

The need to distinguish new from existing medical technologies

Accelerating the green transition through innovation

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Introduction

MedTech Europe shares the ambition of the Chemicals Strategy for Sustainability to pursue substitution of the most hazardous substances.

Medical technologies are strictly regulated by sectoral legislation,¹ which allows for substitution of materials/chemicals after extensive re-design and re-validation regulatory requirements have been followed. Such requirements exist to ensure safety and performance of medical technologies. MedTech Europe therefore proposes an approach that enables manufacturers' resources to focus on pursuing the Green Deal objectives quicker, by innovating new, greener technologies rather than redesigning existing ones.

MedTech Europe's below proposal builds on an approach already taken in a recent Delegated Act to the RoHS Directive, namely exemption 27 of Annex IV (please see further below).

Objectives

- ✓ **Encourage innovation rather than re-design:** Manufacturers can leverage a greater range of materials and components when designing new, greener medical technologies versus re-designing existing ones. Re-designing (e.g., by substituting a chemical in) an existing medical technology is a less efficient way to pursue more sustainable design, can postpone the availability of innovation and in many cases proves neither technically nor economically feasible.
- ✓ **Best leverage companies' finite resources:** Whether designing new technologies or re-designing existing ones, manufacturers must leverage the same internal scientific and R&D resources/time. Additionally, re-designing medical technologies requires the resources of manufacturers' regulatory staff and Notified Bodies, who have extremely limited capacity to process the design changes at this time.²
- ✓ **Preserve patient access to healthcare:** Chemicals are typically present in medical technologies to deliver specific safety or performance functions. When substitution efforts conclude that no suitable alternative is available (e.g., because alternatives adversely affect safety, performance and/or the environment), one outcome can be the discontinuation of medical technologies that patients need.

Proposed Solution

MedTech Europe proposes that future regulatory measures³ on substances in the EU chemicals legislation systematically give special consideration/provision for existing medical technologies, whereby the measures apply to new medical technology designs, but not to existing medical technologies (see proposed concept in next section).

¹ As explained in our REACH consultation response.

² https://ec.europa.eu/commission/presscorner/detail/en/mex_22_5224

³ E.g. date of application of the substance listings in e.g. REACH Annex 14 or 17 or RoHS Annex 2

MedTech Europe's proposed approach to an 'existing medical technology'

MedTech Europe considers an existing medical technology as a device, as defined in MDR Art. 1(4) or IVDR Art. 1(4)⁴, which is in conformity with the applicable EU sectoral legislation and for which the respective Declaration of Conformity was first issued before the date of application of future regulatory measures under the EU chemicals legislation⁵.

The RoHS Directive already applies this approach, via Annex IV Exemption 27, which entered into force May 2022)⁶. MedTech Europe proposes that the legacy approach be followed, systematically, for all future regulatory measures under RoHS and other EU chemicals legislation.

Important points to be additionally considered in this approach are:

- An appropriate transitional period is needed for new products and those under development.
- This approach needs to also cover the production of equivalent devices in the EU, not intended for the EU market.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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⁴ The Medical Devices Regulation 2017/745 (MDR) and the *in vitro* Diagnostic Medical Devices Regulation 2017/746 (IVDR)

⁵ E.g. date of application of substance listings in REACH Annex XIV or XVII or RoHS Annex 2

⁶ EU Official Journal publication, available at the link here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=pl-com%3AC%282022%293041>