MedTech Europe
from diagnosis to cure

MedTech Europe views on the Chemicals Strategy for Sustainability and the revision of REACH

18 July 2022

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About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

OUR MEMBERS

130+ multinational corporations*

*medical devices, diagnostics and digital health

50+ medical technology associations

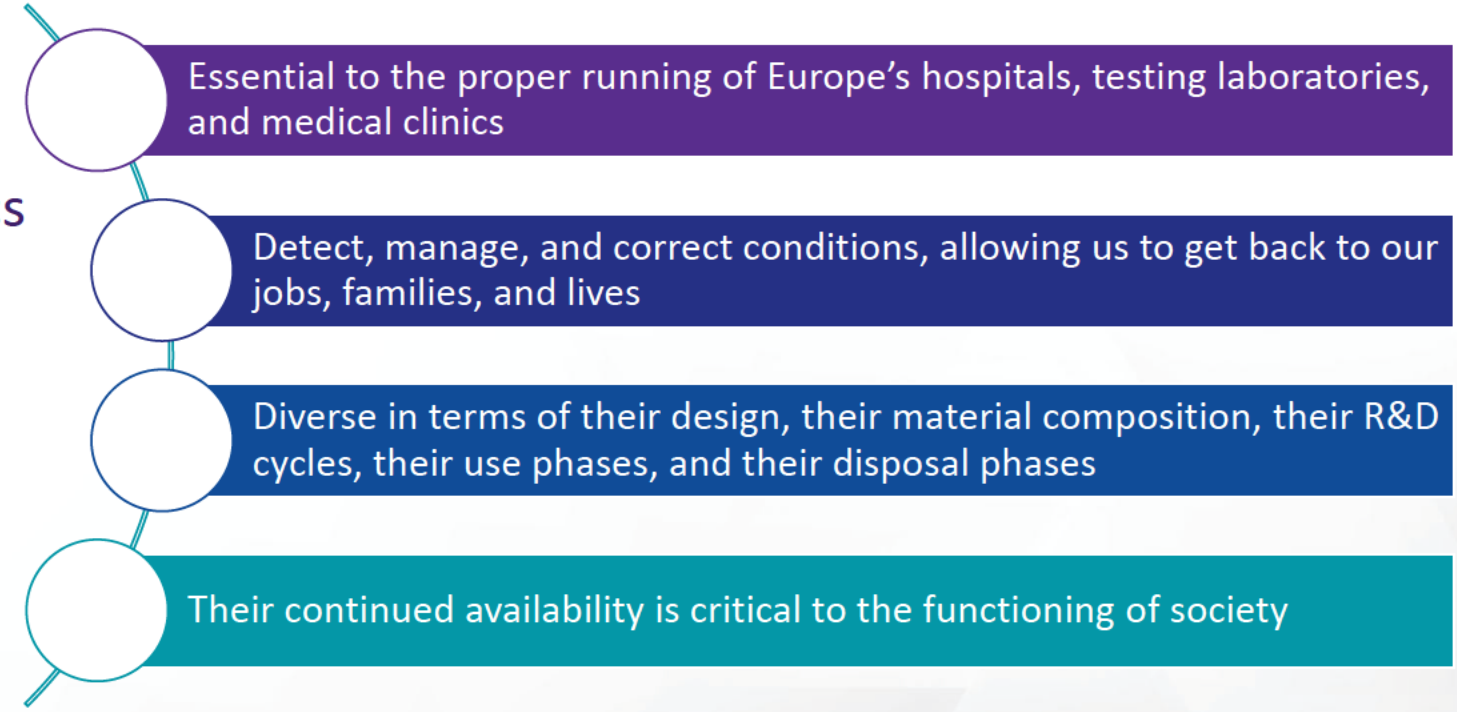
About medical technology

Medical technology is any technology used to **save** and **improve** lives of individuals suffering from a wide range of conditions.

There are more than **500,000 products, services and solutions** currently available

Role of medical technologies

In Vitro Diagnostics (IVDs) & Medical Devices (MDs)

