European Economic and Social Committee

OPINION

European Economic and Social Committee

In vitro medical devices/ Transitional provisions

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices [COM(2021) 627 final - 2021/0323 (COD)]

INT/970

Rapporteur: **Christophe LEFÈVRE**

www.eesc.europa.eu

EN

www.eesc.europa.eu/facebook www.eesc.europa.eu/twitter www.eesc.europa.eu/linkedin www.eesc.europa.eu/instagram

Referral	European Parliament, 18/10/2021 Council, 22/10/2021
Legal basis	Articles 114 and 168(4)(c) of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted at plenary	08/12/2021
Plenary session No	565
Outcome of vote (for/against/abstentions)	206/0/4

1. Conclusions and recommendations

1.1 The EESC, taking into account the extraordinary circumstances created by the SARS-CoV-2 (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.

1.2 The EESC emphasises that health is a high priority for Europe's citizens and reaffirms that in vitro diagnostic medical devices play a crucial role in the prevention, diagnosis and treatment of diseases[1]. They are central to our health and to the quality of life of people suffering from diseases and disabilities, even more so during a global pandemic.

1.3 The EESC welcomes the concern expressed by the Parliament and the Council of Health Ministers (EPSCO) of 15 June 2021 at the extremely critical situation and their call to the Commission to present as a matter of urgency a legislative proposal to facilitate the transition to the new regulatory framework and to ensure the availability of in vitro diagnostic medical devices on the EU market.

1.4 The EESC considers it essential that citizens are able to trust the reliability of these tests. The aim is to considerably reduce the proportion of both "false positive", and "false negative" results. Only 8% of all in vitro diagnostic devices available on the market are subject to monitoring by notified bodies under Directive 98/79/EC, compared to a target of 80% of in vitro diagnostic medical devices set in this draft Regulation.

1.5 The EESC is therefore fully in favour of rapidly increasing the certification capacity of in vitro diagnostic devices.

1.6 The EESC also recommends that the results of these tests receive specific medical support in the event of a positive result, particularly where devices can be used by individuals to carry out tests themselves.

1.7 The EESC notes that postponing the date of application by one year would not solve the problems regarding implementation of Regulation (EU) 2017/746 and that a gradual introduction of the requirements of the new regulation over a longer period of time should be allowed, while giving priority to high-risk in vitro diagnostic medical devices. This can be achieved by amending Article 110 of the Regulation, which concerns transitional provisions, providing a period for existing higher risk class devices that is shorter than the one for existing lower risk class devices. At the same time, the existing transitional period for devices covered by notified body certificates issued under Directive 98/79/EC should be extended by one year, until 26 May 2025.

1 EESC opinion, OJ C 133, 9.5.2013, p. 52.

1.8 The EESC therefore supports the Commission's proposals to:

- extend the transitional period for devices covered by a certificate issued under Directive 98/79/EC;
- introduce tailor-made transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time;
- introduce a transitional period for requirements applicable to devices manufactured and used within the same healthcare facility.

2. The Commission proposal

2.1 Directive 98/79/EC[2] on in vitro diagnostic medical devices will be replaced as of 26 May 2022 by Regulation (EU) 2017/746[3] establishing a new regulatory framework for these devices (HIV tests, pregnancy tests or SARS-CoV-2 tests)[4].

2.2 The new regulation aims to ensure the smooth functioning of the internal market and a high level of protection of public health, patients and users, taking into account the high number of SMEs active in this sector.

2.3 One of the main changes concerns the involvement of independent conformity assessment bodies. With the new Regulation, around 80% of in vitro diagnostic medical devices will be under the control of notified bodies (compared to 8% at present). This means that manufacturers will have to apply to a notified body and obtain one or more certificates following a procedure that takes approximately one year.

2.4 Article 110 of Regulation (EU) 2017/746 contains transitional provisions for devices with a certificate issued by a notified body in accordance with Directive 98/79/EC prior to 26 May 2022.

2.5 The COVID-19 pandemic has confirmed the need for a regulatory framework for in vitro diagnostic medical devices in the EU but has also given rise to additional, unprecedented challenges for the implementation of Regulation (EU) 2017/746.

2.6 Thus, substantial additional resources have been necessary from Member States' competent authorities, health institutions, notified bodies, manufacturers and other economic operators to increase the availability of vitally important medical diagnostics.

2.7 The fact that the six currently designated notified bodies are located in only three countries (Germany, France and the Netherlands) also makes the situation particularly difficult for SMEs in other Member States. In addition, travel restrictions have hampered, and continue to hamper the proper conduct of conformity assessment by notified bodies.

---

2 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). EESC opinion, OJ C 18, 22.1.1996, p. 12.

