European Parliament
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Plenary sitting

B10-0125/2024

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MOTION FOR A RESOLUTION

to wind up the debate on the statement by the Commission

pursuant to Rule 136(2) of the Rules of Procedure

on the urgent need to revise the Medical Devices Regulation
(2024/2849(RSP))

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on behalf of the PPE Group

B10-0125/2024

European Parliament resolution on the urgent need to revise the Medical Devices Regulation
(2024/2849(RSP))

The European Parliament,

– having regard to Article 168 of the Treaty on the Functioning of the European Union, which provides that ‘a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities’,

– having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR)[1], and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (IVDR)[2],

– having regard to the Commission’s 2023 implementation report on the MDR/IVDR[3],

– having regard to the European Medicines Agency’s 2023 Annual Report and its review on market access and safety concerns for medical devices[4],

– having regard to Rule 136(2) of its Rules of Procedure,

A. whereas medical devices and in vitro diagnostic medical devices play a crucial role in modern healthcare, directly affecting the health, safety and well-being of millions of patients across the EU;

B. whereas the introduction of the MDR and the IVDR was intended to strengthen the regulatory framework for medical devices and in vitro diagnostic medical devices, ensuring higher standards of safety, transparency and clinical performance, while also fostering innovation in the sector;

C. whereas despite these aims, significant challenges have been encountered in implementing the MDR and the IVDR, not only leading to delays but also resulting in failures to achieve certification and approval of medical devices and in vitro diagnostic medical devices, particularly impacting small- and medium-sized enterprises (SMEs), as well as resulting in shortages of medical devices and in vitro diagnostic medical devices, thus restricting patient access to innovative therapeutic and diagnostic technologies;

[1] OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
[2] OJ L 117, 5.5.2017, p. 176, ELI: http://data.europa.eu/eli/reg/2017/746/oj.
[3] https://health.ec.europa.eu/system/files/2023-01/mdr_proposal.pdf.
[4] European Medicines Agency, Annual Report 2023 – The European Medicines Agency’s contribution to science, medicines and health in 2023.

D. whereas many stakeholders, especially including SMEs, notified bodies and healthcare providers, have reported difficulties in navigating the complex and costly regulatory procedures under the current MDR and IVDR framework, with potential risks posed to the continuous availability of life-saving medical devices and critical in vitro diagnostic tests in Europe as manufacturers reduce their product portfolios and withdraw from the EU;

E. whereas recent scientific and market data point to concerns about shortages of capacity among notified bodies, leading to bottlenecks in the certification process, as well as a lack of clarity around the interpretation of several key provisions of the MDR and the IVDR;

F. whereas the COVID-19 pandemic further exposed vulnerabilities in the EU's supply chain for medical devices and in vitro diagnostic medical devices, highlighting the need for more flexible and efficient regulatory mechanisms to ensure timely access to essential devices during public health emergencies;

G. whereas given the rapid pace of innovation, including advances in digital health, artificial intelligence and personalised medicine, there is an urgent need to revise the MDR and the IVDR in order to accommodate new technologies and ensure that the regulatory framework remains fit for purpose;

H. whereas practical observations following the adoption of the MDR and the IVDR indicate that significant financial and administrative barriers for orphan and innovative devices stem from the complex procedures of conformity assessment, including obtaining scientific advice, fees required by notified bodies, the extensive and unpredictable duration of the conformity assessment process, and the associated costs;

I. whereas the MDR and the IVDR also present challenges for maintaining equitable access to devices across all of the Member States, with patients in less economically developed regions facing additional delays in accessing new technologies;

1. Calls on the Commission to put forward, in the first hundred days of the new mandate, a proposal for a systematic revision of Medical Devices Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR);

2. Recognises the significant contributions of the MDR and the IVDR to enhancing the safety and quality of medical devices, but stresses the need for an urgent review of some of its provisions to address the delays and bottlenecks that are currently hampering access to medical technologies; underlines that the review must aim to make full use of the mechanisms in Article 36(3) MDR to adopt implementing acts in order to resolve issues of divergent interpretation and of practical application to streamline the regulatory process, improve transparency and reduce the bureaucratic burden by eliminating any unnecessary administrative work for notified bodies and manufacturers, particularly SMEs, without compromising on patient safety;

3. Stresses the importance of increasing the capacity of notified bodies in order to ensure the timely certification of medical devices and in vitro diagnostic medical devices; urges the Member States and the Commission to implement measures that significantly increase the speed and efficiency of these bodies in order to address the critical demand

in the medical device sector;

4. Advocates for the abolition of re-certification for lower-risk products, including Class IIa and certain Class IIb devices, which should continue to be valid subject to appropriate surveillance by the notified body;

5. Asks the Commission also to consider the abolition of re-certification for implantable devices in Class IIb and devices in Class III, provided ongoing compliance with post-market surveillance and periodic safety update reports demonstrate that the devices perform as intended;

6. Asks the Commission also to consider the abolition of repeated re-certification for in-vitro diagnostic medical devices after an initial re-certification after five years, subject to appropriate surveillance by the notified body;

7. Advocates for the creation of transparent, harmonised, maximum durations for procedural steps in conformity assessments by notified bodies, which would create legal certainty for manufacturers regarding the market access procedure and its duration within the EU;

