

MEDICAL DEVICES: Guidance document

Guidance on the vigilance system for CE-marked medical devices

DSVG 00 Introduction to Device Specific Vigilance Guidance

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MEDICAL DEVICES: Guidance document

Contents

1	Introduction	1
2	What Should Be Reported	1
	• Device Specific Reports	1
	• FSCA Reports	1
	• Use Errors	2
	• Periodic Summary Reporting	2
	• Trend Reporting.....	2
3	References	2

DSVG 00 Introduction to Device Specific Vigilance Guidance

MEDICAL DEVICES: Guidance document

1. Introduction

Device Specific Vigilance Guidance documents have been developed to complement the requirements of the Medical Devices Directive [1] and the MEDDEV [2], and should be read in conjunction with those requirements. Device Specific Vigilance Guidance does not replace or extend any of those requirements.

The Device Specific Vigilance Guidance documents provide additional information to manufacturers that can assist them to identify incidents and complaints associated with specific medical devices, and help determine if a type of incident is reportable to the Competent Authority.

2. What Should Be Reported

It is the manufacturer's responsibility to judge each incident on its own merit, and to ensure compliance with the statutory reporting requirements contained within the relevant national regulations which implement the Medical Devices Directive, and / or Active Implantable Medical Devices Directive, and / or In Vitro Diagnostic Medical Devices Directive.

• **Device Specific Reports**

The applicable Medical Devices Directives, [1a, 1b, 1c] and the MEDDEV [2] require manufacturers to notify the relevant Competent Authority if:

They know of any deterioration, or malfunction, of the medical device, or any inadequacy in the instructions for use which has led, or might lead, to a death or a serious deterioration in the state of health. This would include circumstances where:

- a medical device related problem results in a clinically relevant increase in the duration of a surgical procedure, as defined by the physician
- the cause of the medical device related incident is not well defined, or involves a number of aetiological factors, and the manufacturer is unable to obtain further clarification within the reporting timescale
- in cases of doubt, whether the device may have contributed to death or serious deterioration in health, and the manufacturer is unable to obtain clarification within the reporting timeframes as to whether a device malfunction caused the incident it should be reported within MEDDEV timeframes

These should also include reports relating to any clinical incident:

- that is or may be the result of an existing or supposed device deficiency rather than the underlining medical condition or medical procedure, and
- that could lead to, or have led to a death, serious deterioration in state of health, or the need for further intervention to prevent death or serious deterioration in state of health

• **Field Safety Corrective Action Reports**

The medical device has been subject to a Field Safety Corrective Action [2].

DSVG 00 Introduction to Device Specific Vigilance Guidance

MEDICAL DEVICES: Guidance document

- **Use Errors**

The manufacturer should also report “Use errors” that result in death or serious deterioration in health. These “Use errors” should be reported in line with section 5.1.5 of the Medical Devices Vigilance System [2]

- **Periodic Summary Reporting**

Some incidents are appropriate for reporting using periodic summary report; guidance is given in section 5.1.2 [2]. Details of the timing and content of periodic summary reports should be arranged on an individual basis with the Competent Authority.

- **Trend Reporting**

Some incidents are expected and foreseeable, and as a result may be considered not routinely reportable. These incidents should all be clearly identified in the manufacturer’s instructions for use, clinically well recognised and quantifiably predictable, well documented in the device master record with an appropriate risk assessment, and clinically acceptable in terms of individual patient benefit. All such incidents should, however, be subject to trend analysis as part of the manufacturer’s wider post-market surveillance process; the MEDDEV [2] provides guidance on Trend Reporting.

Trends can be indicative for a change in the risk-benefit-ratio. If any trend emerges, this should trigger a vigilance report by the manufacturer to the relevant Competent Authority, as indicated in section 1.

The manufacturer shall also report to the Competent Authority where they know of an increase in the rate of a clinically well-known and expected side effect already clearly included in the instructions for use of the device, in particular if this rate exceeds the rate that was expected according to the conformity assessment such as defined within the relevant section of the MEDDEV [2].

3. References

1a. Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993 last amended by Directive 2007/47/EC.

1b. Council Directive 90/385/EEC concerning Active Implantable Medical Devices, OJ L189 of 20 July 1990 last amended by Directive 2007/47/EC.

1c. Council Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices, OJ L331 of 7 December 1998.

2. The European Commission Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 8, January 2013