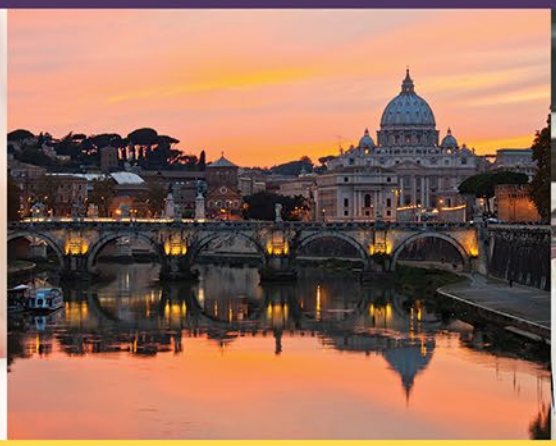
EU

Medical Device Vigilance Reporting in Europe

A review of Incident Reporting and FSCA reports you must submit to Competent Authorities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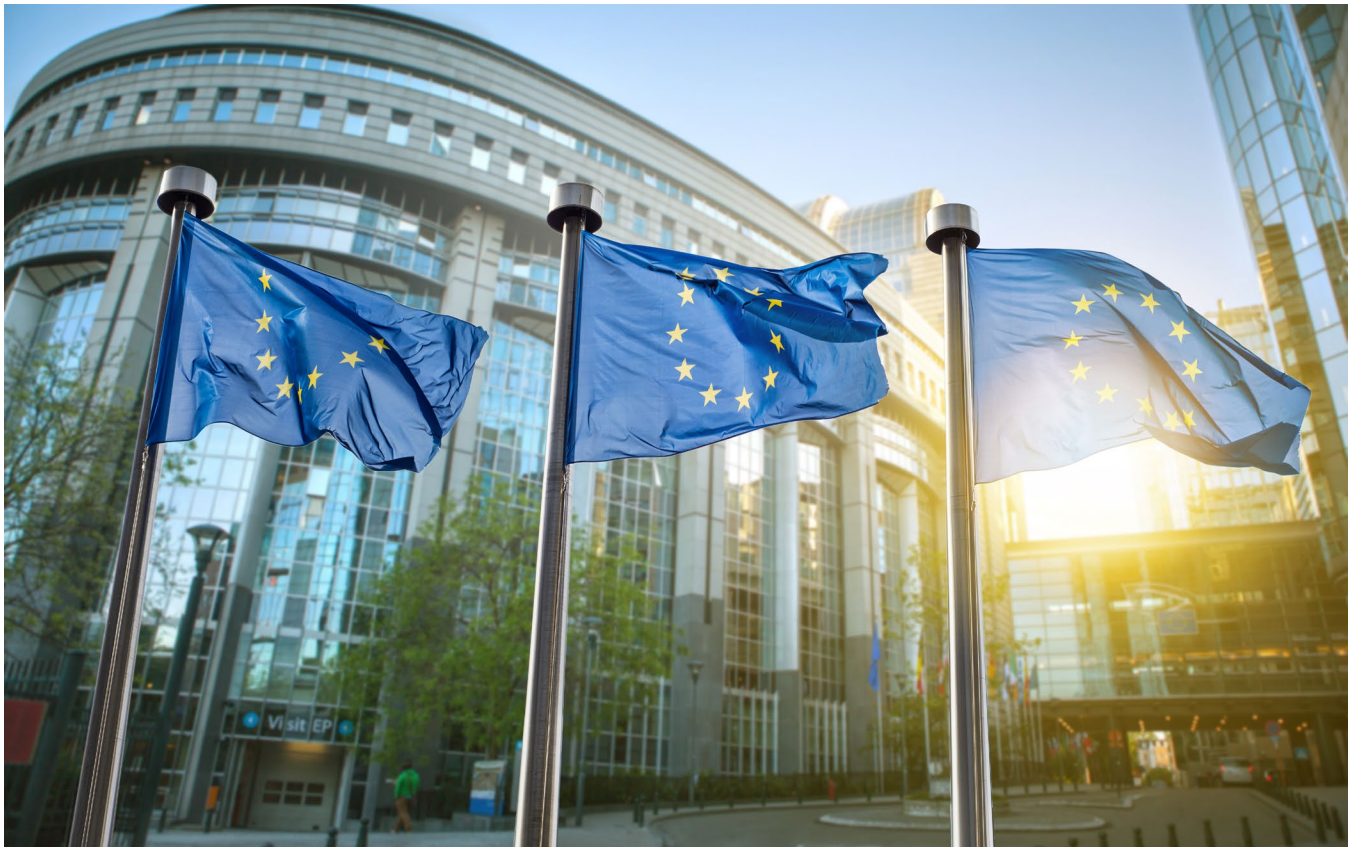
Some Background on Vigilance Reporting in Europe

