European Commission

THE INFORMATION OBLIGATION IN CASE OF INTERRUPTION OR DISCONTINUTION OF SUPPLY OF CERTAIN MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Q&A on practical aspects related to the implementation of the obligations to inform about interruption or discontinuation of supply of certain devices laid down in Article 10a MDR and IVDR as introduced by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

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Q&A on practical aspects related to the implementation of the Article 10a obligation in case of interruption or discontinuation of supply of certain devices as introduced by Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices[1].

Disclaimer: This Q&A document is intended to facilitate the application of Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices. This document has not been formally endorsed by the European Commission and is without prejudice to any interpretation of the relevant provisions by the Court of Justice of the European Union or national courts. The information in this Q&A document is of a general nature and not intended to address specific circumstances of any particular case; the document does not intend to provide professional or legal advice. The information is not necessarily comprehensive nor complete. If needed, this document will be updated in order to address additional questions that may arise.

[1] Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices (OJ L, 9.7.2024, p. 1). Regulation (EU) 2024/1860 has entered into force on 9 July 2024.

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[2] Please see MDCG 2024-16 'Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices'.

Introduction – Objectives of the MDR/IVDR amendment

The amendment of the MDR and of the IVDR through Regulation (EU) 2024/1860 addresses three topics:

1. Regulation (EU) 2024/1860 aims to ensure a high level of patient safety and public health protection, including the mitigation of risks related to discontinuation or interruption of supply of *in vitro* diagnostic medical devices (IVDs) needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements. For that purpose, manufacturers and notified bodies are given extra time to carry out, in accordance with the IVDR, the conformity assessment of IVDs covered by a certificate or a declaration of conformity issued in accordance with Directive 98/79/EC. Questions and answers regarding the extension of the IVDR transitional periods are set out in a separate document.
2. Regulation (EU) 2024/1860 also imposes a requirement on manufacturers to inform the relevant competent authority and health institutions before the supply of certain medical devices or IVDs is interrupted or discontinued. If manufacturers do not supply directly to health institutions or healthcare professionals, they must inform the relevant economic operators in the supply chain, which then must inform the health institutions. This mechanism will enable the competent authority and health institutions to consider mitigating measures to ensure patient health and safety. Questions and answers regarding this topic are set out in this document.
3. Regulation (EU) 2024/1860 also enables a gradual roll-out of the electronic systems integrated into the European database on medical devices ('Eudamed') that are finalised, instead of deferring the mandatory use of Eudamed until the last of the six modules is completed. The use of Eudamed – and especially its systems for the registration of economic operators, devices and certificates – will improve transparency and provide information on devices on the EU market, helping to monitor the availability of devices. Questions and answers regarding this topic will be set out in a separate document.

Q&A revision history

Date	Action
October 2024	Initial issue
December 2024	1st update (Rev. 1) - Table of Contents: update of footnote 2 - Q&A no 8: update of footnote 8 - Q&A no 11: update of footnote 11 - Q&A no 12: addition of footnote 12
April 2026	2nd Update (Rev. 2) - In Question 9.2, the following note has been revised from 'This question may be further complemented by a decision tree diagram' to: 'Note: This question is complemented by a decision tree diagram.' Footnote 10 has been updated and includes a link to the location of the decision tree diagram.

The information obligations in case of the interruption or discontinuation of supply

The answers to the questions set out below have been developed taking into account the objectives pursued by the amendment with a view to providing clarity on the information sharing obligations introduced in Article 10a.

PART A – GENERAL

1. From when does the new Article 10a of the MDR/IVDR apply?

The provisions of Article 10a of the MDR/IVDR apply from 10 January 2025, as defined in Article 3 of the Regulation 2024/1860. Interruptions or discontinuations of the supply of a device anticipated by the manufacturer prior to this date, do not need to be reported, even if the interruption of discontinuation itself occurs after 10 January 2025.

Nonetheless, manufacturers are encouraged to inform the users of their devices of supply interruptions or discontinuations on a voluntary basis before 10 January 2025, in line with existing best practices.

2. To whom does the obligation to inform of an anticipated interruption or discontinuation of supply of certain devices under Article 10a(1) of the MDR/IVDR apply?

The obligation to inform about an anticipated interruption or discontinuation of supply of certain devices rests with the manufacturers only, whether established inside or outside the European Union. The manufacturer cannot delegate its legal responsibility for this task, however it can engage the assistance of its authorised representative, other economic operators or a third party, in the practical implementation of the required operational tasks.

