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Implementing New European Vigilance Procedures

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The new European vigilance guidelines come into force on 1 January 2008. In addition, the Directive amending the medical devices Directives, which includes some aspects of the vigilance system, was recently published. This article discusses the amendments concerning vigilance requirements, the new European vigilance guidelines and steps that manufacturers should take now to prepare for these.

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This article was first published in *Medical Device Technology*, vol. 18, no. 7, Nov.-Dec. 2007.

Vigilance and the new amending Directive

Directive 2007/47/EC,[1] which amends the Medical Device Directive (MDD) (93/42/EEC) and Active Implantable Medical Device Directive (AIMDD), came into force on 12 October 2007. Member States must publish laws implementing the changes to the MDD and AIMD by 21 December 2008 and must apply these laws by 21 March 2010. This means that manufacturers must comply with the amended requirements by 21 March 2010. In spite of these timelines, there are indications that some Member States may begin to incorporate some of the changes into their national laws long before 21 March 2010.

Other than aligning the AIMDD with the text of the MDD, the amending Directive contains no changes regarding the types of incidents that should be reported by manufacturers to the relevant Competent Authorities. However, other amendments related to the European vigilance system include

- a requirement that custom made device manufacturers maintain a postmarket production review system and report incidents to Competent Authorities
- requirement in Article 8 of the AIMDD and Article 10 of the MDD that Competent Authorities inform the European Commission and other Member States of the measures that have been taken or are contemplated to minimise the recurrence of the reported incidents, including information on the underlying incidents
- a new Article 10b added to the AIMDD that aligns it with the MDD and In Vitro Diagnostic Medical Device Directive (IVDD) regarding the European databank, which will contain regulatory data generated in accordance with the Directives that will be accessible to Competent Authorities and is intended to enable them to perform their tasks related to vigilance in a more effective manner; the databank will contain various types of data, including data obtained in accordance with the vigilance procedure.

More detailed guidance

In April 2007, the European Commission published a newly revised medical device vigilance guidelines document,[2] which replaced the 2001 version. The new guidelines come into force on 1 January 2008 to provide a transitional period for its phased implementation.

The vigilance guidelines are part of a set of European medical device guidelines, known as MEDDEV documents, which are intended to promote a common approach by all involved parties on interpreting and complying with the medical device Directives. The 2007 update, which comprises 55 pages, provides significantly more guidance than the previous 36-page version. It includes new reporting terminology and concepts such as "periodic summary reporting" and "trend reporting." In addition, the timescale for reporting incidents is stricter. The terms "advisory notice," "near incident" and "recall" have been eliminated or replaced by the new terms. As with the 2001 version, the new version refers to the incorporation of the views of the Global Harmonization Task Force (GHTF) into the European context. This indicates a continuing support of the regulatory harmonisation initiatives of the GHTF.

Although the MEDDEVs are not legally binding, it is likely that all Competent Authorities will follow the →

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Table I: New vigilance terminology.

New term	Definition
Abnormal use	An act or omission of an act by the operator or user of a medical device as a result of conduct that is beyond any means of risk control by the manufacturer.
Field Safety Corrective Action (FSCA)	An action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market; these actions should be notified via a Field Safety Notice.
Field Safety Notice (FSN)	A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action.
Indirect Harm	Some diagnostic devices and all IVDs do not act directly on the individual. Harm may occur as a consequence of the medical decision, action taken/not taken on the basis of information or result(s) provided by the device.
Periodic Summary Reporting	An alternative reporting regime that is agreed between the manufacturer and the National Competent Authority for reporting similar incidents with the same device or device type in a consolidated way, where the root cause is known or an FSCA has been implemented.
Trend reporting	A reporting type used by the manufacturer when a significant increase in events not normally considered to be incidents according to section 5.1.3 occurred and for which predefined trigger levels are used to determine the threshold for reporting.
Unanticipated	A deterioration in state of health is considered unanticipated if the condition leading to the event was not considered in a risk analysis.
Use error	Act or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator of the medical device.

