legislative proposal agreed in the context of the Medical Devices Regulation (MDR) giving shape to a clear and credible process to substitute potentially harmful substances in Medical Devices.

Annex I, Part II, 7.4, requires manufacturers to analyse all substances that may be released or leached from a device and minimize the risks related to this through safe design and manufacturing.

Under the new legislation, if a device or parts thereof may lead to a relevant exposure of patients or users to substances which are carcinogenic, mutagenic or toxic to reproduction (CMRs) or substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health (and not using these substance is not an option) the manufacturer has to find ways to minimize/prevent the exposure of patients or users with the released substances.

Furthermore, in cases where despite measures taken by the manufacturer, a patient or user exposure could occur, the manufacturer is obligated to provide a particular justification for the use of such substances and is subject to specific labelling requirements. We believe that the justification process should be evidence-based including the latest relevant scientific guidelines and opinions on the concerned substances, and where available analyses on possible alternatives.

MedPharmPlast Europe stresses that the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, whilst achieving an equivalent functionality, can be a very complex

and time-consuming process and that it requires appropriate testing in terms of environmental and health-related impacts. For the sake of patient's health and safety, extreme care must be taken to ensure that one hazard is not being exchanged for another, especially one that could even be a more serious hazard.

The complexity of the alternatives assessment and substitution processes has been recognized, amongst others, by the Organisation for Economic Co-operation and Development (OECD) [1] and in a draft report mandated by the European Commission[2]. The latter called for policies aimed at stimulating the substitution of hazardous chemicals to address the following factors, amongst others: functional equivalence, the availability of the substitute (i.e. it should be developed and tested to a sufficient extent); availability of information on the substitute and its consequences (including risks and uncertainties, as well as gaps in knowledge); awareness in the organisation of the problems related to the currently used substance and preparedness to change; the costs of the substitute; environmental performance of the substitute; the risk of other negative (side) effects.

MedPharmPlast Europe calls on the European Commission to take the above into account when preparing and updating guidelines on the benefit-risk assessment of the device in question and an assessment of the available alternatives. These guidelines must provide flexible guidance and best practices to help manage the complexity and uncertainties in the process to support companies to engage into alternatives assessments and substitution processes. They should be updated on the basis of the latest scientific evidence, leading to an automatic phasing out of potentially harmful substances through their substitution with viable alternatives, as instructed by Annex I, Part II, 7.4.1 of the MDR.

[1] OECD. Synthesis Report From The OECD Workshop On Alternatives Assessment and Substitution of Harmful Chemicals. 2016
[2] European Commission. Substitution of hazardous chemicals. 2006