MDCG 2024-1-4

Guidance on the vigilance system for CE-marked devices

DSVG 04

Breast Implants

January 2024

Contents

1. Introduction

The aim of this Device Specific Vigilance Guidance (DSVG) is to harmonise vigilance reporting and provide guidance for manufacturers of **Breast Implants**.
It provides further clarification for vigilance reporting of **Breast Implants** to the relevant Competent Authority and should be read in conjunction with the requirements of Regulation (EU) 2017/745 on medical devices (MDR) [1].
This DSVG does not replace or extend any of those requirements.

This document outlines the way to report incidents and serious incidents, defined in Article 2(64) and (65) MDR, in accordance with Articles 87 and 88 MDR, which occurred with **Breast Implants** to the relevant Competent Authority.

2. What should be reported

It is the manufacturer's responsibility to judge each event on its own merit and to ensure compliance with the statutory reporting requirements contained within the MDR [1].

- **Individual serious incident**

In accordance with Article 87 MDR [1] manufacturers shall report serious incidents to the relevant Competent Authority. **Serious incidents** are defined in Article 2(65) MDR.

This includes circumstances where the manufacturer is uncertain whether the incident that occurred with a specific device is reportable or need time to obtain clarification about the root cause of the incident, in accordance with Article 87(6) and (7) MDR.

The notification to the relevant Competent Authority should be reported within the timeframes referred to in Article 87(2) and (5) MDR.

For further information and clarification on what constitutes a serious incident and for details on how to apply the reporting timelines of the MDR, please refer to MDCG 2023-3[1] "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices"* [2].

- **Periodic Summary Reporting**

A "**Periodic Summary Report**" (PSR) is an alternative reporting regime by which the manufacturer, in agreement with the respective national Competent Authority that is coordinating the periodic summary reporting (and in consultation with the Competent Authorities referred to in Article 92(8)(a) MDR, can report similar serious incidents with the same device or device type in a consolidated way.

This is possible when similar serious incidents involving the same specific device or device type occur and for which the root cause has been identified or a field safety

[1] MDCG 2023-3 guidance is under revision to include IVDR aspects. Please refer to the updated version when available at the following link: https://health.ec.europa.eu/medical-devices-sector/new-regulations_en#guidance.

corrective action has been implemented or where the serious incidents are common and well documented, as defined in Article 87(9) MDR.

The format, content and frequency of periodic summary reports should be agreed with the Coordinating Competent Authority (in consultation with the Competent Authorities participating in the Periodic Summary Reporting) (Article 87(9) MDR).

Until EUDAMED becomes fully functional, Competent Authorities, economic operators and other relevant parties should follow MDCG 2021-1 Rev. 1 *"Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional*" [3] (as required under the MDR).

- **Trend Reporting**

The requirements for **trend reporting** are outlined in Article 88 MDR [1].

In accordance with the **MDR**, the manufacturer should report to a Competent Authority any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits. Trends should be identified by the manufacturer as they can be indicative of a change in the risk-benefit ratio.

For further information and clarification on what constitutes incidents and undesirable side-effects please refer to MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*" [2].

3. DSVG 04 examples

The following table details **Breast Implants** examples indicating what should be reported as device-related problems that caused or contributed to the incidents or serious incidents.

The list is for illustrative purposes only and does not constitute an exhaustive list:

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

To be read in conjunction with the MDR

Title: Breast Implants

Report as individual serious incidents Serious incident: Art. 2(65) and Art. 87 MDR Reporting timelines: by 15, 10 or 2 days from the Manufacturer's awareness in accordance with Art. 87(3) to (5) of the MDR	**Can be included in Periodic Summary Reports (PSRs)****		**Report at the time the trend is identified** Incidents (Art. 2(64) and Art. 88 MDR) and expected undesirable side-effects***
Clinical/symptomatic (IMDRF Annex E codes*) • Breast cancer **E180101 / E1403** • Suspected and confirmed cases of BIA-ALCL **E180102** • Lymphoma **E180104** • Double capsule **E2341** • Siliconoma **E2317** • Recurrent seroma/fluid collections **E0307** • Unexpected breast swelling (seroma / fluid collections with no clinical history for trauma or infections) **E0307** • Unexpected breast inflammatory reaction (Breast inflammatory reaction and/or lymphadenopathy with no clinical history for trauma or infections) **E0308** • Unexpected breast infection (Breast Infections with no clinical history for previous systemic infections) **E1906** • Systemic adverse reaction, Hypersensitivity, allergic reaction **E0402** • Autoimmune disease or Syndrome Induced by Adjuvants (ASIA) **E0401** **Device (IMDRF ANNEX A codes*)** • Silicone migration **A010402** • Valve failure (during or after implantation) **A041001 / A05 / A1501 / A1406**	**Clinical/symptomatic (IMDRF Annex E codes*)** • Capsular contracture causing breast deformity and/or pain and/or hard breast for implants in place less than 10 years **E2303 / E1402 / E2332 / E2308** **Device (IMDRF ANNEX A codes*)** • Implant ruptures for implants in place less than 10 years **A0412 / A040101/ A0413 / A0414 / A140102** • Post FSCA/FSN incidents****	**Periodicity** 3 Months 3 Months X Months to be agreed with the CA	**Clinical / Symptomatic (IMDRF Annex E codes*)** • Capsular contracture causing breast deformity and/or pain and/or hard breast for implants in place more than 10 years **E2303 / E1402 / E2332 / E2308** • Wrinkling of the breast **E1723** • Loss of nipple sensitivity **E1409** • Breast swelling/ infection/ inflammatory reaction and/or Lymphadenopathy with positive clinical history for previous systemic infections or trauma **E2338** • Calcium deposits **E230901** **Device (IMDRF Annex A codes*)** • Implant ruptures for implants in place more than 10 years **A0412 / A040101 / A0413 / A0414 / A140102** • Rotation /folding/ displacement of the implant **A010402 / A0512** • Extrusion of the implant **A0411 / A050401**

*** The IMDRF Annexes code associated with each text description are included as guides (please see the Section 5).**

**** If you can't use PSR, then report these serious incidents individually, using MIR Form. The format, content and frequency of PSRs should be arranged with the Coordinating Competent Authority.**
***** Any statistically significant increase in the frequency or severity of incidents, expected undesirable side-effects shall be reported by the manufacturer in accordance with Article 88(1) MDR.**
****** Serious incidents that occur after implementation of an FSCA provided they have been previously agreed with Competent Authority.**

4. Clinical Reference and Clinical Guidelines

Clinical references or current clinical guidelines for **Breast Implants** may be used by manufacturers in order to identify incident examples and complications.

Breast Implants manufacturers may refer to relevant local clinical guidelines when identifying incident examples and complications.

5. IMDRF Terminologies for Categorised Adverse Event Reporting

The text descriptions of Medical device problems (IMDRF Annex A) and Health effects - Clinical signs and symptoms (IMDRF Annex E) in the table are examples of what should be reported and refer to the IMDRF Annex A and E release No. 2023.

Please note that manufacturers should consult the most recent version of the IMDRF adverse event code.

The following link is provided to facilitate consultation:
https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes.

6. References

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[2] MDCG 2023-3 "*Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices*". Link: https://health.ec.europa.eu/system/files/2023-02/mdcg_2023-3_en_0.pdf.

[3] MDCG 2021-1 Rev. 1 "*Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional*". Link: https://health.ec.europa.eu/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf.