Press release – Parliament decides to postpone new requirements for medical devices

Parliament adopted the Commission proposal on Friday, by urgent procedure with 693 votes to 1 and 2 abstentions, allowing the application of the Medical Devices Regulation to be postponed by one year until 26 May 2021.

Given the current pressure on national health authorities and manufacturers of medical devices, there is a fear that there could be shortages or delays in getting the medical devices needed to fight COVID-19, were they to follow the new rules of the Medical Devices Regulation from May this year.

The European Parliament is therefore supporting the proposal to postpone the application of this Regulation by one year to allow authorities and manufacturers alike to prioritise the fight against the coronavirus pandemic by continuing under current procedures.

Next steps

The proposal now also has to be approved by the member states and published in the Official Journal before it will enter into force. This is expected at the latest by 26 May.

Background

European legislation ensures that medical devices are safe to use and facilitates patients' access to devices on the European market.

In 2017, two new regulations on medical devices and in vitro diagnostic medical devices were adopted to improve patient safety and increase transparency on medical devices across the EU. The new regulation for medical

devices was supposed to be fully applicable on 26 May 2020. The date of application of the In Vitro Diagnostics Medical Devices Regulation is not affected by the new proposal and becomes applicable from 26 May 2022, as planned.