

MDCG 2023-3

Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices

February 2023

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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Introduction

This document aims to clarify important terms and concepts that are outlined in Section 2 of Chapter VII of the Regulation (EU) 2017/745 on medical devices (MDR). Establishing a common understanding of these terms and concepts is necessary for an effective and harmonised implementation of the vigilance requirements under the MDR.

The document is written for competent authorities, economic operators and other relevant parties.

Some of the definitions presented in this document are reintroduced from the Guidelines on a Medical Devices Vigilance System¹ with, where relevant, modifications for alignment with the MDR.

The term 'devices' will be understood to include medical devices, accessories for medical devices and products listed in Annex XVI to the MDR.

The document is non-exhaustive and should be read in conjunction with the MDR, relevant standards² and MDCG guidance documents³.

Terms and concepts that are outlined in the corresponding articles of the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR) are outside the scope of this document.⁴

1. What is the difference between an 'incident' and a 'serious incident' with a device under the MDR?

The main difference between an 'incident' and a 'serious incident' under the MDR is the severity of the related health or public health outcome (or potential outcome) linked to an issue with a device made available on the market.

An '**incident**' (Article 2(64) MDR) is any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer⁵ and any undesirable side-effect.

Incidents are not reportable to competent authorities under Article 87(1) MDR. However, incidents must be documented and considered in the manufacturer's quality management system and reported in accordance with requirements outlined in Article 88 MDR.⁶

¹ Guidelines on a Medical Devices Vigilance System, MEDDEV 2/12-1 rev. 8, January 2013.

Please note that the **MEDDEV 2.12/1 rev. 8, January 2013 was in operation under the Directives (Directive 93/42/EEC concerning medical devices (MDD) and Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (AIMDD)) and is not applicable under the MDR.**

² For definition of a 'standard' please refer to Article 2(1) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation. A summary list of titles and references of harmonised standards can be found on the European Commission Medical Devices website:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

³ All MDCG Guidance documents can be found on the European Commission Medical Devices website:

https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en.

⁴ Please note this document is intended to be updated to include the IVDR.

⁵ The general requirements regarding the 'information supplied by the manufacturer' are outlined in Section 23 of Annex I MDR and a definition is provided in EN ISO 15223-1:2021. The information supplied by the manufacturer should be regarded as part of the medical device or accessory. For the purpose of this document, this information includes the label (packaging or marking), instructions for use, technical description, installation manual, quick reference guide, training material, any promotional material, sales material and statements by the manufacturer and other information accompanying the device (accompanying information).

⁶ Trend reports (Article 88 MDR) should be reported to the competent authority(ies) of the Member State(s) in which the incidents occurred.

A **‘serious incident’** (Article 2(65) MDR) is an incident as outlined in Article 2(64) MDR that has in addition, either led to or has the potential to lead to the significant health or public health outcomes outlined in Article 2(65)(a) to (c) MDR. More specifically, serious incidents are the subset of incidents that directly or indirectly led, might have led or might lead to the death or the temporary or permanent serious deterioration in the state of health of a patient, user or other person or posed a serious public health threat.

The manufacturer must report serious incidents in accordance with Article 87(1) to (5) MDR to the relevant competent authority.^{7 8}

Reportability under the MDR

If an incident is determined on first evaluation not to be a serious incident, it must nonetheless be investigated whether it might lead to/might have led to one of the outcomes specified in Article 2(65)(a) to (c) MDR, if the circumstances were less fortunate (for instance without the performance of an intervention by a third party or if there was exposure of more vulnerable patients to the same situation, etc.).

If the manufacturer cannot exclude that the incident could potentially have led to the outcomes specified in Article 2(65)(a) to (c) MDR, the incident must be considered serious and reported to the relevant competent authority.