A Note to Readers
The European Medical Devices Directive (93/42/EEC) stipulates that manufacturers are legally obligated to report adverse events, incidents, and recalls. But, according to the European Commission and European Competent Authorities, medical device vigilance reporting remains low enough to assume that underreporting is still widespread.

Medical device vigilance reporting is a confusing subject for many manufacturers active in European markets. MEDDEV 2.12/1 is the European guidance document on vigilance reporting and it has been revised many times over the years. In this whitepaper, we'll discuss which types of incidents must be reported to Competent Authorities and which do not.

Events involving medical devices that occur in the EU need to be assessed to determine if they meet the criteria for reportable incidents. In some cases, the incident may require a recall (the EU moniker is Field Safety Corrective Action (FSCA)). If a manufacturer performs an FSCA in the EU, that action needs to be reported through an FSCA Report to the relevant Competent Authorities. In addition, if there is an FSCA performed outside the EU that impacts devices in the Union, this would also need to be reported as an FSCA (Report in) the EU.

The term vigilance report encompasses Incident Reports and FSCA Reports. In addition, the manufacturer should provide the vigilance report to their Notified Body if the manufacturer possesses a CE marking certificate that was issued by a Notified Body for their device. However, this paper does not focus on reporting to Notified Bodies.



To Report or Not to Report?

Manufacturers are often reluctant to file vigilance reports with Competent Authorities because doing so may be construed as an implicit admission of guilt. In fact, the opposite is true; filing a vigilance report will not cause regulators to automatically conclude that the medical device in question caused or contributed to an incident.

The overall purpose of the European vigilance reporting process is to safeguard public health and prevent problems from recurring in the future - to allocate blame.

In general, companies are respected for reporting vigilance, and such moves are often perceived as acts of responsible corporate citizens. Accordingly, Competent Authorities are more concerned about manufacturers who have no vigilance cases to report.

Common triggers of medical device vigilance reports:

- Failure of a device to perform its intended purpose even though the manufacturer's instructions were followed
- Poor or inadequate design or production of the device
- Labeling or Instructions for Use that are unclear, poorly written or omit crucial information needed to properly use the device
- New information that becomes available through use, testing or research
- Use error

What needs to be reported

Any medical device event that leads to or could have caused death or serious injury and that occurred in the EU must be reported to the relevant Competent Authorities. In addition, if a manufacturer takes an action to reduce the risk of death or serious deterioration in state of health (definition of FSCA), this is reportable as an FSCA Report to the relevant Competent Authorities.

Reportable vigilance can also stem from omissions of information, such as a manufacturer leaving out a critical step in its Instructions for Use (IFU) that could lead to injury or death. In instances of omissions, firms cannot simply reprint their Instructions for Use and hope nothing happens with their devices already available in European markets. One would also generally expect that such an IFU omission would be reported as an FSCA Report to all the Competent Authorities in territories where the device is marketed.

In some cases, a manufacturer may not have enough information available to immediately determine whether an event is reportable or not. For example, if a distributor tells you a hospital reported a patient injury involving your device, you or your distributor must follow-up with the hospital in question to learn more about the event.