Once the notification is complete, it is the responsibility of the notified economic operators to cascade the information as provided by the manufacturer (without changing, adding to or paraphrasing this communication so as to preserve its integrity) to the downstream supply chain, including until it reaches health institutions or healthcare professionals as relevant.

3. To which "certain devices"' does Article 10a (1) of the MDR/IVDR apply?

With the exception of custom-made devices, Article 10a of the MDR/IVDR as of its application date 10 January 2025, applies to all models or types of devices[3], placed on the Union market and for which it is reasonably foreseeable that a supply interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States.

The manufacturer must determine whether it is reasonably foreseeable that an interruption or discontinuation of their device could result in serious harm or a risk of serious harm to patients or public health.

[3] Note that Article 10a also applies to legacy devices, see Article 120(13) of the MDR and Article 110(11) of the IVDR.

PART B – MANUFACTURERS' OBLIGATIONS

4. Who should the manufacturer inform under Article 10a (1) of the MDR/IVDR?

The manufacturer should inform:

- the economic operators (EO)[4], health institutions (HI)[5] and healthcare professionals (HCP) to whom the manufacturer directly supplies the device,
- the competent authority of the Member State where it or its authorised representative is established.

It is essential that manufacturers inform all EOs, HIs and HCPs whom they directly supply, who are impacted by the supply interruption or discontinuation. Cases where EOs, HIs or HCPs are not impacted would include e.g. where the manufacturer had already ceased supply before such time that it anticipated an interruption or discontinuation.

It is also important for HIs and competent authorities to be adequately informed so that they can, where necessary, consider mitigating measures to ensure the continued health and safety of patients.

Manufacturers are not obliged, however, to inform those actors whom they do not directly supply. The responsibility for onward information sharing in the downstream supply chain lies with the EOs following the receipt of the information from the manufacturer or another EO.

Example of the onward information sharing in the context of a supply interruption where the manufacturer does not directly supply to the health institution:

On 1 May 2025, a manufacturer of a CE-marked pacemaker confirms that a supply interruption is expected to begin in approximately seven months i.e. 1 December 2025. The manufacturer, located outside of the Union, does not supply the pacemakers directly to HIs. Instead, the devices are supplied to importers, who then supply them to a network of distributors that ultimately deliver them to HIs across several Member States. In this case, the information flow should proceed as follows:

1. Initial manufacturer information obligation: by 1 June 2025, i.e. at least six months before the confirmed anticipated start of the supply interruption on 1 December 2025, the manufacturer must inform the competent authority in the Member State where its authorised representative is established, as well as the importers to whom it supplied the device in question.

2. Downstream information flow:
    - Importers**:** Upon receiving this information from the manufacturer, the importers of the device in question must, without undue delay, transmit the information, as provided by the manufacturer, to all distributors to whom they directly supply.
    - Distributors: When receiving the information from the importers, distributors must without undue delay, relay it, as provided by the manufacturer to any other distributors to whom they supply the device in question as well as the HI they supply.

5. When should a manufacturer inform under Article 10a (1) of the MDR/IVDR?

The information should, other than in exceptional circumstances, be provided to the relevant actors referred to in Article 10a (1) of the MDR/IVDR at least six months before the manufacturer's anticipated interruption or discontinuation is expected to occur.

"At least six months" means the manufacturer should inform at a minimum 6 months in advance but can and is encouraged to inform of interruptions or discontinuations earlier in time where possible, following its assessment

[4] The term "economic operator'' as defined in Article 2(35) of the MDR and Article 2(28) of the IVDR includes the manufacturer, authorised representative, importer, distributor and for MDR only, the person referred to in Article 22(1) and 22(3) (also referred to as: system and procedure pack producer).

[5] Article 2(36) of the MDR, Article 2(29) of the IVDR

and confirmation. This is especially encouraged in the case of a planned discontinuation.

It is acknowledged that exceptional circumstances may prevent a manufacturer from meeting this requirement. Under such exceptional circumstances the manufacturer should inform the relevant actors without undue delay (see question 6).

It is encouraged that the manufacturer has adequate processes and monitoring systems in place in order to fulfil its notification obligation in a timely manner.

6. What is meant by "exceptional circumstances" in Article 10a (1) second subparagraph of the MDR/IVDR?

Exceptional circumstances exist when a manufacturer is unable to anticipate or confirm a supply interruption or discontinuation at least six months in advance of its onset. This may include cases where the interruption or discontinuation occurs due to sudden and unexpected external or internal circumstances. For instance, a natural disaster, an interruption due to a sudden inability to obtain raw materials or components, or a discontinuation due to unexpected circumstances including of an economic or financial nature.