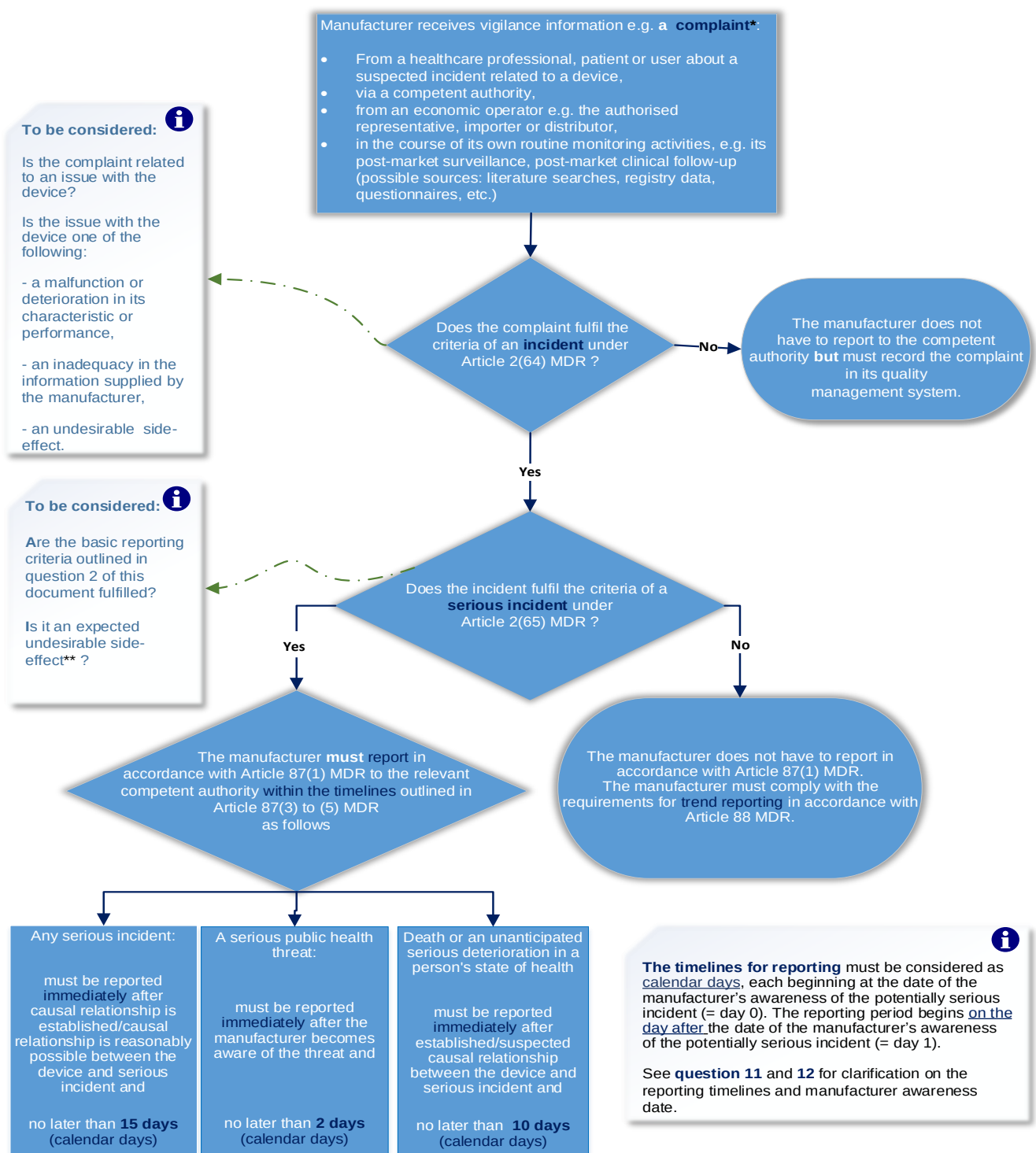
If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it must nevertheless submit a report within the timeframe required in accordance with Article 87(2) to (5) MDR.⁹

Flowchart 1 below illustrates the process to be followed by manufacturers for the management of incidents and serious incidents.

⁷ In this context, the relevant competent authority is the competent authority of the Member State in which the serious incident occurred. Serious incidents are to be reported to the competent authorities by means of the Manufacturer Incident Report (MIR), which became applicable from 1st January 2020. The MIR can be found on the European Commission Medical Devices website: <https://ec.europa.eu/docsroom/documents/41681>.

⁸ Once Eudamed is fully functional, reports of serious incidents, will be automatically transmitted to the notified body that issued the certificate (Article 56 MDR) for the device in question (Article 92(9) MDR). In the interim, manufacturers and notified bodies are advised to agree on how that information is provided to the notified body that issued the certificate for the device in question and may continue with the same procedures used under the Directives (MDD and AIMDD).

⁹ Article 87(7) MDR.



* A 'complaint' is defined in EN ISO 13485:2016 and can be described as a written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device or related to a service that affects the performance of such medical devices. It is important to note that complaints and information relevant for vigilance reporting are not only externally generated but can also be created due to the manufacturer's own activities for routine monitoring of a device's safety and performance.

** Expected undesirable side-effects are clearly documented in the product information and quantified in the technical documentation and subject to trend reporting pursuant to Article 88 MDR (see *question 8* for elaboration of *undesirable side-effects*).

2. What are the basic reporting criteria for a serious incident?

Any incident which meets all three basic reporting criteria A – C listed below is considered a serious incident and must be reported to the relevant competent authority:

- A. an incident (Article 2(64) MDR) has occurred, and
- B. the incident directly or indirectly led, might have led or might lead to any of the outcomes of a serious incident (Article 2(65) MDR), and
- C. a causal relationship between the serious incident and the manufacturer's device has been established, is reasonably possible or suspected.