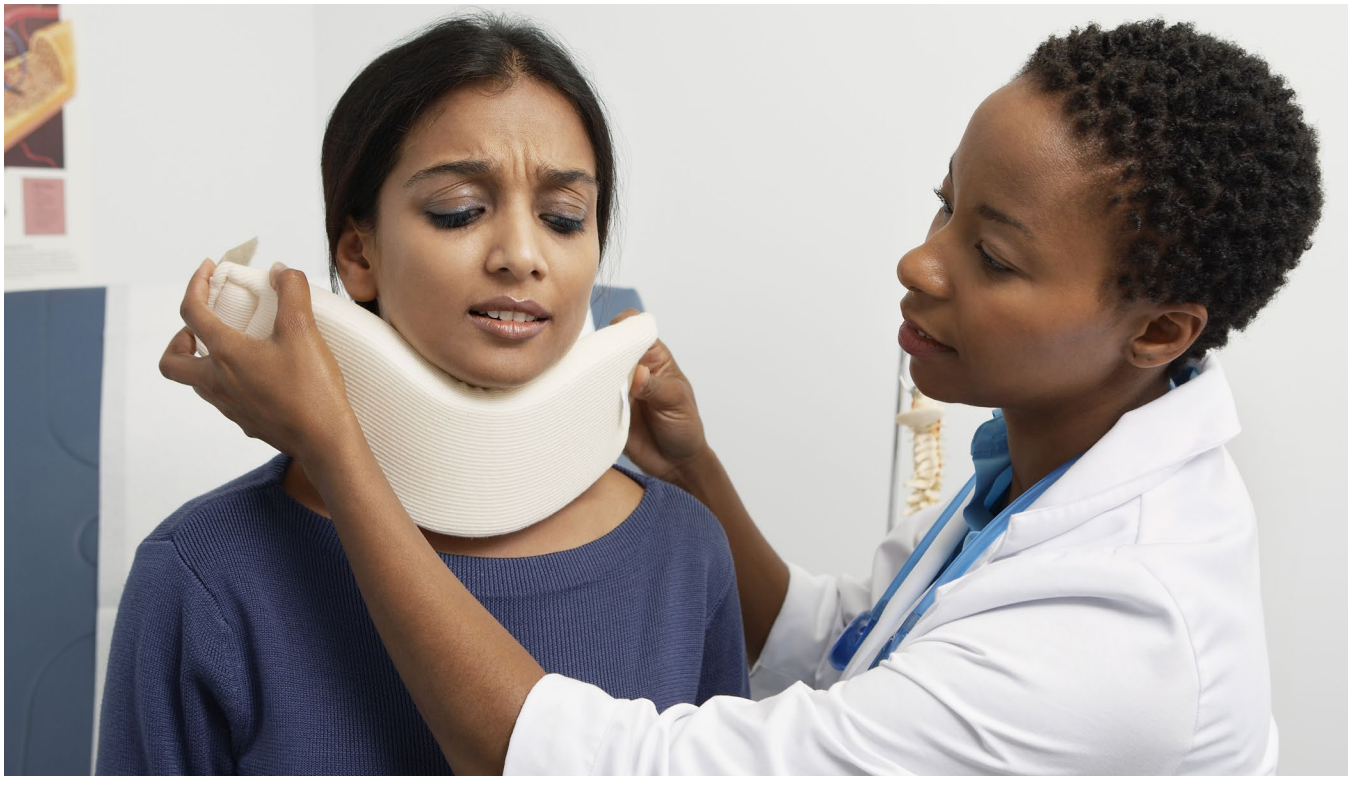
Competent Authorities expect manufacturers to make reasonable efforts to obtain enough information to determine if events with their devices are reportable. Enlist the support of your distributor and Authorized Representative.

You should also consider the opinion and track record of any healthcare provider involved in a potentially reportable incident. Your preliminary assessment of incidents involving your device should factor into your reporting decision.

What doesn't need to be reported

Some events do not require manufacturers to notify Competent Authorities, including:

- Problems or deficiencies found by a user before the device is used on a patient—unless failure to make such an observation could have resulted in injury to the patient.
- Incidents caused by patient conditions: In these cases, the manufacturer must prove that its device operated as intended and did not cause the incident or near incident. If too many such instances occur, however, the manufacturer may have to reappraise its risk analysis and possibly revise device label contents, and determine if a Trend Report is required. (Use error is reportable if it leads to serious injury or death.)
- Expired shelf or service life of the device: If an incident occurs due to a device exceeding its clearly specified serviceable or shelf life, there is no need to report.
- Device malfunction protection worked as intended: If your device included a built-in capability to prevent a malfunction from becoming a hazard, and no serious injury occurred due to a malfunction or "single fault," reporting is not required.
- Expected side effects listed on the device label: If use of your device may lead to expected and foreseen side effects that are clearly noted on your product labeling, incidents stemming from those side effects do not need to be reported to Competent Authorities.
- Advisory notice already issued: If you have already provided an advisory notice regarding an incident, in most cases you do not need to file individual reports, just summary reports as determined by Competent Authorities.