7. What is meant by the "anticipation of an 'interruption or discontinuation' of the supply of a device" as outlined in Article 10a (1) of the MDR or IVDR?

An "interruption of supply" should be understood as the consequence of a manufacturer confirming that they cannot or are unwilling to operate as previously intended or planned in relation to the supply of a device, which can lead to a temporary disruption of supply. With the view to making the application of the Article 10a information obligation workable in practice and to avoid unnecessary reporting, an interruption of supply should be understood as having a temporary inability to place individual devices of a given model or type on the Union market, with an expected duration of more than 60 days, as a general indication. However, this should not prevent the manufacturer from notifying of a supply interruption lasting less than 60 days if they assess that this may result in serious harm or a risk of serious harm to patients or public health.

A "discontinuation of supply" should be understood to include when a manufacturer can confirm that it will cease the supply of a device and therefore no longer places the individual devices of this model or type on the Union market.

In this context, **"**anticipation" should be understood to mean that the manufacturer confirms that an interruption or discontinuation of a device supply will occur. This 'confirmation' includes the analysis of the problem or business decision at hand, the evaluation of mitigation measures in operations and in the supply chain as well as the development of appropriate communication strategies for stakeholders to be addressed.

The "anticipation" of the interruption or discontinuation of supply is limited to the manufacturer's:

- confirmation of its own supply, based on its manufacturing activities or, information received from third parties e.g. critical suppliers or
- confirmation of its own capabilities to produce the device or
- its own decision to stop placing the device on the Union market.

It does not include the subsequent making available of the device by other economic operators. Furthermore, the anticipated interruption or discontinuation should be related to the notifying manufacturer's own device exclusively, considering also its own market share. When assessing whether an interruption or discontinuation in supply is anticipated, the manufacturer is not required to consider information related to the following examples:

- the appropriateness of devices of other manufacturers which serve a similar intended purpose, and which may be alternatively used according to the advice of healthcare professionals,
- the available stock of alternative devices at the various economic operators in the supply chain,
- the capability of other manufacturers to produce in sufficient quality or quantities.

Manufacturers are, in principle, not required to inform under Article 10a of the MDR/IVDR if:

- the manufacturer replaces the device subject to the supply interruption or discontinuation with a successor device that covers a similar intended purpose and is intended to be used alternatively.
- the manufacturer has a stockpile to serve the demand during an interruption or to bridge the time until the availability of the impacted device and/or successor device.
- the manufacturer has received information from health institutions or healthcare professionals that no serious harm or a risk of serious harm to patients or public health would occur from a device discontinuation or supply interruption, for example due to the availability of a suitable alternative device which has been confirmed to respond to the expected demand.

8. What are the categories of reasons for the interruption or discontinuation which the manufacturer would be expected to specify in its notification to the competent authority under Article 10a (1) of the MDR/IVDR?

The anticipation of the interruption or discontinuation of the supply of a device can be for many reasons[6] and is not limited to regulatory considerations. This may for example, include external factors with a direct impact on the manufacturing process or supply of the device. Potential reasons for the anticipated interruption or discontinuation may include the below examples under the following headings (non-exhaustive):

- Regulatory
  - A loss of compliance with a condition in Article 120 of the MDR / Article 110 of the IVDR to place a legacy device[7] on the market
  - Delay in certification of the type of device (including a corresponding substitute) against the requirements of the MDR or IVDR
  - Suspended or withdrawn certificate
  - Decision by the manufacturer of the type of device to not pursue certification in compliance with the MDR/IVDR and to stop marketing of the device (discontinuation)

- Manufacturing
  - Device performance reasons

- Supply Chain
  - Shortage of or inability to obtain raw materials or components

- Other
  - Marketing or business reasons
  - Unpredicted major event outside manufacturer's control

Note: the manufacturer should specify the reasons for the interruption or discontinuation of supply in the 'Manufacturer Information Form'[8]. In this form, the manufacturer can provide further information or details to the competent authority.

[6] 'See Recital 15 of Regulation 2024/1860 'where manufacturers anticipate, for any reason, the interruption or discontinuation of supply of medical devices or *in vitro* diagnostic medical devices'.
[7] MDCG 2020-3 Rev.1 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD, Section 1, May 2023, applied mutatis mutandis to IVDs.
[8] Please see MDCG 2024-16 'Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices'.

