Guidance on the vigilance system for CE-marked medical devices

DSVG 05

Insulin Infusion Pumps and Integrated meter systems

September 2020

Contents

1. Introduction

This document provides guidance for manufacturers of **Insulin Infusion Pumps and Integrated meter systems**. 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 Directive [1] and the MEDDEV [2,3] 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 examples of what should be reported as device performance problems that caused or contributed to the incident. The examples are for illustrative purposes only and do 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 Rev8

Insulin Infusion Pumps and Integrated meter systems (Insulin Infusion Pumps operating in combination with a Blood glucose monitoring system)****

Report as individual incidents
(in line with MEDDEV timescales)

Clinical / Symptomatic

- Death
- Severe Hypoglycaemia / Severe Hyperglycaemia
- Hypoglycaemia / Hyperglycaemia resulting in Loss of consciousness / coma
- Hyperosmolar hyperglycaemic state
- Diabetic Ketoacidosis
- Unexpected medical intervention by professional or other

Device (IMDRF Annex A Codes***)**

- Device alarm system problem **(A1601)**
- Pumping problem (without alarm) **(A1412)**
- Power Problem (without alarm) **(A0708)**
- Unexpected Shutdown (without alarm) **(A0719)**
- Electrical Power Problem (without alarm) **(A07)**
- Excess Flow or Over-Infusion (without alarm) **(A1402)**
- Improper Flow or Infusion (without alarm) **(A1405)**
- Insufficient Flow or Under Infusion (without alarm) **(A1407)**
- No Flow (without alarm) **(A1408)**
- Incomplete or inadequate connection of associated components **(A1207)**
- Software problems impacting dosing, function, user interface, safety information and patient status (e.g. information about battery status, calibration and blood glucose value) **(A11)**
- Incorrect, Inadequate or Imprecise Result or Readings of Blood Glucose (resulting in medication error) **(A0908)**
- No Display / Image (Sudden onset) **(A090206)**
- Human-Device Interface Problem (Sudden onset) (e.g. Loss of keypad function) **(A22)**
- Fluid Leak (impacting dosing) **(A050401)**
- Wireless Communication Problem (including cybersecurity) impacting dosing, function, user interface, safety information and patient status (e.g. information about battery status, calibration and blood glucose value) (**A1305**)
- Computer system security problem (cybersecurity) impacting dosing, function, user interface, safety information and patient status (e.g. information about battery status, calibration and blood glucose value) (**A1105**)

Can be included in periodic summary reports (PSR)*

Device (IMDRF Annex A Codes*****)	Periodicity
• Incident related to FSCAs following agreement between CA and manufacturer** • Display or Visual Feedback Problem (Gradually evolving) **(A0902)** • Human-Device Interface Problem (Gradually evolving) (e.g. *Keypad failure, degraded keypad*) (**A22)** • Case Break (with potential for serious deterioration in state of health) (**A0401)** • Moisture or Humidity Problem (with potential for serious deterioration in state of health) (**A1905)** • Battery compartment crack (with potential for serious deterioration in state of health) (**A0404)** • Charging problem (with potential for serious deterioration in state of health) (**A0706**) • Incorrect, Inadequate or Imprecise Result or Readings of Blood Glucose (not resulting in a medication error) (**A0908)** • Fluid Leak (not impacting dosing) (**A050401)**	To be agreed

Report at the time the adverse trend is identified

- All reportable adverse incidents***

Clinical / Symptomatic

- Hypoglycaemia / Hyperglycaemia episodes or other clinical symptoms not meeting MEDDEV 2.12-1 rev 8 incident reporting criteria, that are increasing in the frequency or severity of events

Device (IMDRF Annex A Codes***)**

- Use Error (without adverse patient event) (**A23)**
- Pumping problem (with alarm) (**A1412)**
- Priming Problem (with alarm) (**A1414)**
- Power Problem (with alarm) (**A0708)**
- Unexpected Shutdown (with alarm) (**A0719)**
- Electrical Power Problem (with alarm) **(A07)**
- Excess Flow or Over-Infusion (with alarm) **(A1402)**
- Improper Flow or Infusion (with alarm) **(A1405)**
- Insufficient Flow or Under Infusion (with alarm) **(A1407)**
- No Flow (with alarm) **(A1408)**

*** If you can't use PSR then report these events individually**
**** Post FSCA adverse incidents provided they have been previously agreed with CA**
***** Within a Trend Report Manufacturers may choose to include additional events associated with the same problem which have been reported as incidents, to explain their conclusion that a statistically significant increase has been identified**
****** The scope of this DSVG includes Insulin Infusion Pumps and Integrated meter systems (Insulin Infusion Pumps operating in combination with a Blood glucose monitoring system). CGM devices are not included in the scope of this DSVG, nor are associated devices such as infusion sets and/or cartridges etc. Guidance may be developed at a future date to address these devices.**
******* The IMDRF Annex A [5] code associated with each text description is included as a guide. If a medical device problem matches a text description, but has been coded to a different IMDRF Annex A code, this event should be reported in line with the respective column the text description resides in. Similarly, if a medical device problem has been coded to an IMDRF Annex A code that is included in this document, but does not match the associated text description, this does not need to be reported in line with the respective column the code resides in.**

3. Clinical Reference Guidelines

Manufacturers of Insulin Infusion Pumps and Integrated meter systems may refer to relevant local clinical guidelines when identifying incident examples.

4. Medical Device Directives References

1. Council Directive 93/42/EEC concerning Medical Devices, OJ L169 of 12 July 1993 last amended by Directive 2007/47/EC.
2. The European Commission Guidelines on a Medical Devices Vigilance System, MEDDEV 2.12-1 rev 8, January 2013
3. The European Commission Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8.

5. IMDRF Terminologies for Categorized Adverse Event Reporting

Annex A: Medical device problem codes.