Elaboration of the reporting criteria A - C is provided below

Criterion A: an incident has occurred

Examples of an incident can include:

- a malfunction or deterioration in the characteristics or performance of the device, e.g. a device that fails or is losing its ability to achieve its intended purpose (Article 2(12) MDR) when used as indicated in the information supplied by the manufacturer (see question 4 for further clarification of a malfunction or deterioration in the characteristics or performance a device),
- a deterioration in the characteristics of the device that is related to manufacturing errors, e.g. sterilisation process failures,
- a use error due to ergonomic features, e.g. a use error caused by a mismatch between the user interface¹⁰ and the physical or medical condition of the intended user (see question 7 for further clarification of use-error due to ergonomic features),
- any inadequacy in the information supplied by the manufacturer, e.g. insufficient information on how to maintain, adjust or calibrate the device in the instructions for use that can lead to a use error,
- unclear instructions in the labelling or the manufacturer's instructions for use, e.g. the information is not written in a way that is suitable for/readily understood by the intended user,
- undesirable side-effects e.g. allergic skin reactions such as allergy to nickel or wound therapies (see question 8 for further clarification of undesirable side-effects).

Criterion B: the incident directly or indirectly led, might have led or might lead to any of the outcomes of a serious incident

For this criterion to be fulfilled, it is sufficient that an incident associated with the device happened and the incident was such that, if it occurred again, it might have led or might lead to any of the following outcomes:

- death of a patient, user or other person,
- the temporary or permanent serious deterioration of a patient's, user's or other person's state of health,*
- a serious public health threat.**

¹⁰ According to EN 62366-1:2015, the 'user interface' is the means by which the user and the device interact.

The user interface covers all the elements of the medical device with which the user interacts, including the physical aspects of the device as well as visual, auditory, tactile displays and is not limited to the software interface. For the purpose of this document, the information supplied by the manufacturer such as the accompanying information is considered part of the device and its user interface.

*** A serious deterioration in state of health of a patient, user or other person** can include:

- I. a life-threatening illness or injury,
- II. permanent or temporary impairment of a body structure or a body function (including impairments leading to diagnosed psychological trauma),
- III. a condition necessitating hospitalisation or prolongation of existing hospitalisation,
- IV. medical or surgical intervention to prevent I or II, examples of this can be:
 - professional medical care or additional unplanned medical treatment,
 - a clinically relevant increase in the duration of a surgical procedure
- V. a chronic disease,
- VI. foetal distress, foetal death or any congenital abnormality (including congenital physical or mental impairment) or birth defects.

Please note that any indirect harm that may occur as a consequence of the medical decision or action taken/not taken on the basis of information or result(s) provided by a device can also lead to serious incidents, including a serious deterioration in the state of health of a patient, user or other person (*see question 3 for clarification of indirect harm*).

**** A serious public health threat** (Article 2(66) MDR) is an event which could result in imminent risk of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

These events would include:

- I. the possibility of multiple deaths occurring at short intervals,
- II. events that are of significant and unexpected nature such that they become alarming as a potential public health hazard.

Examples of serious public health threats can be the following (non-exhaustive list):

- contagious illnesses, such as human immunodeficiency virus (HIV), Creutzfeldt-Jakob Disease (CJD), Ebola, Zika virus, severe acute respiratory syndrome (SARS), Coronavirus disease (COVID-19),
- events involving high risk of exposure to a disease (e.g. cancer) after use of a medical device, which affects a significant number of the population, or a specific patient population (diabetics, cardiac patients, etc.) or a vulnerable population (children, pregnant women, etc.),
- exposure to toxic compounds with a potentially negative/harmful effect on humans,
- widespread distribution of falsified or incorrectly labelled devices leading to multiple serious incidents, e.g. distribution of non-sterile devices labelled as sterile,
- cyberattack related to life supporting or life-saving devices.

A serious threat to public health will in principle not be limited to one isolated case or individual patient issue, and identifying these events may depend on signal detection or trending of multiple events of the same nature/typology, same root cause, etc.

Criterion C: causal relationship between the serious incident and the manufacturer's device has been established or is reasonably possible or suspected

The manufacturer has to investigate if there is a causal relationship between the serious incident and their device or if such a causal relationship is reasonably possible, i.e. the device cannot reasonably be excluded as a contributory cause of the serious incident.

In assessing the link between their device and the serious incident, the manufacturer should take account of factors such as:

- clinical or medical plausibility,
- the opinion of healthcare professionals,
- the results of the manufacturer's own preliminary assessment,
- known information provided in the technical documentation and evidence of previous similar serious incidents,
- other relevant evidence held by the manufacturer.

Establishing or identifying the link between the manufacturer's device and the serious incident may be difficult, especially when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device may have or potentially could have contributed to the serious incident, and the manufacturer should therefore be cautious in its evaluation and conclusions. In case of doubt, the manufacturer must nevertheless submit the report referred to in Article 87(1) MDR.¹¹

3. How can incidents indirectly lead to a serious deterioration of health?

In a number of cases, the device may, due to its intended use, not directly (or instantly) lead to physical injury or damage to a person's health but lead to indirect harm.