9. What is considered as an "interruption or discontinuation that may result in serious harm or a risk of serious harm to patients or public health" in one or more Member States under Article 10a (1) of the MDR/IVDR?

The potential consequence of the interruption or discontinuation of a supply of a manufacturer's device, is that a particular diagnosis method or patient therapy may not be available in one or more Member States. This non-availability of the particular diagnosis method or patient therapy, may result in "serious harm or risk of serious harm to patients or public health".

"Serious harm or risk of serious harm to patients or public health" should be understood as any serious injury to patients or threat to public health that occurs, or where there is a significant probability of this occurring. Cases where 'non-availability' may result in 'serious harm or a risk thereof' include where patients face:

- an imminent risk of death,
- a serious deterioration of patient health[9], or
- a life-threatening condition

and for which, no suitable alternative diagnosis method or therapy (including, but not limited to, pharmaceutical therapy) is available.

It should be noted that serious harm can also be due to the inability of a healthcare professional to deliver a specific medical treatment due to an interruption or discontinuation in the supply of a device.

9.1 How can the manufacturer approach the assessment to determine whether the interruption or discontinuation in the supply of the device may result in serious harm to patients or public health?

It is the responsibility of the manufacturer to assess whether the interruption or discontinuation in the supply of the device may result in serious harm to patients or public health. For the assessment the following should be considered:

- the potential for serious harm to patients should not be assessed based on an individual patient case; rather, the harm should be considered for the patients of the population for which the device is intended.
- it is not expected that the manufacturer conducts a comprehensive market analysis but that it bases its assessment on available information at its disposal, limited to the manufacturer's awareness of its own device supply.
- the manufacturer may consult with physicians, medical societies, or healthcare facilities to gather any further information which it determines to be necessary for assessing the impact that interrupted supply or discontinuation of the device may have on patient safety and health.

9.2 Which indicators can the manufacturer take into account when performing its assessment?

When determining whether an anticipated supply interruption or discontinuation may result in serious harm to patients or public health, the following possible indicators may assist the manufacturer in its assessment. These indicators are non-exhaustive and not all indicators are to be considered for each assessment by the manufacturer.

<u>The relevance of the device for ensuring essential healthcare services</u>:

- the intended purpose of the device e.g. is it a life-sustaining or life-saving device or accessory.
- is the device intended for a specific patient population e.g., vulnerable populations such as paediatric or geriatric patients.

[9] Definition provided in MDCG 2023-3 'Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices'.

- if the disruption or interruption will limit the patients from access to treatment e.g. are there any secondary possibilities of getting the treatment without the device?
- is there a dependency of patient health and safety on the continuous availability of the device in question.

Alternative solutions:
- if the manufacturer is able to provide a suitable successor or alternative solution. For interruptions, this should be also taken into account the expected length of the interruption.
- is there any required infrastructure, or any training required to use the alternate successor device or any other alternative solutions.
- is, to the current knowledge of the manufacturer, a suitable alternative device available from another manufacturer which can meet expected demand.

Other factors
- whether there is an objective reason to anticipate an interruption or discontinuation of supply of a certain device or range of devices or an entire product line?
- the quantities of devices already made available on the market in one or more Member States.
- available stocks or timelines for procuring alternatives for such devices.
- market share of the device in question.
- have mitigations measures to prevent the interruption or discontinuation of supply been considered?
- will the devices continue to be available from stockpile during the interruption?

Note: This question is complemented by a decision tree diagram [10].

10. Is the information provided to the competent authority subject to Article 109 MDR/102 IVDR?

The information provided to the competent authority pursuant to Article 10a of the Regulations is subject to Article 109 of the MDR and Article 102 of the IVDR.

However, the competent authority that receives the information will need to share some of the information provided with competent authorities of the other Member States and the Commission to inform them of the anticipated interruption or discontinuation per Article 10a (2). Also, the competent authorities receiving the information regarding the anticipated interruption or discontinuation may need to act upon the information received and share part of the information received with health institutions, healthcare professionals, importers or distributors within their jurisdiction.

11. How should the information to the competent authority under Article 10a be provided?

To inform the relevant competent authority, the manufacturer, its mandated authorised representative, or any other actor acting on behalf of the manufacturer should provide the information specified as required in the 'Manufacturer Information Form'[11]. The information should then be submitted to the competent authority of the Member State where the manufacturer or its authorised representative is established.

It should be noted that Member States may provide additional information on how to submit the information in the form, on the websites of the relevant competent authority.

