CONFINDUSTRIA
Dispositivi Medici

Rome, 10 June 2022

TRIS notification details (2022/0196/I): Decree No 114 of the 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

Confindustria Dispositivi Medici is the non-profit Italian association for the medical technology industry including in vitro diagnostic medical devices, medical devices, digital health, medical imaging, radiotherapy, electromedical industries, borderlines, and complex and hearing aids. It represents over 400 hundreds of companies, from start-up and small-medium enterprises up to multi-national ones. It is a very heterogeneous, highly innovative and specialized sector, where small companies coexist with large groups.

Confindustria Dispositivi Medici would like to provide its views on the possible violation of EU legislation that could take place if the provisions of Article 219(5) of Legislative Decree No 152/06 (as amended by the Legislative Decree no 116/2020) and the guidelines on the labelling of packaging would apply.

Such consultation is welcomed by the medical technology industry since it represents the best tool through which ensure uniformity at EU level. At the moment, there are several provisions on the subject on the verge of being approved by various Member States. Central coordination on the issue of environmental labelling is needed in order to prevent restrictions on the free movement of goods in the single European market given the risk of regulatory fragmentation.

Particularly in consideration of the medical devices and in vitro diagnostic sectors, the following aspects should be carefully taken into account in the application of the Article 219(5) of Legislative Decree No 152/06 on packaging labelling:

1. the level of harmonization achieved by the recent application of Regulation (EU) 2017/745 on medical device and Regulation (EU) 2017/746 on in vitro diagnostic medical devices and the guarantee of free movement of goods within the single market would risk being compromised by the additional obligations imposed on Italian manufacturers. Indeed, the national requirements on packaging labelling infringe the Treaty on the Functioning of the European Union (TFUE) and Directive (EU) 2015/1535 on the Technical

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Regulations Information System (TRIS). In a concise manner, Italian requirements under discussion, as well as the proliferation of any other similar national measures from other Member States, are in contrast with article 34 of TFUE where it is stated that: "*Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States*". This orientation was further confirmed in several Judgment of the EU Court, such as the *Dassonville* (no. 8-74, 11 July 1974) and the *Cassis de Dijon* (no. 120/78, 20 February 1079) ones. Additionally, as per article 5(1) of Directive (EU) 2015/1535, the Legislative Decree no. 116/2020 amending article 219(5) of the Legislative Decree no. 152/06 should have been notified to the EU Commission before its adoption as a technical regulation concerning products, but it never happened. Rather to that, Italy notified the Decree no. 228/2021 that just postpones the application of packaging labelling requirements included in the Legislative Decree no. 116/2020 and does not address any product characteristics or conditions of use as requested by article 1(f) of Directive 2015/1535 (via the unproper use of the emergency procedure since no unforeseeable or serious circumstances or public health or safety hazards warrant the urgent adoption of packaging labelling requirements).

2. Regarding the text of the Guideline on the labelling of packaging of the Ministry for the Ecological Transition:
    a. It is not adequately taken into account that the European law for medical devices (MD) and in vitro diagnostics (IVD) (European Regulations 745 and 746 of 2017 – Annex I) prevails on national law as *lex specialis*. Additionally, the Regulations (EU) 745 and 746 already provide for specific provisions regarding the safety, efficacy, intended use and correct storage/maintenance of products. These provisions involve the entire life cycle of the device, already including aspects of device labelling and disposal. Finally, there are several specific UNI EN ISO technical standards on the subject for medical devices and in vitro diagnostics (ISO 15223 Medical devices — Symbols to be used with information to be supplied by the manufacturer and ISO 20417 Medical devices - Information to be supplied by the manufacturer)
    b. The provision that "On all packaging (primary, secondary and tertiary) manufacturers must indicate the alpha-numeric code provided for in

Decision 97/129/EC" at page 5 of the draft guideline does not take adequately into account the specific characteristics of certain devices (e.g., provided in a sterile state) in which it is impossible to abide to such obligation on the primary packaging without affecting the safety and efficacy of the device itself and thein its conformity as assessed by the manufacturer.

c. The provisions regarding the use of digital technology, within the section *Special cases – Clarifications note from the Ministry for the Ecological Transition of 17 May 2021* (page 16) must be welcomed and considered as a general rule to abide to such obligations on a European level. However, the use of digital technology will not mitigate the negative economic impacts upon manufacturers, that will be asked to gathering resources to implement country-specific website or, more generally, to modify their own website. Additionally, despite the use of digital technology is welcomed and appreciated, it will not preserve industry from updating product artworks or stickers to redirect consumers to the dedicated webpage whereby the environmental information on packaging label would be included.

3. On a national level, it is useful to underline that the definition of medical waste, as per the Italian decree of the President of the Republic July 15, 2003, n. 254, already excludes health products from the general waste management provisions since they are already treated separately as "special waste". Thus, such provisions would be in contrast with the existent national legislation.

In conclusion, for all the aspects explained above, the application of Italian requirements for packaging labelling as set out in the Legislative Decree no. 116/2020 may create a barrier to the free movement of goods with the single market of the European Union and place higher costs for companies that place packaging on the Italian market than those that place packaging (only) on the territory of other Members States. This would constitute a measure having an equivalent effect to a quantitative restriction, or an obstacle to the free movement of goods within of European Union. Additionally, medical device and in vitro diagnostics have their own European Regulations applicable in all the Member States (Regulation 2017/745 and Regulation 2017/746) that already include specific provisions

regarding the safety, efficacy, intended use, pancaking and correct storage/maintenance of products that cannot be overtaken by a national law. For all these reasons, the Guidelines on the labelling of packaging, pursuant to Article 219(5) of Legislative Decree No 152/06 under notification should not be considered applicable and practicable by the European Commission.

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