Indirect harm may occur as a consequence of the medical decision, action taken or lack of such on the basis of information or result(s) provided by the device or as a consequence of a treatment. Indirect harm, due to an incident that meets or has the potential to meet the outcomes of a serious incident must be reported in accordance with Article 87(1) to (5) MDR.

Examples of indirect harm may include:

- a misdiagnosis,
- a delayed diagnosis,
- delayed treatment,
- inappropriate treatment,
- absence of treatment,
- transfusion of inappropriate materials.

¹¹ Article 87(7) MDR.

4. With reference to Article 2(64) MDR, what is meant by a ‘malfunction or deterioration in the characteristics or performance of a device’?

A ‘malfunction¹² or deterioration¹³ in the characteristics or performance of a device’ can be described as a situation where a device fails to achieve, or is unable to uphold, the performance (Article 2(22) MDR) intended by the manufacturer when used in accordance with the information supplied with the device.

Examples of device malfunctions may include the following:

- a device that due to a sudden software error fails to make correct assessments and provides an incorrect treatment (dosage) to the patient,
- electrical short circuit causing the device to catch fire or stop working,
- premature battery depletion e.g. a malfunction resulting in high current drain depleting the device battery faster than indicated in the instructions for use,
- a device that breaks during use although it was used/handled in accordance with the instructions for use.

Examples of deteriorations in the characteristics or performance of a device may include the following:

- a gradual occlusion of fluid or gas path, change in resistance to flow or electrical conductivity of a device as a result of ageing or repeated use,
- a sensor drift caused by physical changes, e.g. a gradual decrease in accuracy on a sensor caused by physical changes such as airborne pollutants (dust, chemicals, vapor and other contaminants),
- UV degradation of a device e.g. cracking or disintegration of device materials due to ultraviolet radiation, such as sunlight exposure,
- elasticity changes (increase or decrease), e.g. of compression stockings that due to an elasticity increase are not suitable for their intended use anymore,
- failure of a device component or other types of significant loss of electrical, material or mechanical integrity of a device due to wear or fatigue.

The manufacturer should always conduct a root cause investigation when a device, used in accordance with information supplied by the manufacturer itself, fails to achieve or uphold its performance.

5. Who is considered as the ‘user’ of a device?

For the purpose of this document, the ‘user’ (Article 2(37) MDR) is any healthcare institution, healthcare professional or lay person (e.g. caregiver, patient) who uses the device, or persons installing or maintaining the device. The user of a device can also be referenced as the operator, e.g. in standards.

¹² See also the following definition of a ‘malfunction’ provided in EN ISO 14155:2020: ‘a malfunction is a failure of a device to perform in accordance with its intended purpose when used in accordance with the manufacturer’s instructions for use or to meet its performance specifications’.

¹³ For the purpose of this document, the following definition of *deterioration* was taken into account: ‘the action or process of a device becoming impaired or inferior in quality, function or condition’ (Merriam-Webster.com Dictionary, Merriam-Webster, <https://www.merriam-webster.com/dictionary/deterioration>).

6. What is a 'use error' in comparison to 'abnormal use'?

A 'use error' is when the user's action or lack thereof while using the device leads to a different result or outcome than that expected by the user or intended by the manufacturer.¹⁴

Use errors can be caused by a user's failure to pay attention, memory lapses or mistakes during device use, or lack of understanding or knowledge in relation to device use. Such use errors do not fall within the definition of an incident. However, use errors that are caused by the ergonomic features of a device qualify as incidents and in case of serious incidents reportable under Article 87(1) MDR (see question 7 for elaboration).

Use errors must nevertheless be documented and handled within the manufacturer's quality management system.

'Abnormal use' is the deliberate violation of the intended use of a device. It is a deliberate act or omission of an act by the user that is counter to or violates normal use of a device, and is beyond any further reasonable means of interface-related risk control by the manufacturer.

An example of abnormal use may include off-label use of a device such as a doctor that, based on a medical decision, uses a device for a different indication than indicated in the manufacturer's instructions for use.

Abnormal use of a device, must be documented and handled within the manufacturer's quality management system.¹⁵

7. What is a 'use-error due to ergonomic features' as mentioned in Article 2(64) MDR?

'Use-error due to ergonomic features' can be described as use errors caused by device features that were designed to allow the device to be easily, effectively and safely used by the intended user.

Ergonomic features can be described as the physical features of a device that are designed to facilitate and ensure that the interaction between the user and the device is safe, effective and efficient. The ergonomic features of the device includes components such as measurement and monitoring features, display scales, alarms, software menu and any other factor related to the user interface.

Use errors due to ergonomic features may be caused by a mismatch between the device features (including the information provided in the instructions for use) and factors such as the user profile¹⁶ and/or the environment in which the device is intended to be used.

