

UPDATES

New Important EU Guidelines on Union-Wide Derogations and Clinical Investigations Safety Reporting for Medical Devices

June 9, 2020

In response to the COVID-19 pandemic, the EU legislator published an amendment to the EU Medical Devices Regulation (MDR) delaying its application by one year to May 26, 2021 (see Sidley Update [here](#)). The amending regulation entered into force on April 24, 2020.

The amending regulation also modifies Article 59 of the MDR to allow the immediate application of the Union-wide emergency procedure in the context of the COVID-19 pandemic. Recently, the European Commission (Commission) communicated guidelines on the adoption of Union-wide derogations for medical devices in accordance with Article 59 (Guidelines).

In addition, the Commission's Medical Device Coordination Group (MDCG) issued key guidance on safety reporting in clinical investigations of medical devices under the MDR. This Sidley Update highlights the key aspects of these new important guidelines.

Union-Wide Derogations

Article 59 of the MDR empowers EU Member States to authorize non-CE-marked medical devices in exceptional circumstances. It also permits the Commission to extend the validity of such national derogations for a limited period of time to the entire Union via a Union-wide emergency procedure.

As amended, the MDR makes the Union-wide emergency procedure immediately applicable. The MDR now also extends its Article 59 to national derogations granted under Article 11(13) of the EU Medical Devices Directive (MDD) prior to or after the adoption of the amending regulation.

The Guidelines provide further detail on the adoption process of the Union-wide derogations to facilitate access of much-needed non-CE-marked medical devices on the EU market. The adoption process is divided into three steps:

1. As a first step, the Commission will consult the EU Member States via the MDCG to determine

whether a national derogation could be of Union relevance.

2. As a second step, where the potential Union relevance has been identified, the Commission will assess whether the procedural requirements referred to in subsection A of section 3 of the Guidelines have been met.
3. As a third step, the Commission will decide, on the basis of the requirements in sub section B of section 3 of the Guidelines, whether the extension of national derogations to the territory of the Union is necessary and justified.

Required documentation from manufacturers should contain, in particular:

- An explanation as to why the conformity assessment procedure has not been initiated or completed before placing the medical device on the market
- An explanation of the vitally important use of the medical device, which should be supported by statement(s) of health institution(s), including the reasons why the medical device cannot be substituted
- A detailed plan on how to ensure compliance or withdrawal of the medical device from the market after the temporary derogation expired

The Guidelines are of crucial importance to the MedTech industry in the context of the current COVID-19 global outbreak. The Union-wide emergency procedure aims to make certain medical devices available faster in response to the demand for non-CE-marked medical devices such as surgical masks and exploration gloves, which has seen an exponential growth. The Commission and the EU Member States are now allowed to effectively address potential shortages at the EU level of vitally important medical devices.

Clinical Investigations Safety Reporting

The MDCG recently published its guidance document [MDCG 2020–10/1](#) on safety reporting in clinical investigations of medical devices under the MDR (Guidance). The Guidance is accompanied by document [MDCG 2020–10/2](#), which is the Clinical Investigation Summary Safety Report Form (new form, currently version 1.0).

The Guidance explains the transition to the new reporting scheme under Eudamed, including:

- Obligations and requirements relating to performing safety reporting via Eudamed will not apply immediately on the date of publication of the notice declaring that the new version 3 of Eudamed is available and fully functional (Eudamed application date), but only six months after.

However, there will not be an immediate transition to safety reporting via the new version 3 of Eudamed as from six months after the Eudamed application date. Sponsors of ongoing clinical investigations at that time must continue submitting follow up and final report events to the national competent authorities by the same procedure used to submit the initial reports.

- Reporting of serious adverse events must be carried out according to the MDR requirements using the new form as from May 26, 2021. However, it remains unclear whether retrospective

uploading of previous event reports to the new version 3 of Eudamed will be required or even possible.

The MedTech industry should take note of this important Guidance and its accompanying new form to prepare for the application of the MDR, which will apply in only one year.

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