8. Demands the transparency and EU-wide harmonisation of notified bodies' fees and fee structures, published in a standardised EU dashboard to allow economic operators to compare notified bodies and make informed choices, ensuring that fees remain a fair compensation for the public service provided;

9. Calls for a revision of the qualification criteria for persons responsible for regulatory compliance (PRRCs) in the MDR and the IVDR; recommends that the criteria be changed to allow practical experience and training as an alternative to academic qualifications, thereby ensuring that a broader range of competencies are considered for the qualification of PRRCs;

10. Calls for the regulatory adaptation of the MDR and the IVDR to accommodate new technologies; recognises that the current framework of the MDR and the IVDR does not fully accommodate rapid advancements in medical technology, especially in fields such as digital health, AI-driven diagnostics and personalised medical devices; calls for amendments to the MDR and the IVDR to establish clear and fast-track pathways for the approval of innovative technologies, ensuring their safety and performance; proposes the introduction of a prioritisation procedure for innovative medical devices and in vitro diagnostic medical devices, including a fast-track approval process for breakthrough devices that are potentially life-saving or otherwise significantly improve the standard of care;

11. Calls for clear definitions of 'orphan device,' 'orphan population' and 'orphan subpopulation', as determined by the Medical Device Coordination Group in the MDR and the IVDR, to be given in order to provide legal clarity and facilitate the adoption of harmonised measures across the EU, thereby ensuring a high level of safety, quality and transparency in the granting of market access to critical medical devices and in vitro diagnostic medical devices;

12. Calls for the introduction of simplified rules for niche market (and orphan) medical

devices analogous to those in other jurisdictions, such as the US; emphasises the need for less burdensome conformity assessment procedures tailored to medical devices and in vitro diagnostic medical devices serving relatively small markets, such as products for the treatment of children or rare diseases;

13. Urges the creation of a register to monitor and ensure the safety and efficacy of these niche and orphan devices; suggests, further, the creation of EU-wide clinical registries, or the amalgamation of data from current national registries, in order to gather comprehensive clinical data on small patient groups that benefit from the availability of orphan devices; notes that this initiative aims to enhance the overall quality of care and support manufacturers in collecting necessary clinical data, especially in indications where multiple orphan devices are available, allowing for combined treatment data to be evaluated and published regularly; observes that the goal is to assure maximum transparency and safety while allowing a streamlined and less bureaucratic approach for niche and orphan devices;

14. Recognises the disproportionate regulatory burden faced by SMEs, which are responsible for the majority of products in the medical device and in vitro diagnostic medical device sector; highlights that this burden threatens to stifle innovation and reduce competition; urges the Commission to develop specific measures to support SMEs, including the provision of model application documents and forms, financial assistance, regulatory guidance and tailored certification pathways that reduce costs and complexity while maintaining high standards of patient safety; proposes the reduction of conformity assessment costs for SMEs by implementing specific provisions such as a reduction in fees, deferral of the payment of fees and provision of administrative assistance through a central EU contact point;

15. Calls for enhanced flexibility in the regulatory process during public health emergencies; stresses the need for a dynamic regulatory framework capable of a rapid response to public health crises, such as pandemics or unforeseen emergencies; urges the Commission to establish emergency provisions that allow for the temporary streamlining of certification processes for critical medical devices, ensuring that such adjustments do not compromise safety standards, thereby facilitating timely access to essential devices during times of crisis; calls for the Commission, in cooperation with the Health Emergency Preparedness and Response structure, to establish a non-exhaustive list of critical medical devices;

16. Calls for the establishment of a central governance structure or medical device office within the Commission’s Directorate-General for Health to centralise responsibilities and powers in the designation management and surveillance of notified bodies, the harmonisation of administrative practices, the development of guidance on the implementation and application of EU regulations applicable to medical devices and in vitro diagnostic medical devices, and the coordination of the applicability of other EU regulations to medical devices and in vitro diagnostic medical devices with other directorates-general of the Commission;

17. Calls for a stronger and more harmonised post-market surveillance system that makes use of real-world data and patient feedback to identify and address safety issues more rapidly; encourages, therefore, the establishment of a centralised EU database for post-

market data as part of the module for vigilance and post-market surveillance of the European Database on Medical Devices that ensures transparency and facilitates cross-border cooperation in monitoring device performance and addressing risks;

18. Calls on the Member States to inform the central governance structure or office of the results of notified body audits and specific instructions issued to notified bodies concerning administrative practices and conformity assessment procedures; highlights the need for this central governance structure or office to coordinate Member States' market surveillance and vigilance activities in order to enhance the efficiency of market surveillance across the EU;

19. Urges the Commission to strengthen international cooperation on the simplification, assimilation and mutual recognition of national certification processes, in particular with the US Food and Drug Administration;

20. Calls for an appropriate transition period before the implementation of new rules; emphasises the need to set a transition period before the enforcement of new regulations that would allow enough time for manufacturers to prepare and for the necessary institutional infrastructure to be established; notes that this measure ensures that all stakeholders are fully equipped to meet the regulatory requirements without compromising the overarching objectives of the legislation;

21. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.