European Parliament
2024-2029

Plenary sitting

B10-0121/2024

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))

Catarina Martins
on behalf of The Left Group

B10-0121/2024

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 the Charter of Fundamental Rights of the European Union, in particular Article 35 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] (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] (IVDR),

– having regard to Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions[3],

– 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[4],

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

A. whereas medical devices play a pivotal role in the healthcare industry, facilitating the diagnosis, prevention, monitoring and treatment of various medical conditions;

B. whereas people rely on these devices every day and expect them to be safe, available and affordable;

C. whereas after a series of scandals, in which patient safety was jeopardised for profits, including cases of leaking breast implants, the new MDR and IVDR were agreed;

D. whereas these regulations updated the rules on the placing on the market of medical devices for human use and their accessories, as well as the rules for making such

[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 130, 24.4.2020, p. 18, ELI: http://data.europa.eu/eli/reg/2020/561/oj.
[4] OJ L 80, 20.3.2023, p. 24, ELI: http://data.europa.eu/eli/reg/2023/607/oj.

devices and accessories available on the market and putting them into service in the EU; whereas they also contain rules on how clinical investigations concerning such devices and accessories are carried out in the EU;

E. whereas the main aim of the regulations is to improve patient safety by introducing more stringent procedures for conformity assessment (to ensure that unsafe or non-compliant devices do not end up on the market) and post-market surveillance;

F. whereas in 2020, amending Regulation (EU) 2020/561 was adopted to allow EU Member States and their authorities and institutions to prioritise the fight against the COVID-19 pandemic; whereas the application of certain of the MDR's rules was deferred by one year to ensure the smooth functioning of the EU's internal market, to maintain a high level of public health protection and patient safety, to provide legal certainty and to avoid potential market disruption during the pandemic;

G. whereas in 2023, amending Regulation (EU) 2023/607 was adopted as regards the transitional provisions for certain medical devices and *in vitro* diagnostic medical devices, permitting extensions where needed;

H. whereas some of the manufacturers of medical devices remain persistently unprepared to meet the requirements of the regulations;

I. whereas some of the notified bodies who carry out the assessment and certification of medical devices have created an unpredictable work environment for manufacturers of medical devices;

J. whereas there is no clarity on any actual shortages of medical devices nor on risks posed by shortages for specific therapeutic areas; whereas more factual information is needed to properly address the situation;

K. whereas the European Database on Medical Devices (EUDAMED) is an integral part of the MDR and the IVDR;

1. Expresses its continued support for the strong and strict protection of patient health and safety, including through the correct implementation of the MDR and the IVDR; underlines that patient safety must never be compromised;

2. Regrets possible shortages of medical devices and risks thereof, notably in the areas of paediatric care and orphan devices, resulting mainly from a suboptimal implementation of the legal framework;

3. Points out that the President of the European Commission has tasked the Commissioner-designate for Health and Animal Welfare with ensuring 'the availability and competitiveness of medical devices, including by stepping up the implementation of current framework and evaluating the need for potential legislative changes';

4. Welcomes the Commission's ongoing non-legislative actions to support the transition to the new regulations, including advice and guidance on the clinical evidence needed for fee-free conformity assessment, training, coaching and internship activities for notified bodies and conformity assessment bodies, and support for the development of

innovative and orphan devices;

5. Stresses that the ongoing evaluation of the MDR and IVDR will generate much needed data and should be concluded and its results fully taken into account in any future revision of the MDR and IVDR, which should be accompanied by the customary full impact assessment;

6. Underlines that citizens, including patients in particular, as well as governments, civil society organisations and manufacturers of medical devices, have a right to information on the processes used by notified bodies for the certification of medical devices, including information on the timelines and fees;

7. Regrets the fact that notified bodies seem to have been misusing their critical position in the value chain, and points to the fact that this endangers patient safety and treatment options;

8. Expects all manufacturers of medical devices to be able to meet the requirements of the MDR and IVDR without any further delay;

9. Expects all notified bodies to ensure, through their work, that safe and reliable medical devices obtain timely and affordable access to the market, in a predictable and consistent manner;

10. Calls on the Commission to step up its efforts to ensure that the notified bodies use common and transparent working methods; invites the Commission to explore the possibility of ensuring more harmonisation, transparency and predictability of the certification processes, timelines and fees of the notified bodies, by means of implementing or delegated acts;

11. Calls on the Commission also to investigate ways to increase the transparency of the entire certification process conducted by notified bodies, to ensure that the public, civil society, academia and governments can scrutinise the work done; stresses that this would enhance the safety of the medical devices;

12. Calls for the full implementation of EUDAMED in accordance with the agreed timeline;

13. Underlines that any future legislative proposal on medical devices should be patient-centred and should put patient safety first;

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