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**INT/907**

**Medical devices/Dates of application**

**POSITION PAPER**

European Economic and Social Committee

**Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions**[COM(2020) 144 final – 2020/0060 (COD)]

Rapporteur-general: **Renate** **HEINISCH**

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| Legal basis | Articles 114, 168(4) and 304 of the Treaty on the Functioning of the European Union |
| Section responsible | Single Market, Production and Consumption |
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# **Conclusions and recommendations**

## The EESC, taking into account the extraordinary circumstances created by the COVID-19 crisis and its impact on various areas covered by Regulation (EU) 2017/745, supports the Commission proposal, which in the Committee's view is an appropriate and necessary measure to ensure a high level of protection of health and the economic interest of this sector.

# **Commission proposal**

## Regulation (EU) 2017/745 of 5 April 2017[[1]](#footnote-1) establishes a new regulatory framework to ensure the smooth functioning of the internal market as regards medical devices covered by that Regulation, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector.

## The COVID-19 outbreak and the current public health crisis represent an unprecedented challenge to the Member States and a significant burden for national authorities, health institutions, healthcare professionals, EU citizens and economic operators. Additional resources and increased availability of vital medical devices are required. This substantial and additional demand was not, and could not, have been foreseen when Regulation (EU) 2017/745 was adopted.

## As a consequence, it is very likely that Member States, health institutions, economic operators and other stakeholders will not be able to ensure the proper implementation and application of the Regulation from 26 May 2020, as provided for in the Regulation.

## The current proposal aims at ensuring the objectives of the Regulation by deferring the application of certain provisions of Regulation (EU) 2017/745 by one year. It also implies deferring the date of repeal of Directives 90/385/EEC and 93/42/EEC until 26 May 2021. Moreover, it also aims to make EU-wide derogations from the normal conformity assessment procedures for specific devices in the interest of public health possible, in order to address potential shortages of vitally important devices in an effective manner.

# **General comments**

## The EESC reiterates the conviction, often expressed in its opinions, that health is a major priority for Europe's citizens, and reaffirms that medical devices play a crucial role in preventing, diagnosing and treating diseases. They are central to our health and to the quality of life of people suffering from diseases and disabilities.

## The EESC would also like to draw attention to the fact that, due to its high innovation capacity and its high-skilled jobs, this sector is an important part of the European economy. It is therefore important not only to ensure the highest possible level of health protection, but also to take into account the interests of the industry, in which 80% of manufacturers are micro, small or medium-sized enterprises.

## The EESC is well aware that the COVID-19 crisis has created extraordinary circumstances that have an impact on various areas covered by Regulation (EU) 2017/745. That is true, for example, in the case of placing and making available on the market medical devices such as medical gloves, surgical masks, equipment for intensive care and other medical equipment that plays a crucial role in the context of the COVID-19 crisis.

## The crisis has therefore created a major and unprecedented challenge for the healthcare systems of the Member States and placed a serious burden on all of the stakeholders involved (health institutions, healthcare professions, patients and economic operators). It is therefore likely that they cannot guarantee the proper implementation and application of the Regulation by the date initially set out (26 May 2020).

## The EESC therefore supports the one-year extension provided for in the proposal as a reasonable measure aimed at guaranteeing the smooth functioning of the internal market, a high level of protection of public health and patient safety, and legal certainty, as well as at avoiding potential market disruption.

## Finally, the EESC would like to reiterate the request made in its previous opinion on this topic, namely that the functioning of the Regulation should be formally reviewed, jointly by authorities and stakeholders from civil society, three years after its entry into force, to ensure that its objectives are being met.

Luca JAHIER
President of the European Economic and Social Committee

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1. 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 ([OJ L 117, 5.5.2017, p. 1](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2017:117:SOM:EN:HTML)) – EESC opinion: [OJ C 133, 9.5.2013, p. 52](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:133:SOM:EN:HTML). [↑](#footnote-ref-1)