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Irish Medtech Association Submission to the DETE and the DECC on the European Commission's Proposal for a Regulation on Ecodesign for Sustainable Products

The Irish Medtech Association (IMA) Ibec's representative body for medical technology industries in Ireland, who are providing innovative health technology solutions and improving lives through innovation. The medtech industry supports the premise of the Ecodesign for Sustainable Products Regulation (ESPR) as a key measure to ensure there are more sustainable products in the European Union and circular business models. IMA welcomes the move towards the twin green and digital transitions which will unlock a greener, healthier, and more prosperous future for the European Union and its citizens.

IMA has called for a whole of government, integrated approach to policy to bring together all stakeholders and relevant government departments across the ecosystem with assessments to identify strengths and weaknesses. Therefore, we welcome DETE and DECC working in tandem to coordinate this important consultation. We also support Ibec's call for the Departments to arrange timely sector-specific bilateral discussions following on from this consultation

Ireland's global medtech hub alone spans 450 businesses, including 9 of the world's top 10 and is responsible of over €12.6 bn in exports, with over 42,000 people directly employed. The industry here is not only making an international impact as a leading location for FDI investment but is demonstrating its prowess as a location where start-ups can scale.

Any efforts must consider the need to maintain the very high health and safety standards of medical technologies and their need for continued availability on the EU market.

Executive Summary
Medical technologies are diverse and wide ranging, and the relevant sectorial legislations set specific targets on health and safety aspects. IMA welcomes the acknowledgement by the European Commission of the unique requirements of the sector. As stated in Recital 16 of the proposal for a Regulation on Ecodesign for Sustainable Products (ESPR), it is essential to be cognisant of the vital importance of medical technologies (i.e. saving and improving human lives) when addressing societal demands for more sustainable medical technologies.

This document highlights the specific considerations for our sector.

In principle what we support:

- Consistency between the requirements of the ESPR proposal and other horizontal legislation
- An integrated approach where sustainability considerations can be assessed as part of the existing medical technologies design processes;
- Integration of eco-design requirements during new product development and exclusion of existing medical technologies of the scope of eco-design requirements;
- Alignment in Conformity Assessment Procedures and Capacity of Notified Bodies for ESPR
- Sufficient transition time for implementing eco-design requirements
- Special consideration should be given to the potential introduction of eco-design requirements regarding alternative materials for medical technologies.

Key concerns:

- Protection of confidential business data, data within the scope of the Digital Product Passport and interplay with other legislation
- Duplication of efforts and overlaps in regulation, in particular for substances of very high concern (SVHCs);
- Implementation with a disproportionate impact on the competitiveness of economic actors (third party verification, regulation of components and non-enforceable requirements)

1. **Consistency between the requirements of the ESPR proposal and other horizontal legislation**

IMA requests consistency between the requirements of the ESPR proposal and other horizontal legislation. As the Medical Device/IVD regulatory systems take shape there is a need to ensure it is optimised to serve patients, as well as build awareness of its importance to compete with other global markets to attract investment and foster innovation. There is an opportunity for Europe to advocate for a more harmonised approach to global regulation that promotes best practice. Areas of focus include, reinforcing EMA's role in crisis preparedness and management for medtech, the planned revision of the EU's pharmaceutical legislation, the European Green Deal, the European approach to artificial intelligence (AI) and the new EU HTA Regulation, as well as other pertinent horizontal regulations such as the Regulation (EU) 2019/1021 on persistent organic pollutants (POPs Regulation), Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), Directive 94/62/EC on packaging and packaging waste, Directive 2008/98/EC on waste and Regulation (EC) No 765/2008 and Decision No 768/2008/EC

2. **An integrated approach where sustainability considerations can be assessed as part of the existing medical technologies design processes**

IMA calls for an integrated approach between ESPR and existing sectorial legislation**.** Many performance requirements present in the sectoral legislation (Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR)), such as durability and reliability, reflect design elements emphasised in the European Commission proposal. Due to the significant cost to healthcare institutions as well as the prolonged approval process associated, medical technologies are rigorously tested and designed for long useful cycles to guarantee the safety of patients.

Thus, sustainability considerations can be assessed as part of the existing medical technologies design processes. This would allow for safety, performance, and sustainability design considerations to be duly assessed, balanced, and prioritised in the medical technology design.

However, if the alternative approach of setting mandatory sustainability performance targets under a separate legislative framework is taken, it may result in potential conflicts between the different design elements. For example, integrating higher recycled content into products via current technology could reduce the durability or reliability of some medical technologies.

3. **Integration of eco-design requirements during new product development and exclusion of existing medical technologies of the scope of eco-design requirements**

IMA recommends the Exclusion of Existing (Legacy) Medical Technologies of Eco-design Requirements. Considering the typical length of design cycles of medical technologies, measures to systematically address sustainable design can realistically be integrated during new product development when sustainability and other key design inputs have been effectively assessed and can be acted upon. It would not be feasible or effective to apply this approach retrospectively to existing designs. The research and development resources required would be more effectively applied to new rather than to existing technologies.

4. **Alignment in Conformity Assessment Procedures and Capacity of Notified Bodies for ESPR**

The IMA calls for alignment between the proposed conformity assessment procedures under the ESPR and existing ones under IVDR and MDR, as well as guaranteeing sufficient capacity and the availability of the required expertise in Notified Bodies.