Reporting Deadlines

In Europe, manufacturers generally have 10 calendar days to file initial reports to Competent Authorities following incidents involving unanticipated serious injuries or deaths. For serious injuries and near incidents, firms have 30 calendar days to file reports. Serious public health threats have a two-day deadline. Again, note that manufacturers should inform Notified Bodies of vigilance reports.

Once you submit your initial report to the appropriate Competent Authority (the member state where the event occurred), the regulator should provide you with an acknowledgement of receipt and classify your report based on factors including date, outcome, and device type. The manufacturer is also expected to provide a date when the next report will be submitted. Upon receiving an initial report from a manufacturer, a Competent Authority will not usually circulate that report to other Competent Authorities.

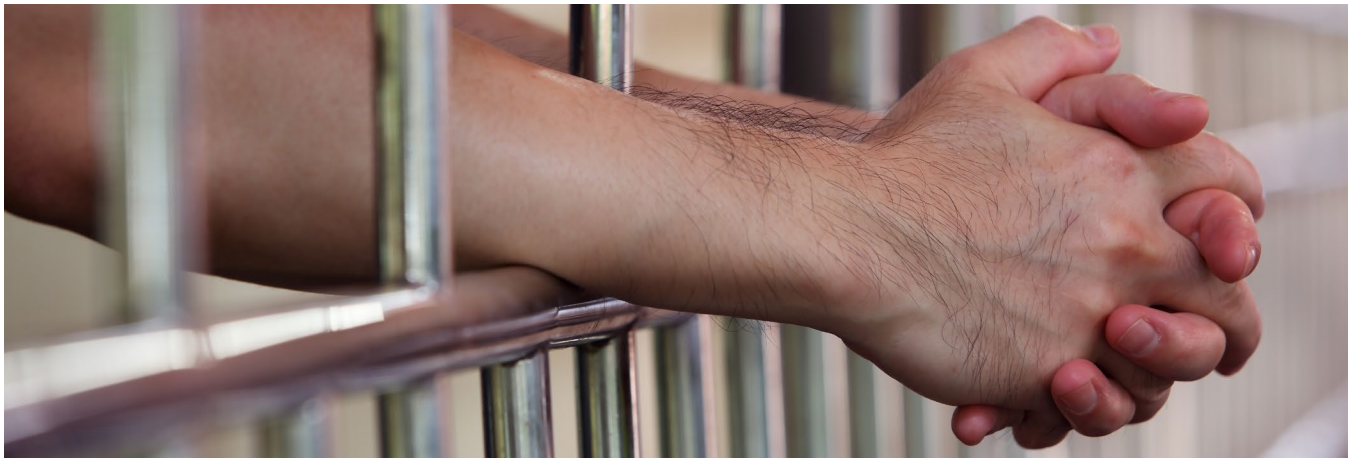
There are no published deadlines for FSCA Reports, though it is expected that these will be immediately submitted to the relevant Competent Authorities.

In certain serious cases, the Competent Authority will communicate with other Competent Authorities in markets that may be affected—though this seems to be the exception. Keep in mind, however, that such arrangements do not preclude other Competent Authorities from initiating their own investigations.

The clock starts ticking the day you or your Authorized Representative receives notice of an incident or near incident—even if it's 5:00 p.m. on a Friday afternoon. By Monday morning, you're already on Day 4, so act fast. If your product has caused an unanticipated serious injury or death, it becomes a moral obligation to report the incident immediately according to the vigilance guidance. You must also submit a final report to your Competent Authority within 30 days of your initial report or inform the Competent Authority of when to expect the next report.

Consequences of not reporting an incident

What might happen if you, the manufacturer, fail to submit an incident report in a timely manner—or at all—to your Competent Authority? European member states have different criminal regimens in place for firms that violate reporting time limits or under-report incidents. Financial penalties are severe. Regulators in Germany, France, and the UK may also issue jail sentences to repeat or serious first-time offenders.