It should be noted that in some cases, use errors caused by ergonomic features may not be immediately identified and can lead to serious outcomes due to the unintentional nature of the

¹⁴ According to EN ISO 14971:2019 and EN 62366-1:2015, use errors include the inability of the user to complete their task when using the device (Note 1, 3.52, EN ISO 14971:2019). Furthermore, according to the EN ISO 14971:2019 the occurrence of an unexpected physiological response of the patient when using the device is not by itself considered a use error (note 4, 3.52, EN ISO 14971:2019) and a malfunction of a device that leads to an unexpected result, is also not considered a use error (note 5, 3.52, EN ISO 14971:2019).

¹⁵ Based on data, e.g. from complaints, related to abnormal use, manufacturers might be able to identify possible systematic misuse or off-label use of their device, and verify that the device's intended purpose is appropriate and, where relevant, identify the need for initiating a field safety corrective action.

¹⁶ According to EN 62366-1:2015/AMD1, the user profile can include 'the mental, physical and demographic traits of an intended user group, as well as any special characteristics, such as occupational skills, job requirements and working conditions, which can have a bearing on design decisions related to the device'.

error and the potential that the user is not aware of its occurrence. This note is especially important for devices where the patient is responsible for installing or adjusting their treatment e.g. drug-delivery devices or devices with a diagnostic or measuring function.

Use errors due to ergonomic features must in the case of a serious incident, be reported in accordance with Article 87(1) to (5) MDR or in case of incidents reported in accordance with Article 88 MDR.

8. What is an 'undesirable side-effect' and how is it reported within the vigilance system?

An 'undesirable side-effect' under the MDR should be understood as any unintended and unwanted medical manifestation in the human body, as a consequence of the normal use of a device.¹⁷ Undesirable side-effects are not the result of a malfunction, deterioration in the device's characteristics or performance, or an inadequacy in the information supplied by the manufacturer.

An unsuccessful treatment (or treatment failure) should not be considered an undesirable side effect.

For the purpose of this guidance, undesirable side-effects can be expected or unexpected and are considered as incidents under the MDR (Article 2(64) MDR).¹⁸

Expected undesirable side-effects must be clearly documented in the product information, and quantified in the manufacturer's technical documentation. They must also be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use (Section 8 of Annex I MDR).¹⁹

Expected undesirable side-effects must be reported in accordance with the requirements for trend reporting pursuant to Article 88 MDR.

If the manufacturer cannot demonstrate that a potentially serious incident is an expected undesirable side-effect within the deadlines set out in Article 87(3) to (5) MDR, it must submit a Manufacturer Incident report (MIR) within the reporting timelines.

Unexpected undesirable side-effects are not considered in the manufacturer's risk analysis, quantified in the manufacturer's technical documentation or documented in the product information. If they occur, they are to be handled like all incidents. That means that, if they qualify as serious incidents within the meaning of Article 2(65) MDR, such side-effects must be reported in accordance with Article 87(1) MDR as individual serious incident reports (i.e. individual MIRs).

9. Article 87(5) MDR outlines the timelines for manufacturers to report an unanticipated serious deterioration in a person's state of health. When is a serious deterioration in a person's state of health considered 'unanticipated'?

A serious deterioration in a person's state of health, is considered 'unanticipated' if the condition leading to the deterioration was not considered in the manufacturer's risk analysis.

A serious deterioration in a person's state of health is anticipated if it was considered in the manufacturer's risk analysis and documented in the risk management report.

¹⁷ It should be noted that the terms 'undesirable side-effects' and 'side-effects' are used synonymously in the MDR.

¹⁸ In addition to footnote 17, note also for reporting purposes that; 'identified side-effects, expected side-effects expected undesirable side-effects and unknown side-effects' as mentioned in the MDR should all be understood as 'undesirable side-effects' and fall under the definition of an incident (Article 2(64) MDR).

¹⁹ In this context, reference to 'patient' should be understood as the individual patient i.e. acceptable in terms of the individual patient benefit.

For a serious deterioration in the state of health, the manufacturer must ensure there is:

- documented evidence that a risk analysis was used to eliminate or reduce the risk related to these events as far as possible, or
- the risk is included in the information supplied by the manufacturer to the user, e.g. in the instructions for use.

10. With reference to the timelines for the reporting requirements outlined in Article 87 MDR, what is meant by 'immediately' and 'without undue delay'?

For the purpose of this document, 'immediately' and 'without undue delay' should both be understood as without any delay that is intentionally or negligently caused by the manufacturer.

As a general rule, the report outlined in Article 87(1) MDR must be provided without any delay or any delay that the manufacturer cannot justify and no later than the timelines outlined in Article 87(2) to (5) MDR.

To ensure timely reporting, the manufacturer can submit an initial MIR which can be followed by a follow-up report (Article 87(6) MDR).

Question 11 of this document provides more clarification on how to apply the reporting timelines outlined in Article 87(3) to (5) MDR.

11. How to apply the reporting timelines defined by Article 87(3) to (5) MDR?

In accordance with the MDR, the reporting referred to in Article 87(1) MDR must take account of the severity of the serious incident.

The timelines for reporting serious incidents must be considered as calendar days meaning the reporting periods include weekdays, public holidays, Saturdays and Sundays²⁰.

