[Organization logo]

[Organization name]

Commented [AES1]: All fields in this document marked by square brackets [ ] must be filled in.

# PROCEDURE FOR VIGILANCE AND ADVERSE EVENT INVESTIGATION AND REPORTING

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| Code: | |
| Version: | 0.1 |
| Created by: | |
| Approved by: | |
| Date of version: | |
| Signature: | |

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## Change history

| Date | Version | Created by | Description of change |
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| | 0.1 | Advisera | Basic document outline |
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## Table of contents

## 1. Purpose, scope, and users

The purpose of this Procedure is to define the process of vigilance and incident investigation, and the minimum requirements for the reporting, investigating, and communicating of adverse events and notification of complaints that meet specified reporting criteria of adverse events used in the Quality Management System (QMS) according to the MDR 2017/745.

This Procedure applies to the process of reporting the events to the Competent Authorities and managing inquiries sent by the Competent Authorities for all the products in the market.

Users of this document are all employees of [organization name] inside the scope of the QMS.

**Commented [AES4]:** The Competent Authority is the national body where all the medical devices, once they receive the CE mark, must be registered.

You can find the Competent Authority relevant for your organization here: https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

**Commented [AES5]:** Include the name of your organization.

## 2. Reference documents

- ISO 13485:2016 standard, clauses 8.2.3 and 8.3.3
- MDR 2017/745, articles 10, 87, 88, 89, and Annex IX – Chapter I
- IVDR 2017/746
- MEDDEV 2.12/1 rev. 8 Guidance document - Market surveillance - Guidelines on a Medical Devices Vigilance System
- Manufacturer Incident Report (MIR) for Serious Incidents (MDR/IVDR) and Incidents (AIMDD/MDD/IVDD), version 7.2.1
- Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8
- [national regulations for vigilance system]

**Commented [AES6]:** Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link: https://advisera.com/13485academy/mdr/

**Commented [AES7]:** Delete if your medical device is not an in vitro diagnostic medical device.

**Commented [AES8]:** Include reference to your national regulation that covers the matter of how adverse events should be handled.

## 3. EU vigilance reporting process

For a medical device used on the EU market, [job title] is responsible for fulfilling the vigilance report when any adverse incident happens, or when any corrective action (also known as a Field Safety Corrective Action – FSCA) is taken to reduce the happening of any such incident.

**Commented [AES9]:** E.g., Quality Manager, person responsible for regulatory requirements

## 4. Adverse event investigation

### 4.1. Adverse event definitions

An adverse event is any unwanted medical device-related incident that may occur during the utilization of a pharmaceutical product or medical device, but which does not automatically relate to this treatment.

An adverse event is any event that meets the criteria mentioned below, and the occurrence of any adverse event must be communicated to the relevant institution without delay.

At least one of the following must be fulfilled in order to report the adverse event:

- an identifiable user or any other identifiable person reporting the event
- [illegible]
- [illegible]

[Job title] is responsible for conducting the investigation in a timely manner and documenting the results of the investigation. [illegible]

If the incident has the sort of consequences where authorities must conduct the investigation, all further actions will be done according to their demands and instructions.

### 4.2. Severity of the incident

[Job title] is responsible for assessing the severity of the incident. While assessing the severity of the incident, [job title] must consider the following definitions for death or serious deterioration of health:

- life-threatening illness
- permanent impairment of a bodily function or permanent damage to a bodily structure
- [illegible]
- [illegible]

[Job title] performs hazard analysis of the medical device in question in order to determine the severity of the risk according to the Procedure for Risk Management.

### 4.3. Potential use error or misuse

To assess if the incident resulted from a use error or misuse, [illegible]

## 5. Reporting to Competent Authorities

After defining the severity of the incident, [job title] is responsible for preparing the Manufacturer Incident Report and sending it to the Competent Authority within the deadline as defined in the table below:

| Category of the incident due to medical device malfunction | Reporting deadline |
|---|---|
| Incident posing a threat to public health | Immediately, but not later than 2 days |
| [illegible] | [illegible] |

**Commented [AES10]:** A user is someone who used the [illegible]

**Commented [AES11]:** Also, a relative of the patient can report [illegible]

**Commented [AES12]:** E.g., QA Manager or Safety Officer

**Commented [AES13]:** E.g., QA Manager or Safety Officer

**Commented [AES14]:** Insert the link to the web page of a [illegible]

**Commented [AES15]:** E.g., QA Manager or Safety Officer

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**Commented [AES17]:** E.g., QA Manager or Safety Officer

**Commented [AES18]:** You can find a template for this [illegible]

**Commented [AES19]:** E.g., QA Manager or Safety Officer

**Commented [AES20]:** E.g., QA Manager or Safety Officer

| | |
|---|---|
| [illegible] | [illegible] |

[Job title] must use the Manufacturer Incident Report template as defined by the European Commission to submit the manufacturer incident report to the Competent Authority.

### 5.1. Managing responses to the Competent Authority

If [job title] receives an alert from the Competent Authority about a declaration made by a patient or user of the medical device, he must send the response to the Competent Authority within [deadline].

