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(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment

(Text with EEA relevance)

(2021/C 8/01)

1. Legal requirements

Regulation (EU) 2017/745 ([1]) ('the medical devices Regulation') and Regulation (EU) 2017/746 ([2]) ('the *in vitro* diagnostic medical devices Regulation'), hereafter in this notice referred to as 'the medical devices Regulations', lay down, in their respective Chapter I of Annex IX, sections 2.3 and 3.3, requirements related to a quality management system to be undertaken by manufacturers prior to placing on the market or putting into service a device, according to the provisions established by Article 52 of the medical devices Regulation and Article 48 of the *in vitro* diagnostic medical devices Regulation.

These requirements are subject to the conformity assessment to be carried out by third-party bodies designated under the medical devices Regulations ('notified bodies'). The conformity assessment procedure includes specific provisions concerning audits and surveillance assessments too. In particular, the assessment procedure of the manufacturer's quality management system performed by the notified body shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes. Similarly, the surveillance assessment performed by the notified body, at least once every 12 months, shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.

Under Article 44(2) of the medical devices Regulation and Article 40(2) of the *in vitro* diagnostic medical devices Regulation, the national authorities responsible for notified bodies shall monitor the notified bodies established on their territory and their subsidiaries and subcontractors, to ensure on-going compliance with the requirements and the fulfilment of obligations set out in the medical devices Regulations. According to Article 46(4) of the medical devices Regulation and Article 42(4) of the *in vitro* diagnostic medical devices Regulation, where an authority responsible for notified bodies has ascertained that a notified body is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to fulfil those obligations.

([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).

([2]) 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 (OJ L 117, 5.5.2017, p. 176).

According to Article 113 of the medical devices Regulation and Article 106 of the *in vitro* diagnostic medical devices Regulation, Member States shall lay down the rules on penalties applicable for infringement of the provisions of these Regulations and shall take all measures necessary to ensure that they are implemented. The penalties determined must be effective, proportionate and dissuasive.

2. **The exceptional circumstances in the context of the COVID-19 pandemic**

Member States, as well as notified bodies and other stakeholders, have informed the Commission that travel and quarantine restrictions imposed in response to the COVID-19 pandemic, both in Member States and non-EU countries, have significantly affected notified bodies' ability to conduct on-site audits on the premises of manufacturers and their supplies and/or subcontractors.

In addition, the current epidemiological indicators for COVID-19 in the EU and around the world, and the short-term forecast, make the situation more serious and increase the need to possibly take temporary extraordinary measures in specific cases when the inability of notified bodies to conduct on-site audits could raise the risk of shortages of vital devices.

Calls for the possibility to take temporary extraordinary measures, including remote audits, related to notified body on-site audits under the medical devices Regulations have been made by industry as well as notified bodies.

The potential risks related to inability for notified bodies to carry out conformity assessment activities in the context of COVID-19 circumstances and consequent travel restrictions had been discussed by the Medical Devices Coordination Group (MDCG) in their meetings in October and December 2020. As result, the potential need, in exceptional circumstances, to take temporary extraordinary measures, including remote audits, was recognised by the MDCG and supported by the vast majority of the Member States.

3. **Considerations by the Commission**

The Commission would like to hereby comment on the situation.

First of all, the Commission recalls the obligation of Member States authorities to monitor notified bodies established on their territory, to ensure compliance with the requirements for audits set out in Chapter I of Annex IX, sections 2.3 and 3.3, under due consideration of the principle of proportionality.

Secondly, as regards the imposition of penalties in accordance with Articles 113 and 106 respectively of the medical devices Regulations, the Commission recalls the requirement to apply any national provisions on penalties for breaches of the requirements laid down in these Regulations, also considering the principle of proportionality.

In that context, and in order to apply the general principles of Union law effectively, the following cumulative set of circumstances should be considered:

1. the exceptional and unforeseen circumstances caused by the COVID-19 crisis;

2. the need to ensure continuous availability of safe and performant medical devices and *in vitro* diagnostic medical devices, and to help prevent the risk of shortages of such devices within the EU in the interest of public health, especially when devices are clinically necessary during the period of COVID-19 restrictions;

3. compliance with the requirement for on-site audits in the medical devices Regulations generally serves to verify conformity with regard to manufacturing and other relevant on-site processes. Although, at this time, it has not been possible to fully quantify the impact of the need referred to in point 2 above, information at the disposal of the Commission on notified bodies' use of extraordinary measures, including remote audits, related to assessments performed under the medical devices Directives ([3]) appears to demonstrate an adequate level of safety and not to compromise the overall reliability of such assessments. This is provided that these measures are taken only following an objective case-by-case analysis of each individual situation in light of the relevant circumstances, including travel restrictions and national orders, to identify if there are concrete obstacles, which would prevent the taking place of a safe on-site audit and where the inability to carry out such an on-site audit could prevent granting access or ensuring continued supply of devices to the market.

([3]) In April this year, the MDCG endorsed guidance on temporary extraordinary measures related to notified body audits (MDCG 2020-4) under Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC.

However, the failure of notified bodies to carry out on-site audits should:

— be limited in duration, namely any notified body's decision on certification is limited to the time strictly necessary to allow for a proper on-site audit to take place as soon as possible;

— be identified and justified on a case-by-case basis, and the individual circumstances should be documented and duly substantiated by the notified body; and

— not go beyond what is required to ensure continuous availability of safe and performant devices, when concrete obstacles to complete conformity assessments on-site have been created by COVID-19 circumstances.

In addition, authorities responsible for notified bodies should ensure that notified bodies, when carrying out their audits and assessments, always act responsibly and apply a risk-based approach. This approach requires authorities to confirm notified bodies always perform a careful review of the manufacturer's technical documentation relating to the status and operations concerning the audits and devices in question. The activities conducted at the site to be audited, the manufacturer's quality management system and, where applicable, the level of compliance from previous audits should be taken into due account by the notified bodies. Following this review, a risk analysis should be conducted by the notified bodies, and the results documented and duly substantiated. No decision that could jeopardize the technical or clinical validity of a specific activity or the safety and performance of devices should be taken.

The above-mentioned temporary extraordinary measures taken in response to the exceptional circumstances of the COVID-19 should only be used during a limited period of time until on-site audits are again possible.

The Commission will closely and regularly monitor the situation related to the implementation of the medical devices Regulations, including in particular the provisions on conformity assessment. This will require close cooperation with the authorities responsible for notified bodies as well as the national competent authorities of the Member States. In particular, given the difficulties to fully quantify the extent of the problem in advance, namely the need to recourse to extraordinary temporary measures in order to ensure continuous availability of devices and prevent the potential risk of shortages, it is vital to carefully follow how these measures are applied in practice.

Therefore, the Commission invites all Member States to systematically notify the use of temporary extraordinary measures and submit information about:

1. measures taken by individual notified bodies (including identification of the notified body and affected types of devices and manufacturers) to perform conformity assessment not in compliance with the on-site requirements for audits, also in case of surveillance assessment, including information to justify the use of such measures; and
2. the period of time for which certificates issued by notified bodies following the abovementioned will be affected by non-compliant procedures concerning audits not performed on-site.