European Parliament
2024-2029

Plenary sitting

B10-0124/2024

16.10.2024

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))

Andreas Glück
on behalf of the Renew Group

B10-0124/2024

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

The European Parliament,

– having regard to the Treaty on the Functioning of the European Union, in particular Article 168 thereof,

– 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[1] (the Medical Devices Regulation – MDR),

– having regard to 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[2] (the *In Vitro* Diagnostic Medical Devices Regulation – IVDR),

– having regard to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices[3],

– having regard to Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices[4],

– having regard to the Commission's 2023 report on the implementation of the MDR and the IVDR,

– having regard to Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment[5],

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

A. whereas access to quality medical devices and *in vitro* medical devices is indispensable for patients' health and for healthcare systems;

B. whereas more than 500 000 different medical devices are marketed in the EU, covering a broad range of products from plasters to x-ray machines, and they are used for

[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] OJ L 80, 20.3.2023, p. 24, ELI: http://data.europa.eu/eli/reg/2023/607/oj.
[4] OJ L 20, 31.1.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/123/oj.
[5] OJ L 458, 22.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/2282/oj.

diagnosis, prevention, treatment and rehabilitation and, overall, to improve the quality of life of patients and the work of healthcare professionals and carers;

C. whereas large differences still remain in access to medical devices across the EU, leading to healthcare inequalities;

D. whereas the MDR and the IVDR were adopted to strengthen the regulatory framework in response to several scandals involving the use of unsafe medical equipment, such as hip and breast implants; whereas patient safety and quality standards should never be compromised;

E. whereas the deadlines set in the MDR and the IVDR have been extended several times to give more time to device developers and notified bodies, and to avoid shortages of devices;

F. whereas despite these deadline extensions, healthcare professionals have reported shortages of medical devices and *in vitro* medical devices, especially for paediatric and orphan devices;

G. whereas it is still uncertain exactly which medical devices are at risk of withdrawal and shortages, because of a lack of transparency from notified bodies;

H. whereas the majority of developers of medical devices and *in vitro* medical devices are small and medium-sized enterprises with limited resources;

I. whereas the process of applying for certification can be burdensome, lengthy and expensive, especially in some Member States;

J. whereas many stakeholders, such as developers, patient organisations and healthcare providers, have reported difficulties in navigating the regulatory framework for medical and *in vitro* medical devices;

K. whereas increasing numbers of medical devices are supplied by producers in non-EU countries, some of which are autocratic regimes, raising concerns about the protection and possible misuse of personal medical data collected by medical devices;

1. Deplores the shortages of medical devices and the lack of access to certain medical devices in parts of the EU; stresses that access to and quality of healthcare, including medical devices, should not depend on where in the EU a patient is located;

2. Welcomes the increased capacity of notified bodies; invites the Member States and the Commission to assess whether measures can be taken to further improve the speed and efficiency of these notified bodies without jeopardising patient safety;

3. Stresses the need for more transparency, information and guidance from the authorising authorities to manufacturers undergoing the certification process, including information regarding notified body fees and fee structures; underlines that this is already possible under the current regulation;

4. Further stresses the need for greater transparency and better access to information for

patients organisations and healthcare professionals from notified bodies and from national authorities;

5. Underlines that product updates or adjustments should not necessarily lead to the need for a full recertification of the product; calls, in this regard, for harmonised guidance to ensure consistency for medical device developers across the EU;

6. Welcomes the non-legislative actions already initiated by the Commission and calls for further actions to be taken to counter shortages and reduce the administrative burdens, where possible;

7. Welcomes the pilot programme by the European Medicines Agency to support manufacturers producing and notified bodies certifying orphan devices in the processes of development and assessment;

8. Notes that post-authorisation market surveillance can be burdensome, and that a more harmonised approach could benefit both developers and the Member States;

9. Recalls that the MDR should be evaluated by 2027 at the latest; stresses, in this regard, the need for a proper evaluation and impact assessment; further stresses that all relevant stakeholders should be part of the evaluation process;

10. Believes that reducing administrative burdens and ensuring access to medical devices throughout the EU should be key considerations in the evaluation of the regulation;

11. Believes that the evaluation should also examine dependency on non-EU countries, including the protection of personal medical data;

12. Emphasises that any new rules or changes to existing rules must come with an appropriate transition period to allow all stakeholders sufficient time to adjust to change;

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