Guidance on the vigilance system for CE-marked medical devices

Device Specific Vigilance Guidance Template

Contents

1. Introduction

This document provides guidance for manufacturers of Specific **Devices**. It outlines specific scenarios that should be considered when determining if an incident is reportable. This document should be read in conjunction with DSVG00: Introduction to Device Specific Vigilance Guidance.

The aim of this guidance is to complement the requirements of the Medical Devices Directives [see section 6], and the MEDDEV [2] and should be read in conjunction with the aforementioned. Device specific guidance does not replace or extend these requirements.

2. What Incidents Should Be Reported

The following table details **Device Name** examples indicating what should be reported as device performance problems that caused or contributed to the incident. The list is for illustrative purposes only and does not constitute an exhaustive list:

Guidance for manufacturers on reporting device-specific adverse incidents under the European vigilance system

To be read in conjunction with the European Commission's guidelines on a medical devices vigilance system MEDDEV 2.12/1

Title: Device Name*

Report as individual incidents (in line with MEDDEV timescales)	**Can be included in periodic summary reports (PSR)****		**Report at the time the adverse trend is identified**
Clinical / Symptomatic •	**Clinical / Symptomatic**	**Periodicity**	• All reportable adverse incidents***
Device •	•		**Clinical / Symptomatic** •
	Device		**Device** •
	•		
	•		

***If in an incident appears to meet criteria contained in more than one column, ensure it is included in submissions under each reporting format, even if this results in duplication of reporting for that incident.**

**** If you can't use PSR, then report these events individually.**

***** Until the new MIR form, which includes similar incident data, is adopted, trend reports should be submitted for reportable events, in line with the requirements of MEDDEV 2.12/1.**

5. Clinical Reference Guidelines

Clinical reference guidelines for a specific device may be of use to manufacturers when identifying incident examples and complications.

Current clinical guidelines for **Device Name** procedures can be found on the **organisation name** web-site.

6. Medical Device Directives 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