Consideration should be given to ensure the alignment between proposed conformity assessment procedures under the ESPR and existing conformity assessment procedures that medical technologies must follow under the MDR and IVDR and other environmental legislation, e.g.on batteries. Guaranteeing sufficient capacity* and availability of the right level of expertise in Notified Bodies will be critical for certifying and CE marking medical technologies.
*Currently, there is significant limited Notified Bodies capacity for MDR and IVDR certification, a major implementation challenge for such. This has the potential to exacerbate the situation further.

5. **Sufficient transition time for implementing eco-design requirements.**

The IMA calls for sufficient transition time for implementing new requirements. Changing or updating the design of medical technology can take up to 10 years. (See Annex I) Automated laboratory equipment is designed for a minimum of 10 years of service, while up to 25 years of service is frequently witnessed in medical laboratories. During these rigorous processes, the continued availability of critical medical technologies must be ensured.

6. **Special consideration be given to the potential introduction of eco-design requirements regarding alternative materials for medical technologies.**

The highly regulated nature of medical technologies can often limit or prevent changes in materials. IMA recommends that special consideration be given, regarding the transition to alternative materials to ensure that the devices still fully comply with the relevant industry regulations.
The transition to and validation of alternative materials with an adequate level of quality to replace existing ones takes time and must safeguard consistency, reliability, and biocompatibility of

materials. Some applications can easily incorporate recyclable materials such as capital equipment whereas, some other medical technologies which are higher risk such as implantable devices may not be easily adapted or updated.

Specific Elements of the Commission Proposal

Digital Product Passport (DPP)

- The DPP should be leveraged for registration in the Substances of Concern in Products (SCIP) database where there is overlap (i.e., where substances of very high concern (SVHCs) are present in a product or another way to consider this might be to reverse this i.e. leverage registration in SCIP to populate DPP).

- The DPP represents a potential for reduction in physical documentation (manuals, leaflets, etc.) that should be reflected in other pieces of legislation.

- It is critical to ensure the right balance between transparency and the use of the data in the DPP, on one hand and protection of companies' Intellectual Property Rights and trade secrets on the other. Adequate safeguards must be established to prevent misuse and avoid competitive disadvantage upon disclosure of data. Access to data on a need-to-know basis should be established. Another way to consider this might be to restrict access at actor level (regulator, consumer etc.).

- Alignment is needed to disclose substances of concern with Article 33 of the REACH Regulation and the 0.1% w/w threshold.

- Clarification of definitions and requirements:

- Missing definitions include the terms "model", "batch" and "item" as they have not been defined in Article 2.

- The 'human-derived products' exemptions should include reagents made from these products.

Annex I
Validation and Design Changes in Medical Technologies
Medical technologies are usually complex products strictly regulated by the MDR and IVDR. The sectorial legislation provides regulatory oversight regarding the design, manufacture, clinical trials, labelling, and adverse event reporting to ensure that medical technologies marketed in the European Union are safe and effective for their intended uses.

Medical technologies require a protracted time to market and, in general, it may take 3 up to 7 years for a new medical device (MD) and over 10 years for a new *in vitro* diagnostic medical device (IVD) or Active Implantable Medical Device (AIMD) application. Furthermore, if applicable, collecting clinical data and getting Notified Body approval is required. The lengthy approval process for compliance with the MDR and IVDR may result in a product having to be removed from the market until all regulatory testing is completed.

Under the sectorial Regulations, a change in the design of a medical technology that could impact the safety, effectiveness or reliability of the product may trigger a requirement for additional clinical

testing and validation. The aim is to ensure that criteria for patient safety and the performance of medical technology are still met by the new design. If this is not the case, a design change may be required to ensure continued product performance and patient safety.

This requires a longer transition period than those currently proposed for the following purposes:

1. validate the performance of the new battery combined with the medical technology
2. determine if the change in battery specifications requires product design changes and make applicable changes
3. re-register (to get approval from a Notified Body when a medical device or IVD dossier is submitted or re-submitted for change) affected products on an individual basis.

As recognised in multiple pieces of existing legislation (e.g., RoHS Directive and the Regulation (EU) 2019/1021 on persistent organic pollutants (POPs Regulation) and REACH Regulation, additional implementation time is needed to ensure the smooth transition to improved environmental protections without interruption to the supply of medical care.

Conclusion

Our membership supports the overall objectives of the proposed Ecodesign for Sustainable Products Regulation (ESPR). The existing Ecodesign Directive, which it will replace, has proven to be an effective regulatory instrument for improving the energy efficiency of electrical and electronic products. However, we caution against introducing greater bureaucratic rules (red tape), increasing the administration burden and delaying certification processes further potentially resulting in a stifling of innovation and investment. In what is already a highly regulated industry, grappling with a challenging new regulatory environment under MDR and IVDR, it is important that the new ESPR is proportionate and pragmatic to ensure the EU remains a global medtech hub and the location of choice for innovation.

To sustain our hard-won competitiveness and position ourselves on the world stage as champions in the evolving world of health innovation and drivers of growth we need the right industrial policies which promote a more coordinated and strategic way of thinking.

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