If you already obtained CE Marking to commercialize your device in Europe, you likely have procedures in place for incident reporting. Ensure your procedures are up-to-date and reference the appropriate version of the MEDDEV.

One area of your vigilance reporting process that deserves special attention is assigning responsibility to your distributor, Authorized Representative, and outsourced manufacturer (if applicable). These parties must understand the importance of informing you of any complaint or vigilance information they receive so that you (or your Authorized Representative) can inform the Competent Authority and Notified Body as soon as possible.

Communicating incidents

In general, manufacturers should submit Incident Reports to Competent Authorities in countries where the incidents occurred. For FSCA Reports, these should be submitted to all the Competent Authorities in the countries where the devices mentioned in your FSCA are marketed. All vigilance reports should be provided to the Notified Body.

If you're using your distributor as your European Authorized Representative, keep in mind that your distributor may have additional reporting responsibilities. Also note that your distributors may have commercial interests, so ensure that you have a formal Authorized Representation agreement in place with that distributor. If no such agreement exists, you and your distributor could get into trouble.

Next steps

Once you've filed your report, the Competent Authority will ask for quantitative data—number of devices involved, length of time on the market, details of design changes—and will monitor the course and outcome of your investigation, as will the Notified Body.

Your Final Incident Report should include the outcome of your investigation as well as your plans for how to proceed. Plans may include initiating FSCAs (recalls), conducting additional surveillance on devices still in use, disseminating information such as advisory notices (that are not related to FSCAs)—or nothing at all. Your Final FSCA Report will include more data, and will provide information on the success of the FSCA activity.

Competent Authorities and Notified Bodies, if applicable, typically work with manufacturers to fix problems and prevent their recurrence. They often consult with you to determine which course of action will best address and correct your reported incident. If corrective action is necessary or if serious risks to patients/users remain, the Competent Authority will usually disseminate your Final Incident Report information to other EU member state regulators. Your Notified Body will probably become involved. Your Final Incident Report will not be made public unless it warrants an overriding concern for public health. Some Competent Authorities routinely publish FSCA Reports to their Web sites.

In addition, your final report should be added to your quality system records for either the expected life of your device or five years (15 years for implantable medical devices), whichever is longer. Your report data will be included in the EUDAMED database.

Outsourced manufacturing issues

Companies that outsource part or all of their medical device manufacturing to other firms are not off the hook when it comes to vigilance reporting. As the manufacturer, you are the entity who is responsible, even if you've outsourced your manufacturing operations. You must work quickly and effectively with your contract manufacturers to investigate vigilance, and meet the same reporting requirements as firms with in-house manufacturing operations.

Vigilance Obligations in the MDR Era

Following the three year transition, the date of application for Europe's new Medical Devices Regulation (MDR) will likely be April or May of 2020. The MDR will modify vigilance system timelines. The clock starts ticking after manufacturer's awareness, with a 10-day deadline for serious incidents that were death or unanticipated serious deterioration in state of health and 15-day deadline for other serious incidents.

Many vigilance terms (previously only defined in the MEDDEV or not defined at all) are defined in the MDR. Serious incidents are defined as an "incident that directly or indirectly led, might have led, or might lead" to death, temporary, or permanent serious deterioration of health or a serious public health threat. FSCAs are defined as well and, while there is no timeline for reporting FSCAs, it is plausible that the EU Commission can adopt an Implementing Act to do so. Trend reports are also described and presented in the MDR. Last, EUDAMED must be used to file these reports.

Conclusion: Improving future vigilance

The goal of European regulators' vigilance reporting requirements may seem obvious, but bears repeating: it is the manufacturer's moral and legal responsibility to ensure the devices it places on the market are safe and perform as intended. Maintaining open and consistent communication with the Competent Authorities, your Notified Body, customers, distributors, and Authorized Representative is a good business habit in general, but can prove especially helpful when it comes to effectively managing vigilance. The MDR will clearly impose greater vigilance requirements on all parties involved.

About the Author

Evangeline Loh, Ph.D., RAC (US/EU): Evangeline is Vice President of Global Regulatory Affairs at Emergo. Evangeline's areas of expertise include European CE Marking, clinical evaluation reports, vigilance, and device classification in markets worldwide. She previously worked for Cook Medical and holds a Ph.D. in pharmacology from The University of Texas Health Sciences Center at San Antonio.