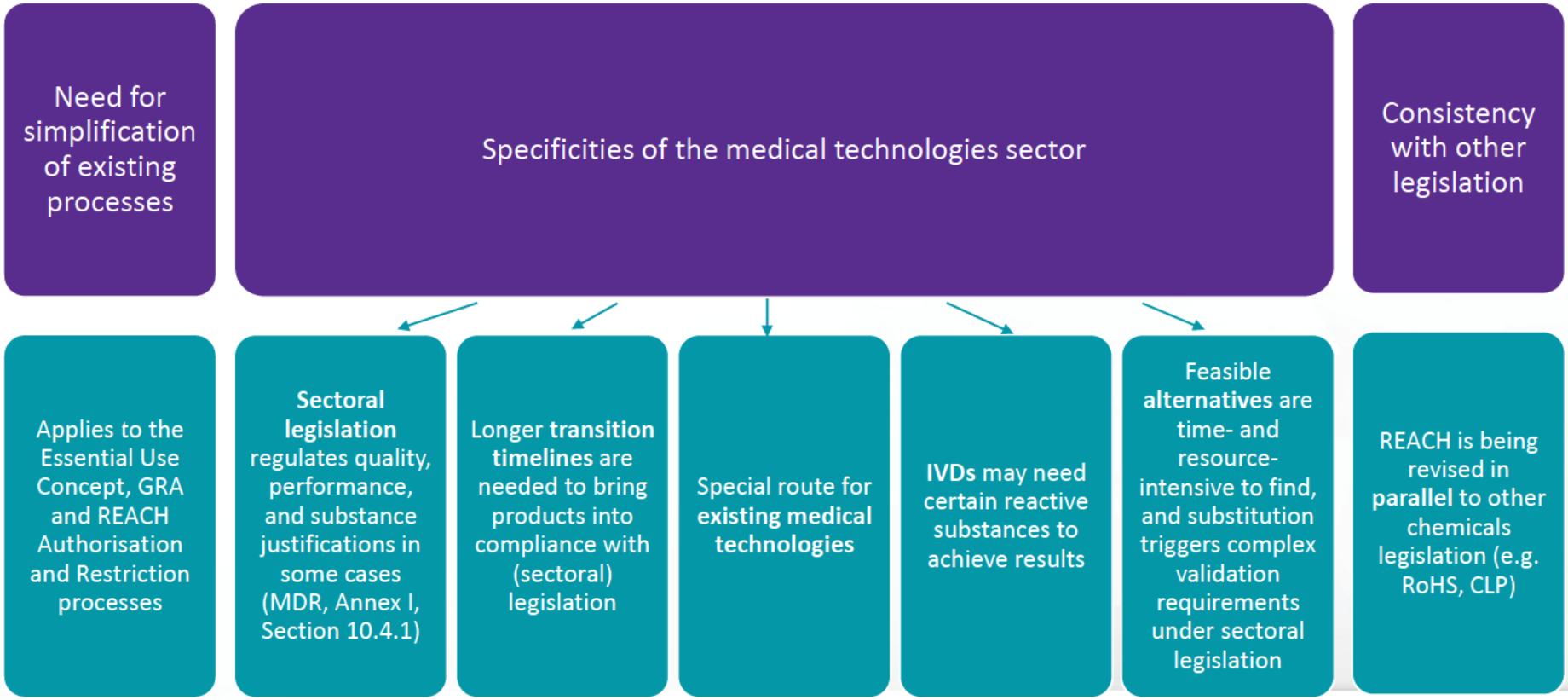


Vision for the Chemicals Strategy for Sustainability and the revision of REACH

Sustainability as the way forward

- We support the goals of the Green Deal, and the Chemicals Strategy for Sustainability
- Sectors like ours must do their part to contribute to the goals of more sustainable use of chemicals and reducing its environmental footprint
- We are committed to meeting these goals, whilst preserving access to medical care and technologies that save, extend, and maintain quality of life
- Need of a balance between:
  - ✓achievable objectives
  - ✓fair expectations
  - ✓conditions and timelines that correspond to the realities in which the medical technology industry operates
  - ✓product performance should not be compromised by phasing out essential hazardous substances

Vision for the Revision of REACH



Case studies

Case study – Microplastics

Proposed REACH Restriction on intentional uses of microplastics

- The IVD sector contributes **270 kg/year** of microplastics released to the environment (that is, less than 0.1% of all microplastics use)
- Re-design involves extensive development, testing, re-validation and regulatory approval of the design changes under the IVDR. This is a process that can take up to **5-12 years** for each product
- Compliance costs for companies in the sector, would be equal to **€8,683 billion** over 20 years, if conditional derogations would not apply.

RAC Opinion extract, June 2020, page 58:

> Municipal solid waste is a relevant release pathway for microplastics in cosmetic products or paints that are present on used tissues or wipes. Minor contributes derive from other uses like medicinal products and medical devices and ***in vitro*** diagnostic medical devices. Releases

Case study – OPE/NPE

REACH Authorisation of OPEs and NPEs

- An estimated 700 tonnes/ annum of OPEs used by other industries. The IVD industry was estimated to use 40 tonnes
- For an IVD test reagent it is not possible to know if an alternative will work until feasibility testing is complete (1-2 years) - per product
- In some cases, some MedTech Europe members are re-designing hundreds of reagent products, tying up the R&D teams for up to 12 years

Case study – Lead and lead components

REACH Annex XIV Consultation, regulated under RoHS & Batteries Directives

Function

- Imparts desired harmonic frequency of PZT ceramics used in harmonic shears, thus allowing simultaneous cutting and sealing needed for minimally invasive surgeries
- Few applications for leaded solder where no alternative exists, e.g. in active implantables to avoid 'Tin Whiskers'

Use

- PZT ceramics used in harmonic oscillator shears
- Active Implantables: pacemakers, defribulators, and neuromodulation devices
- EEE components used in medical devices

Alternatives

- No known alternatives for the uses above
- Larger incisions would be necessary during surgical procedures; larger incisions are correlated with increased intraoperative blood loss, longer procedures, extended healing times, and increased potential for infection of the surgical site
- Reduced reliability resulting in patient deaths or complete redesigns with possible loss of available functions

Concluding remarks

To address the:

- challenges the sector has faced with REACH
- future opportunities with more sustainable use of chemicals
- specificities of the medical technologies sector
- time & resources needed to find alternatives
- low quantities used compared to the resources needed to bring products into compliance with legislation

We propose a 'legacy approach' or special consideration for existing products whereby:

- ✓ Restrictions and Authorisations only apply to new product designs and not to legacy products and spare parts
- ✓ for new product designs, sufficient time is granted for substitution (where technically possible) taking into consideration the time/design cycle of medical technologies and sectoral legislation

Thank you!

[redacted]

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