Medical devices

2020/0060(COD) - 03/04/2020 - Legislative proposal

PURPOSE: to defer the application of certain provisions of Regulation (EU) 2017/745 on medical devices in order to allow Member States, health establishments and economic operators to give priority to the fight against the coronavirus pandemic.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2017/745 of the European Parliament and of the Council establishes a new regulatory framework to ensure the proper functioning of the internal market for medical devices. At the same time, it sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such devices. Regulation (EU) 2017/745 significantly reinforces key elements of the existing regulatory approach in Council Directive 90/385/EEC and Council Directive 93/42/EEC, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance, whilst introducing provisions ensuring transparency and traceability regarding medical devices, to improve health and safety.

The coronavirus pandemic and the resulting public health crisis represent an unprecedented challenge for Member States and a heavy burden for national authorities, health care institutions and economic operators.

The coronavirus crisis has created exceptional circumstances that require considerable additional resources and increased availability of vitally important medical devices such as medical gloves, surgical masks or intensive care equipment. None of these measures could reasonably have been anticipated at the time of the adoption of the Medical Devices Regulation.

These extraordinary circumstances have a significant impact on different areas covered by the Medical Devices Regulation. It is therefore very likely that Member States, health care institutions, economic operators and other stakeholders would not have been able to ensure its proper implementation and application from the date of application initially foreseen on 26 May 2020.

CONTENT: for exceptional reasons, in the current context of the coronavirus epidemic, the Commission proposes to defer by one year, to 26 May 2021, the date of application of the provisions of Regulation (EU) 2017/745 which should have applied from 26 May 2020.

The proposed amendment aims to achieve the objectives of Regulation (EU) 2017/745, namely the establishment of a rigorous, transparent, predictable and sustainable regulatory framework for medical devices that ensures a high level of protection of public health and patient safety and the proper functioning of the internal market for these devices.

At the same time, it is proposed to defer the date of repeal of Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices by one year. These postponements would ensure that an operational regulatory framework for medical devices would be in place from 26 May 2020.

In addition, the proposed amendment aims to ensure that, in exceptional cases, the Commission may adopt, as soon as possible, EU-wide derogations following national derogations, in order to effectively address potential shortages of vitally important medical devices in the EU.

In view of the urgent need to respond immediately to the public health crisis related to the COVID-19 pandemic, the proposed amending Regulation should enter into force as a matter of urgency.