Minutes – Meeting MedTech Europe on ESU

19 November 2021, Microsoft Teams

Participants:
MedTech Europe: [redacted]
ENV: [redacted]
GROW: [redacted]

- The meeting was requested by MedTech Europe to discuss the implementation of the essential uses (ESU) concept in the upcoming REACH revision and the impact on the Medical Technology sector.
- The Commission recalled the key dates for the REACH Revision and invited industry to participate in the workshop on ESU in February 2022 and the public consultation on the REACH revision that will run from December 2021 until March 2022. It was agreed that MedTech Europe will be contacted by the contractor of the ESU study for the targeted consultation.
- MedTech expressed concerns on how the ESU concept will be implemented in the medical sector as the ban of a harmful substance would mean time to redesign the affected product as well additional time to go through the whole approval of a medical device. Industry asked for longer timelines than those currently in REACH and appropriate consideration to safe use and disposal of harmful substances. Streamlining both legal frameworks is important to minimise administrative burden.
- COM clarified that the ESU concept and the extension of GRA to new hazard classes will be applicable after inclusion in the REACH revision. Until then, the current REACH Regulation applies. Concerning GRA, COM also clarified that restrictions under Art 68(2) will follow in subsequent proposals – as in the current system.
- MedTEch proposed different approaches for the use of substances in new products and in legacy uses (medical articles already on the market). COM referred to the recently adopted legislation on legacy spare parts and invited industry to inform COM about possible problems in implementing the new legal framework.
- COM is open to further dialogue with the sector after the workshop in February 2022, once the policy options on ESU are further developed.