As a *general rule*, the reporting period begins on the day after the awareness date of a potentially serious incident²¹ at 0:0:1 AM²². The awareness date (day=0) refers to the date when the manufacturer is first made aware or receives information of the occurrence of the (potentially) serious incident and not after it has conducted its investigation. See also question 12 for elaboration of the manufacturer awareness date.

The reporting timelines outlined in the MDR are the following:

- any serious incident, that did not involve a death or an unanticipated serious deterioration in a person's state of health, must be reported immediately after a causal relationship between device and the serious incident has been established or is

²⁰ Article 3(3) Regulation (EEC, EURATOM) NO 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits, OJ L 124, 8.6.1971, p. 1. For the calculation of the period, Articles 3(4) and (5) of Regulation (EEC, EURATOM) NO 1182/71 needs to be considered, which state: "Where the last day of a period expressed otherwise than in hours is a public holiday, Sunday or Saturday, the period shall end with the expiry of the last hour of the following working day" (Article 3(5)) and "Any period of two days or more shall include at least two working days" (Article 3(4) of that Regulation).

²¹ See Article 3(1), second subparagraph Regulation (EEC, EURATOM) NO 1182/71: "Where a period expressed in days, [...] is to be calculated from the moment at which an event occurs [...], the day during which that event occurs [...] shall not be considered as falling within the period in question."

²² Article 3(2) (b) Regulation (EEC, EURATOM) NO 1182/71: "beginning of the first hour of the first day".

reasonably possible and no later than 15 days after the *awareness date* of the serious incident (Article 87(3) MDR),

- a serious public health threat must be reported immediately, and not later than 2 days after the manufacturer becomes aware of that threat (Article 87(4) MDR),
- death or an unanticipated serious deterioration in a person's state of health must be reported immediately after a causal relationship between the device and the serious incident is established or as soon as such relationship is suspected, and no later than 10 days *after the awareness date* of the serious incident (Article 87(5) MDR).

In the *exceptional cases* where a manufacturer initially determines that an incident does not meet the reporting requirements of a serious incident, and then some time later obtains new information that impacts or changes the initial reportability assessment, which results in the reporting requirements of a serious incident being met, the period of reporting in this case begins on the date on which the manufacturer received the information that determined that the incident is reportable (Article 2(65) MDR).

In both situations i.e., the general rule and the exceptional case, the period ends on the 15th, 2nd or 10th day thereafter (more specifically at 11:59:59 PM²³). However, if this (last) day is a public holiday, Saturday or Sunday the deadline is moved to the following working day automatically²⁴. Nevertheless, in line with Article 87(3), (4) and (5) MDR requirement to report 'immediately' but not later than the period provided for in those provisions, it is highly recommended for the manufacturer to report immediately or as early as possible in time.

A delay in submitting an initial report e.g. due to incomplete information provided by the healthcare facility, end user or other relevant parties, is not deemed justified. As outlined in Article 87(6) MDR, the manufacturer can submit an initial MIR followed up by a follow-up report providing additional information related to the (potentially) serious incident and progress on the incident investigation(s). Any report must not be unduly delayed because of incomplete information.

The example below demonstrates the timelines for the exceptional case described above, in which the manufacturer is first made aware of an incident, and concludes that it does not meet the reporting requirements of a serious incident, and later obtains new information that impacts or changes the manufacturer's previous determination regarding the need to report.

Example

A manufacturer receives a complaint on 1st June 2022. The manufacturer determines that the criteria of a serious incident were not met and therefore, does not submit a MIR to the relevant competent authority.

The manufacturer subsequently receives additional information on 1st July 2022. Upon review of this information, the manufacturer determines that the complaint is a serious incident. The manufacturer must submit a MIR at the latest by 16th of July 2022.

Variation of the above example:

²³ Article 3(2) (b) Regulation (EEC, EURATOM) NO 1182/71: "expiry of the last hour of the last day".

²⁴ See Article 3(4), first subparagraph Regulation (EEC, EURATOM) NO 1182/71: "Where the last day of a period expressed otherwise than in hours is a public holiday, Sunday or Saturday, the period shall end with the expiry of the last hour of the following working day."

On 2nd July 2022, the manufacturer was made aware that the patient died on 2nd July 2022. Since the consequence of the serious incident is now a patient death, a report must be submitted no later than 10 days after awareness date of the serious incident. Therefore, a MIR must be submitted at the latest by 12th July 2022. In conclusion, it is the earliest date of reporting which should be considered.

12. With reference to the reporting timelines of a serious incident pursuant to Article 87 MDR, what is considered as the 'manufacturer awareness date'?

For the purpose of this document, the 'manufacturer awareness date' is the date when the first employee or representative of the manufacturer's organisation, receives information (e.g. a complaint) regarding the potentially serious incident. If the handling of these incidents is performed by the authorised representative or if the manufacturer has outsourced its complaint and incident handling activities to another natural or legal person (e.g. a subcontractor), then reference to 'manufacturer's organisation' in the context of *awareness date* will also apply to this organisation.