[10] A decision tree diagram that may assist manufacturers when assessing an interruption or discontinuation of supply has been developed by competent authorities within a task force under the Competent Authorities for Medical Devices (CAMD). The decision tree is available here: Guidance - MDCG endorsed documents and other guidance - Public Health.

[11] Please see MDCG 2024-16 'Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices'.

12. Which information should be included in the 'Manufacturer Information Form' for notification to the competent authority under Article 10a?

Manufacturers are requested to include all information specified as required (i.e., not marked as voluntary) in the 'Manufacturer Information Form'[12], when submitting the notification to the competent authority of the Member State where it or its authorised representative is established. Additionally, manufacturers may voluntarily inform the competent authority of any relevant changes to the submitted form by sending an updated form, indicating either 'additional information' or 'follow-up information', reflected as voluntary in section 1, sub-section 'type of information' of the MIF. When using either option, the submitter should specify which sections of the form have been modified, e.g., Section 2, sub-section 'X'. In sections marked as "voluntary", manufacturers can include additional information relating to the interruption or discontinuation that will be useful to the competent authority in the appraisal of the situation.

PART C – OTHER ECONOMIC OPERATORS' OBLIGATIONS

13. What is the responsibility of other economic operators in the supply chain under Article 10a (3) of the MDR and IVDR after receiving the information from the manufacturer?

The information obligation regarding an anticipated interruption or discontinuation of device supply in Article 10a of the MDR/IVDR is intended to have a cascading effect. The information originating from the manufacturer, should be passed to other economic operators in the downstream supply, until it reaches the relevant health institutions, or healthcare professionals.

Relevant economic operators therefore who have received information from the manufacturer under Article 10a(1) of the MDR/IVDR or another economic operator in the supply chain (e.g. from importers or distributors), are expected to further share this information 'without undue delay' with other economic operators, health institutions and healthcare professionals to whom they directly supply the device. It is expected that economic operators do not change, add to or paraphrase the communication received from the manufacturer so as to preserve its integrity.

For the purposes of this document, "without undue delay" should be understood as acting, as soon as possible, and without any delay that is intentionally or negligently caused by the economic operator. This will allow for the rapid further distribution of information following receipt from upstream suppliers, to ensure downstream actors are informed in a timely manner and can prepare any mitigating measures.

It is recalled that Article 25 of the MDR/IVDR requires economic operators to achieve an appropriate level of traceability of devices and be able to identify their upstream and downstream suppliers. Article 25(2) of the MDR/IVDR requires economic operators to be able to identify any economic operator or any health institution or healthcare professional to whom they have directly supplied a device.

14. Does Article 10a of the MDR/IVDR apply to system or procedure packs?

Article 10a (1) of the MDR/IVDR applies to manufacturers of individual CE-marked devices within a system or procedure pack. These manufacturers are responsible for informing the relevant parties, as outlined in Article 10a (1) of the MDR/IVDR, including the competent authority and the system or procedure pack producer, about any interruption or discontinuation of their devices. Upon receiving this information, the system or procedure pack producer must, in accordance with Article 10a (3) of the MDR/IVDR and without undue delay, transmit this information to other economic operators, health institutions, and healthcare professionals to whom they directly supply the device.

Example of the information sharing flow in a scenario where the manufacturer does not directly supply to the health institution/healthcare professional:

A manufacturer of a CE-marked device, which is only used in surgical procedure packs intended for professional use, is informed of a supply interruption that fulfils the information condition of Article 10a (1) of the MDR/IVDR.

[12] Please see MDCG 2024-16 'Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices'.

The manufacturer, which is located in a Member State, does not incorporate the CE-marked device into the surgical procedure pack nor directly supply (their device) or this product to health institutions. Instead, the manufacturer supplies the device to the persons referred to in Article 22(1) of the MDR, who then incorporate the device into surgical procedure packs. These procedure packs are then distributed to health institutions through regional and local distributors. In this case, the information flow should be as follows:

- The manufacturer should inform the relevant competent authority in the Member State where it is established and the person(s) referred to in Article 22(1) of the MDR at least six months before the anticipated interruption.

- The person(s) referred to in Article 22(1) of the MDR must, promptly and without undue delay, inform the distributors to whom they directly supply the device, which is incorporated in the system and procedure pack, of the anticipated interruption.

- The distributors who have received this information must, promptly and without undue delay, inform other distributors, health institutions and healthcare professionals to whom they directly supply the device.