The response must contain one of the following:

- the Manufacturer Incident Report, if the reporting criteria defined in the previous sections are met, or
- [illegible]

[illegible]

### 5.2. Incident investigation and outcomes

After submission of the Manufacturer Incident Report, [job title] performs the investigation, monitored by the Competent Authority. If [job title] does not finish the investigation of the incident by the deadline communicated to the Competent Authority, he must prepare a Follow-up Report. [illegible]

### 5.3. Final report

[Job title] prepares the final Manufacturer Incident Report with the outcome of the investigation and sends it to the Competent Authority. [illegible] The final Manufacturer Incident Report may include any of the following actions:

- no action
- additional surveillance of devices in use
- [illegible]

### 5.4. Periodic summary reporting

When one or more initial Manufacturer Incident Reports for the same medical device have been issued and evaluated by [organization] and the Competent Authority, the Competent Authority may

**Commented [AES21]:** These are mandatory. Do not delete or [illegible]

**Commented [AES22]:** You can download the template from the website of the European Commission on the following link: [illegible]

**Commented [AES23]:** E.g., QA Manager or Safety Officer

**Commented [AES24]:** Consult your Competent Authority on [illegible]

**Commented [AES25]:** You can find a template for this [illegible]

**Commented [AES26]:** E.g., Quality Manager

**Commented [AES27]:** E.g., Quality Manager

**Commented [AES28]:** E.g., Quality Manager

**Commented [AES29]:** Include the name of your organization.

accept periodic summary reporting. Periodic summary reporting must be agreed upon between [organization] and the representatives of the Competent Authority at a defined frequency for certain types of devices and incidents.

[redacted] signs an agreement with the Competent Authority to proceed with periodic reporting and informs the Competent Authorities from other member countries of the European Union where the medical device is registered and released on the market.

[redacted] prepares the Periodic Summary Report and sends it to the Competent Authority at the agreed frequency.

## 6. Field Safety Corrective Action (FSCA) and Field Safety Notice (FSN)

[Job title] is responsible for preparing a Field Safety Corrective Action for each medical device made available on the market. [Job title] must issue a Field Safety Notice and must communicate the Field Safety Notice without delay to the [target group] of the medical device through [method of communication].

[redacted] is responsible for reporting the FSCA to the Competent Authority, and the Notified Body responsible for the conformity assessment of the device.

[redacted] is responsible for reporting FSN requirements to the Competent Authority and the Notified Body responsible for the conformity assessment of the device.

[Job title] is responsible for gathering the completed FSN customer reply forms and the FSN distributor/importer reply forms from the customers, distributors, and importers, and for checking how many medical devices were revoked and how many medical devices should be replaced.

## 7. Investigation and outcomes (without notification)

### 7.1. Trend reporting

[Job title] must report to the relevant Competent Authority each time there is a significant increase in events.

[Job title] is responsible for preparing the Trend Report and sending the report to the National Competent Authority when there is a significant increase in the rate of:

- already reportable incidents
- [redacted]
- [redacted]

[Job title] is responsible for recording the follow-up to the trend of events report, and the event that triggered the trend report, in the [redacted] of each medical device.

**Commented [AES30]:** This should be someone from the top management.

**Commented [AES31]:** E.g., QA Manager or Safety Officer

**Commented [AES32]:** The European Commission has published a template for the Periodic Summary Report, which can be found and downloaded on the following link:
[redacted]

**Commented [AES33]:** The European Commission has published a template for the Field Safety Corrective Action, which can be found and downloaded on the following link:
[redacted]

**Commented [AES34]:** The European Commission has [redacted]

**Commented [AES35]:** If your organization is a manufacturer, then, instead of target groups, write distributors, wholesalers, and importers of your medical device.

**Commented [AES36]:** Describe the method you will use to communicate the Field Safety Notice to your target group.

**Commented [AES37]:** E.g., QA Manager or Safety Officer

**Commented [AES38]:** E.g., QA Manager or Safety Officer

**Commented [AES39]:** The European Commission has published templates for the Field Safety Notices, which can be found and downloaded on the following links:
- FSN Customer Reply
https://ec.europa.eu/docsroom/documents/32516
[redacted]

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**Commented [AES41]:** You can find a template for this [redacted]

### 7.2. Proposal for definition of a significant increase (according to the risk analysis)

[Job title] is responsible for updating the probability of occurrence of the risks on a yearly basis, taking into consideration the number of adverse events received from the market. Based on this analysis, [job title] is responsible for sending a Trend Report to the relevant Competent Authority in cases where the level of the updated risks increases from "acceptable" to "as low as possible" and no risk mitigation could be implemented to further reduce the risk.

[redacted]

[redacted]

Commented [AES42]: E.g., Quality Manager

## 8. EU vigilance contacts point

[Job title] is responsible for keeping an updated list of all [redacted]

Commented [AES43]: E.g., QA Manager or Safety Officer

Commented [AES44]: You can find the list with contact [redacted]

Commented [AES45]: Include the name of your organization.

## 9. Managing records kept on the basis of this document

| Record name | Code | Storage | | Responsibility |
|---|---|---|---|---|
| | | [redacted] | [redacted] | [redacted] |
| Manufacturer Incident Report | PR19.1 | [redacted] | [redacted] | [redacted] |
| Periodic Summary Report | PR19.2 | [redacted] | [redacted] | [redacted] |
| Field Safety Corrective Action Report | PR19.3 | [redacted] | [redacted] | [redacted] |

| | | | | |
|---|---|---|---|---|
| Field Safety Notice Customer Reply Form | PR19.4 | [illegible] | [illegible] | [illegible] |
| Trend Report | PR19.5 | [illegible] | [illegible] | [illegible] |

## 10.Appendices

- Appendix 1 – Manufacturer Incident Report
- Appendix 2 – Periodic Summary Report
- [illegible]
- [illegible]
- [illegible]

[job title]
[name]

[signature]

**Commented [AES46]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.