3 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (OJ L 117, 5.05 2017, p. 176). EESC opinion, OJ C 133, 9.5.2013, p. 52.

4 According to the Commission, around 70% of clinical decisions are made using in vitro diagnostic medical devices.

2.8 This proposal therefore aims to:

- extend the existing transitional period for devices covered by a certificate issued under Directive 98/79/EC;
- introduce tailor-made transitional periods for devices that are to undergo a conformity assessment involving notified bodies for the first time, in accordance with Regulation (EU) 2017/746;
- introduce a transitional period for requirements applicable to devices manufactured and used within the same healthcare facility. This will give health institutions extra time to comply with the new requirements and ensure that in-house tests, which are often essential – especially for rare diseases – can continue to be developed in clinical laboratories.

3. General comments

3.1 The EESC reiterates its conviction, previously expressed in its opinion on the current Regulation ((EU) 2017/746)[5] that "health is a high priority for Europe's citizens" and that "in vitro diagnostic medical devices play a crucial role in prevention, diagnosis and treatment of diseases". They are central to our health and to the quality of life of people suffering and managing their diseases and disabilities, even more so during a pandemic.

3.2 In this context, the EESC had therefore welcomed the recast of the current regulatory system, which strengthened pre-market approval procedures and in particular post-market surveillance. This responds to the needs of citizens for patient safety and efficacy.

3.3 The EESC would also emphasise that, due to its high innovation capacity and its high-skilled jobs, this sector represents 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 small, medium-sized and micro-enterprises.

3.4 The EESC is well aware that the COVID-19 crisis has created extraordinary circumstances which are having an impact on various areas covered by Regulation (EU) 2017/746.

3.5 The crisis created a major, unprecedented challenge for the healthcare systems of the Member States and a serious burden for all stakeholders involved (health institutions, healthcare professions, patients and economic operators).

3.6 The EESC therefore recognises that not all of these stakeholders, which are essential to the operation of healthcare systems, will be able to guarantee the proper implementation and application of the Regulation on the dates initially provided.

3.7 The EESC welcomes the concern expressed by the Parliament and the Council of Health Ministers (EPSCO) of 15 June 2021 at the extremely critical situation and their call to the Commission to present as a matter of urgency a legislative proposal to facilitate the transition to

5 EESC opinion, OJ C 133, 9.5.2013, p. 52.

the new regulatory framework and to ensure the availability of in vitro diagnostic medical devices on the EU market.

3.8 The EESC considers it essential that citizens are able to trust the reliability of these tests. The aim is to considerably reduce the proportion of both "false positive", and "false negative" results. Only 8% of all in vitro diagnostic devices available on the market are subject to monitoring by notified bodies under Directive 98/79/EC, compared to a target of 80% of in vitro diagnostic medical devices set in this draft Regulation.

3.9 The EESC is therefore fully in favour of rapidly increasing the certification capacity of in vitro diagnostic devices.

3.10 The EESC also reiterates that the results of these tests should receive specific medical support in the event of a positive result, particularly where devices can be used by individuals to carry out tests themselves.

3.11 The EESC notes that postponing the date of application by one year would not solve the problems regarding implementation of Regulation (EU) 2017/746 and that a gradual introduction of the requirements of the new regulation over a longer period of time should be allowed, while giving priority to high-risk in vitro diagnostic medical devices. This can be achieved by amending Article 110 of the Regulation on transitional provisions, providing a period for existing higher risk class devices that is shorter than the one for existing lower risk class devices. At the same time, the existing transitional period for devices covered by notified body certificates issued under Directive 98/79/EC should be extended by one year, until 26 May 2025.

3.12 The EESC therefore supports the Commission's proposals to:

- extend the transitional period for devices covered by a certificate issued under Directive 98/79/EC;
- introduce tailor-made transitional periods for devices that have to undergo a conformity assessment involving notified bodies for the first time;
- introduce a transitional period for requirements applicable to devices manufactured and used within the same healthcare facility.

3.13 The EESC considers these provisions reasonable to ensure the proper functioning of the internal market, a high level of protection of public health and patient safety and legal certainty, and, in thereby, to avoid possible market disruptions.

3.14 Lastly, the EESC stresses, as it did previously in its opinion on Regulation (EU) 2017/746, that civil society should be more closely involved in setting the relevant regulatory framework, and again proposes the establishment of an "advisory committee" composed of representatives of legitimate stakeholders organised at the European level. Such a committee should act in parallel and work with the Medical Device Coordination Group (MDCG), advising the Commission and Member States on various aspects of medical technology and implementation of the legislation.

Brussels, 8 December 2021

Christa SCHWENG
The president of the European Economic and Social Committee