In the exceptional cases, where a manufacturer initially determines that an incident does not meet the reporting requirements of a serious incident and then later obtains new information that impacts or changes the manufacturer's previous determination regarding the need to report, the serious incident must be reported to the relevant competent authority and indicated in the MIR. In the MIR, the manufacturer should provide the relevant dates in the following two fields:

- 1.2.c. 'Manufacturer awareness date'
(in this field, the manufacturer should insert the initial awareness date of the incident).
- Section 5 'General comments'
(in this field, the manufacturer should insert the date in which it received the information that determined that the incident is reportable (the 'Manufacturer awareness date of reportability'))²⁵.

Within the general comments in Section 5 of the MIR, the manufacturer should also explain the difference between the two dates (the manufacturer awareness date and awareness date of reportability).

It should be noted that if the manufacturer is uncertain about whether the incident is a serious incident, it must nevertheless submit a MIR within the timelines laid down in Article 87(2) to (5) MDR.

An example is provided below to demonstrate how to correctly apply the awareness date in the MIR in the exceptional cases (described above) that a MIR was initially not submitted to the relevant competent authority as the requirements for reporting a serious incident were not met. However, upon receipt of subsequent information that the criteria for a serious incident reporting was met, a MIR was submitted to the relevant competent authority.

²⁵ Please note that it is intended to update version 7.2.1 of the MIR to include a field for 'Manufacturer awareness date of reportability'. Until the publication of the updated MIR, manufacturers should include this information in Section 5 'General comments' instead.

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If the manufacturer has not finalised its root cause analysis or established the cause and/or contributing factors, the case cannot be considered to qualify as non-reportable. In such cases, a MIR with the report type 'Final (Non-reportable) incident' should not be submitted to the relevant competent authority.

14. What is a 'field safety corrective action'?

A 'field safety corrective action (FSCA)' (Article 2(68) MDR) is a corrective action taken by a manufacturer for technical or medical reasons to either prevent or reduce the risk of a serious incident, which is associated with a device that is made available on the market.

A FSCA may include:

- the return of a device to the supplier or a recall²⁶,
- a device exchange,
- a device modification,
- retrofit by purchaser of manufacturer's modification or design change,
- a device destruction,
- advice given by manufacturer regarding the use of the device, such as additional information on maintenance, cleaning instructions, and training and/or the follow-up of patients, users or others,
- recommended inspections/examination by device user (e.g. regular professional checks of proper functioning in a testing setting),
- changes of software/firmware in the device, including device update (e.g. version rollback).

It should be noted that advice given by a manufacturer may include modifications to the clinical management of patients to address a risk of death or a serious deterioration in the state of health related specifically to the characteristics of a device. An example of this can be cases involving implantable devices where it is often clinically unjustifiable to explant the device. Therefore, special patient follow-up or treatment, irrespective of whether any affected un-implanted devices remain available for return, constitutes measures to be included in a FSCA.

A FSCA must be communicated/transmitted without undue delay for the attention of users or customers of the device in question through a field safety notice (FSN) (Article 2(69) MDR) sent by the manufacturer.

Unless duly justified by the situation of the individual Member State (e.g. a translation error in the instructions for use that appears only in certain languages and therefore affects only specific countries), the content of the FSN must be consistent in all Member States. The FSN must be edited in an official Union language or languages determined by the Member State in which the FSCA is taken.

The MDR requirements for the content of the FSN are outlined in paragraph 2 of Article 89(8) MDR.

Example of a FSCA conducted by a manufacturer:

As part of its post-market surveillance activities, the manufacturer identifies a systematic device malfunction.

²⁶ Removals from the market for purely commercial non-safety related reasons are not included.

If the affected devices are available on the market and they have or potentially could lead to a serious incident, the manufacturer must initiate a FSCA to either prevent or reduce the risk of such incidents.

The FSCA implemented by the manufacturer may include permanent or temporary changes to the device's labelling or instructions for use or a recall of all affected devices that are available on the market.

The manufacturer must without delay inform the relevant competent authority(ies) in the Member State(s) in which the FSCA has been or is to be undertaken. Furthermore, the manufacturer must also ensure that information about the FSCA is brought without delay to the attention of the affected users by means of a FSN.

15. With reference to Article 87(1)(b) MDR, what is meant with ‘..including any field safety corrective action undertaken in a third country...’?

For FSCAs undertaken in a third country, where the device is also legally made available on the Union market,²⁷ all relevant competent authorities must be notified unless the reason for the FSCA is limited to devices made available in the third country.

Example

An example of such a FSCA would be where a recall of a device has taken place in a third country due to a malfunction with certain lots. If the lots affected by this recall have also been made available on the Union market, then all relevant competent authorities must be notified of the FSCA.

16. Within the scope of Article 89 MDR on analysis of serious incidents and field safety corrective actions, what is an ‘evaluating competent authority’?

