GIRP position on the implementation of the Medical Devices Regulation (EU) 745/2017

Representing full-service healthcare distributors of medicinal products and medical devices, and in light of the challenges posed by the implementation of the Medical Devices Regulation, GIRP would like to express its concerns about the approaching deadlines for transitional periods under Article 120 of the Medical Devices Regulation.

Indeed, as admitted by the Medical Devices Coordination Group with data from April 2022, more than 90% of the AIMDD and MDD certificates will expire by the horizon 2024.[1] As a direct consequences of the expiry of current certificates arises a serious and real risk of shortages of medicinal products as medical devices not certified under the MDR will have not access to the EU market.[2] Such a situation is likely to endanger the health of patients across the entire European Union.

GIRP acknowledges the positive step taken towards the enhancement of the capacity of notified bodies, such as those adopted by the MDCG following the EPSCO Council meeting on 14 June 2022,[3] and welcomes the efforts of the European Commission to address the challenges posed by the implementation of the MDR. At the same time, GIRP fears that such recommendations are not sufficient to address the practical problems posed by compliance requirements of the Medical Devices Regulation. In addition, GIRP believes that further guidance is needed for issues specifically targeting distributors of medical devices, such as the sampling operations that distributors have to carry before making a device available on the market, in order to ensure the highest possible level of compliance and thus of safety of medical devices supplied to the patients.

GIRP supports the view, shared amongst the relevant stakeholders, that urgent action is needed in order to prevent a situation in which medical devices that are already placed on the market would neither be marketable, nor usable. In this regard, and as has been noted hereinabove, while the problems in the implementation of the Medical Devices Regulation have correctly been identified by the European Commission, GIRP is concerned that non-legislative action will not provide a proportionate and adequate answer to ensure a swift transition to the new requirements and as such, legislative action is needed. For this purpose, GIRP encourages the European Commission to use the opportunity of the upcoming meetings of health ministers to tackle both short term and long terms issues arising from the implementation of the MDR.

In this regard and in order to ensure the availability of medical devices across the European Union, and in particular in the case of existing devices that must undergo re-certification, GIRP invites the European institutions to consider:

- **Proposing the postponement** of the transitional period deadlines foreseen in Article 120 MDR;

- **Abrogating** Article 120(4) insofar as the current wording would impose an unnecessary destruction of medical devices already usable and placed on the market;

- **Envisaging** conditional certification or a risk based approach for the certification procedures in order to leave enough time to medical devices manufacturers to gather the necessary data to successfully obtain certificates and alleviate the burden put on the notified bodies.

Brussels, 23 November 2022

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[1] MDCG Position Paper, Notice to manufacturers to ensure timely compliance with MDR requirement, MDCG 2022-11, June 2022, https://health.ec.europa.eu/document/download/5ec4d600-d344-4232-9371-1d278b2abc12_en?filename=mdcg_2022-11_en_0.pdf

[2] Ibid.

[3] MDCG Position paper, Transition to the MDR and IVDR Notified body capacity and availability of medical devices and IVDs, MDCG 2022-14, August 2022, https://health.ec.europa.eu/document/download/2db053bc-283c-4d2e-93f4-c3e8032e66da_en?filename=mdcg_2022-14_en.pdf