➔ procedures outlined in the new guidelines and expect manufacturers, their authorised representatives and others involved in the management and reporting of adverse incidents to follow them as well.

New scope and reporting concepts

The new guidelines cover incidents involving

- devices that carry the CE mark
- devices that do not carry the CE mark, but fall under the Directives scope such as custom made devices
- devices that do not carry the CE mark because they were placed on the market before the medical device Directives came into force
- devices that do not carry the CE mark, but where incidents lead to corrective actions relevant to the devices mentioned above.

The 2001 version covers only two of these categories: devices that carry the CE mark and devices that do not carry the CE mark, but where incidents lead to corrective action relevant to CE-marked devices. This means that devices that were designed, manufactured and marketed before the advent of the medical device Directives are now within the scope of the guidelines. This expansion of scope will most certainly be the subject of considerable discussion given the fact that the vigilance requirements specified in the medical device Directives do not apply to devices placed on the market before the implementation of the medical device Directives. It is interesting to note, however, that the MDD and AIMDD have been amended to include custom made devices within the vigilance system.

Table I contains some of the new terms and their definitions found in the new guidance document.

Reporting criteria and timelines

The identification of an event that must be considered an "incident" and therefore reported, has been clarified. Readers should refer to the guidelines to review these criteria. The definition of "serious deterioration in the state of health" has been expanded to include any "indirect harm" as a consequence of incorrect diagnostic or IVD test results.

The revised guidelines include the possibility of submitting periodic summary reports of incidents to Competent Authorities once one or more initial reports have been submitted and evaluated by the Competent Authority. Periodic summary reporting may also be appropriate for reporting incidents that occur after the issuance of a Field Safety Notice (FSN), or for well documented incidents already identified in the product risk analysis, once initial reports have been evaluated by the Competent Authority.

The previous timescales of 10 days for reporting incidents and 30 days for near-incidents have been replaced by text indicating that reports should be filed immediately once the manufacturer becomes aware of the incident, but with maximum time periods, as shown in Table II. In addition, the conditions where reporting is not required have been expanded and clarified.

Field Safety Notices and Corrective Actions

An important modification from the 2001 version concerns the section previously titled "Systematic recalls," which is now termed "Field safety corrective action" (FSCA). The MEDDEV suggests that a draft of the FSN should be submitted to the relevant Competent Authority prior to release, allowing 48 hours for comments to be received.

The previous MEDDEV contained little guidance on what should be included in a FSN, but the new document includes comprehensive advice for manufacturers, including to use company letterhead paper and a clear title, with the words "Urgent Field Safety Notice," plus a factual statement explaining the reasons for the FSCA, and what actions should be taken by the user.

Proper planning of implementation

Although a transition period continues until the end of 2007, the new guidelines will require manufacturers, authorised representatives and distributors to make substantial changes in their standard operating procedures and other documents to conform to the new guidelines. Thus, manufacturers, their distributors and authorised representatives should now begin the process of reviewing the revised guidance document so that necessary changes to the quality management system can be made in a timely manner and will be ready to be implemented from 1 January 2008.

Table II: Reporting timelines.

Incident type	Reporting timeline
Serious public health threat	Immediate, but no later than two calendar days after awareness of the threat by the manufacturer.
Death or unanticipated serious deterioration in state of health	Immediately after the manufacturer establishes a link between the event and the device, but no later than 10 calendar days after the manufacturer's awareness of the event.
Other incidents	Immediately after the manufacturer establishes a link between the event and the device, but no later than 30 calendar days after the manufacturer's awareness of the event.

References

1. Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, Official Journal of the European Union, L 247/21, 21 September 2007.
2. Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 5, April 2007, European Commission DG Enterprise and Industry, Directorate F, Consumer Good, Unit F3, Cosmetic and Medical Devices. mdt

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This article was first published in *Medical Device Technology*, vol. 18, no. 7, Nov.–Dec. 2007.