The ‘evaluating competent authority’ is the national competent authority of the Member State responsible for the assessment of the risks arising from reported serious incidents that occur within its territory, and/or of the adequacy of FSCAs envisaged or undertaken, within its territory, by the manufacturer (Article 89(2) and (3) MDR)

In the scenarios provided below, the evaluating competent authority is:

- **For serious incidents:** the competent authority of the Member State in which the serious incident occurred.
- **For FSCA(s):** the competent authority(ies) of the Member State(s) in which the FSCA is being or is to be undertaken, e.g. Member States in which the devices affected by the FSCA are made available.

The competent authority in the Member State in which the manufacturer or its authorised representative has its registered place of business must always be informed of the FSCA, even if it is not amongst the Member States in which the FSCA is being or is to be undertaken.

²⁷ The ‘Union market’ refers to the territories of the European Union Member States, and due to the European Economic Area (EEA) is extended to Norway, Lichtenstein and Iceland, and via the [Customs Union Agreement](#) to Türkiye. For Türkiye, please see also the [‘Notice to stakeholders’](#) EU-Turkey Customs Union Agreement in the field of medical devices’ on the Commission website.

In the context of commenting on the content of the draft FSN as outlined in paragraph 1 of Article 89(8) MDR, manufacturers must, except in cases of urgency, submit the draft FSN, to the evaluating competent authority to allow it to review and make comments (Article 89(8) MDR).²⁸ In the cases referred to in 89(9) MDR, the draft FSN must be submitted to the designated coordinating competent authority.

In all cases, the final FSN must be transmitted to all evaluating competent authorities.

- **In the cases referred to in Article 89(9) MDR**, the evaluating competent authorities can actively participate in a procedure with the aim of coordinating the assessments referred to in Article 89(3) MDR. Unless otherwise agreed between the competent authorities participating in the coordinated procedure, the coordinating competent authority must be the competent authority of the Member State in which the manufacturer or its authorised representative has its registered place of business. Once designated, the coordinating competent authority must through Eudamed or alternative means inform the manufacturer, the other competent authorities and the Commission that it has assumed this role.²⁹

17. Where can I find information on vigilance reporting in Eudamed?

Eudamed is the new European database on medical devices, which will centralise all relevant information on devices which have been placed on the Union market. The database is defined and described in Article 33 MDR and the specific requirements related to vigilance are outlined in Article 92 MDR.

Until Eudamed becomes fully functional, competent authorities, economic operators and other relevant parties should follow the '[MDCG 2021-1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional](#)', which has been endorsed by the Medical Device Coordination Group (MDCG).

The MDCG guidance details alternative temporary solutions for implementing certain MDR provisions related to Eudamed and on exchange of information to enable Member States and other relevant parties to meet their obligations under the MDR until the full functionality of the database.

Information of how to act and alternative mechanisms to be used to exchange data in case of technical unavailability or malfunction of Eudamed after it is fully functional, can be found in the 'COMMISSION IMPLEMENTING REGULATION (EU) 2021/2078 of 26 November 2021 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards the European Database on Medical Devices (Eudamed)'.³⁰

²⁸ The manufacturer should allow 48 working hours for receipt of comment on the FSN unless the nature of the FSCA dictates a shorter timescale e.g. for a serious public health threat.

²⁹ Until Eudamed is fully functional, alternative means provided in the following guidance are applicable: https://health.ec.europa.eu/system/files/2021-05/2021-1_guidance-administrative-practices_en_0.pdf

³⁰ OJ L 426, 29.11.2021, p. 9–15, link: https://eur-lex.europa.eu/eli/reg_impl/2021/2078

18. In accordance with Articles 10, 13 and 14 MDR, manufacturers, importers and distributors are required to inform competent authorities of devices that present or are considered to present a serious risk. What is meant by a 'serious risk'?

For the purpose of this document, a 'serious risk' is defined as a situation where a serious harm resulting from the use of a device that might affect patients, users or the public is likely to happen³¹. A serious risk may include situations where the effects of the risk are not immediate.

For cases involving a device that presents a serious risk, the manufacturer, importer or distributor must immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 56 MDR.³²

19. What is a 'Periodic Summary Report'?

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. Criteria for periodic summary reporting include situations where; the root cause has been identified, a FSCA has been implemented or where the serious incidents are common and well documented.

The requirements for periodic summary reporting are outlined in Article 87(9) MDR.

20. What are the criteria for a 'common and well documented' serious incident?

A 'common and well documented serious incident' as referenced in Article 87(9) MDR, must be clearly identified in the manufacturer's risk analysis and should have led to incident reports, which have been assessed by the manufacturer and the relevant competent authority. The serious incident and the root cause should be clinically well-known (i.e. a certain qualitative or quantitative predictability is established) by the manufacturer.

³¹ See also Article 2(2).

³² For information on the MDCG 2021-27 - Quidam, see <https://ec.europa.eu/h>



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