MedTech Europe Feedback on the TRIS notification 2022/196/I (Italy)

4 July 2022

Decree No 114 of the Italian Minister for Ecological Transition of 16 March 2022 adopting the Guidelines on the labelling of packaging, pursuant to Article 219(5) of Legislative Decree No 152/06.

1. Object of the TRIS Contribution

MedTech Europe endorses the feedback submitted by Confindustria Dispositivi Medici on 10 June 2022 regarding TRIS notification 2022/196/I of Italy.

This draft Decree adopts Guidelines for economic operators on how to comply with packaging labelling obligations introduced by Article 3(3)(c) of Legislative Decree 116/2020, amending Article 219(5) of Legislative Decree 152/2006.

The guidelines, as well as the packaging labelling obligations that the guidance document aims to specify, and their impacts, constitute the object of this contribution.

2. Impacts

Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on *In Vitro* Diagnostic Medical Devices (IVDR) govern medical technologies, their packaging, and accompanying information with regards to safe disposal. The IVDR and MDR set sector-specific labelling requirements.

MedTech Europe is concerned about the lack of harmonisation between Member States and constant changes of national packaging labelling requirements. As a result, the inconsistency across EU Single Market and changes may adversely impact the delivery of critical medical technology to European citizens where needed.

It is important to ensure that packaging materials and packaged medical technologies can move freely within the EU Single Market. Different packaging requirements across the EU Single Market, or additional local labelling requirements, impede the use of a single packaging/labelling scheme. This leads to manufacturers having to redesign their packaging/labelling in order to adapt them to individual Member States. These changes affect the labelling process and timing.

When countries request additional labelling requirements, existing products must be:

- Relabelled with existing codes or through the creation of new codes to meet national requirements.
- Destroyed: the interruption of established distribution models may lead to the destruction of products that cannot be placed on shelves. Resources are thus wasted along the supply chain from raw material suppliers to citizens and healthcare institutions.
- Redirected to other countries: National labelling requirements can lead to disruptions of efficient distribution systems, requiring suppliers to ship unsold goods over longer distances to relabel them in accordance with the different applicable national legislations. Additional transport increases fossil fuel consumption and

negatively impacts climate and air quality.

These are resource-intensive processes. In some instances, increased labelling requirements may result in larger packaging or regional variants of products to accommodate the addition of inserts.

In addition to the increased environmental impact, which runs contrary to the EU Green Deal objectives, manufacturers must examine whether this makes economic sense for all products intended for individual countries. This can ultimately lead to restricting the availability of medical technologies in these countries.

Therefore, MedTech Europe invites Members States to abstain from imposing unilateral labelling requirements and sorting instructions in line with their commitment to a truly EU Circular Economy.

MedTech Europe also calls for a harmonised European approach towards labelling requirements coming from the revision of the Packaging and Packaging Waste Directive and requirements among Member States and stresses the need for such requirements to remain aligned until the revised legislative text enters into force.

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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