MedTech Europe
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AESGP

COCIR
Advancing Healthcare

Article 10a MDR / IVDR: Notification in Case of Interruption or Discontinuation of Supply

Decision Guide Flowchart, Rev. March 2025

Disclaimer

This flowchart, co-signed by AESGP, COCIR and MedTech Europe (the Associations), has been developed to support companies in implementing a structured decision-making process in accordance with the requirements of Article 10a MDR/IVDR, introduced by Amending Regulation (EU) 2024/1860. It is based on the text of Article 10a MDR/IVDR itself, as well as the Q&A document which has been developed by the European Commission in collaboration with stakeholders and was published in December 2024.

This flowchart is not legally binding and does not constitute legal or regulatory advice. In case of any discrepancies, the official text of Article 10a and the European Commission's Q&A document shall take precedence over this flowchart. The Associations accept no legal responsibility for the use of this flowchart, and companies should seek their own legal or regulatory advice before making any decisions based on its content. The Associations reserve the right to change or amend this document at any time without notice in order to keep the information up to date.

Art. 10a MDR / IVDR legal text – Obligations in case of interruption or discontinuation of supply of certain devices

1. *Where a manufacturer anticipates an interruption or a discontinuation of the supply of a device, other than a custom-made device, and where it is reasonably foreseeable that such 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 shall inform the competent authority of the Member State where it or its authorised representative is established, as well as the economic operators, health institutions and healthcare professionals to whom it directly supplies the device, of the anticipated interruption or discontinuation.*

   The information referred to in the first subparagraph shall, other than in exceptional circumstances, be provided at least 6 months before the anticipated interruption or discontinuation. The manufacturer shall specify the reasons for the interruption or discontinuation in the information provided to the competent authority.

2. *The competent authority that has received the information referred to in paragraph 1 shall, without undue delay, inform the competent authorities of the other Member States and the Commission of the anticipated interruption or discontinuation.*

3. *The economic operators who have received the information from the manufacturer in accordance with paragraph 1 or from another economic operator in the supply chain shall, without undue delay, inform any other economic operators, health institutions and healthcare professionals to whom they directly supply the device, of the anticipated interruption or discontinuation.*

Abbreviations used in this document

MNF	Manufacturer as defined in Art. 2 (30) MDR or Art. 2 (23) IVDR
DEV	Device(s) as defined in Art. 1(4) MDR or Art. 1(2) IVDR
MS	Member State of the European Union
QMS	Quality Management System as required in Art. 10(9) MDR or Art. 10(8) IVDR

References

European Commission Q&A

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, REV 1, December 2024

Manufacturer Information Form - MDCG 2024-16 v 1.02

MDCG 2024-16: Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain in vitro diagnostic medical devices

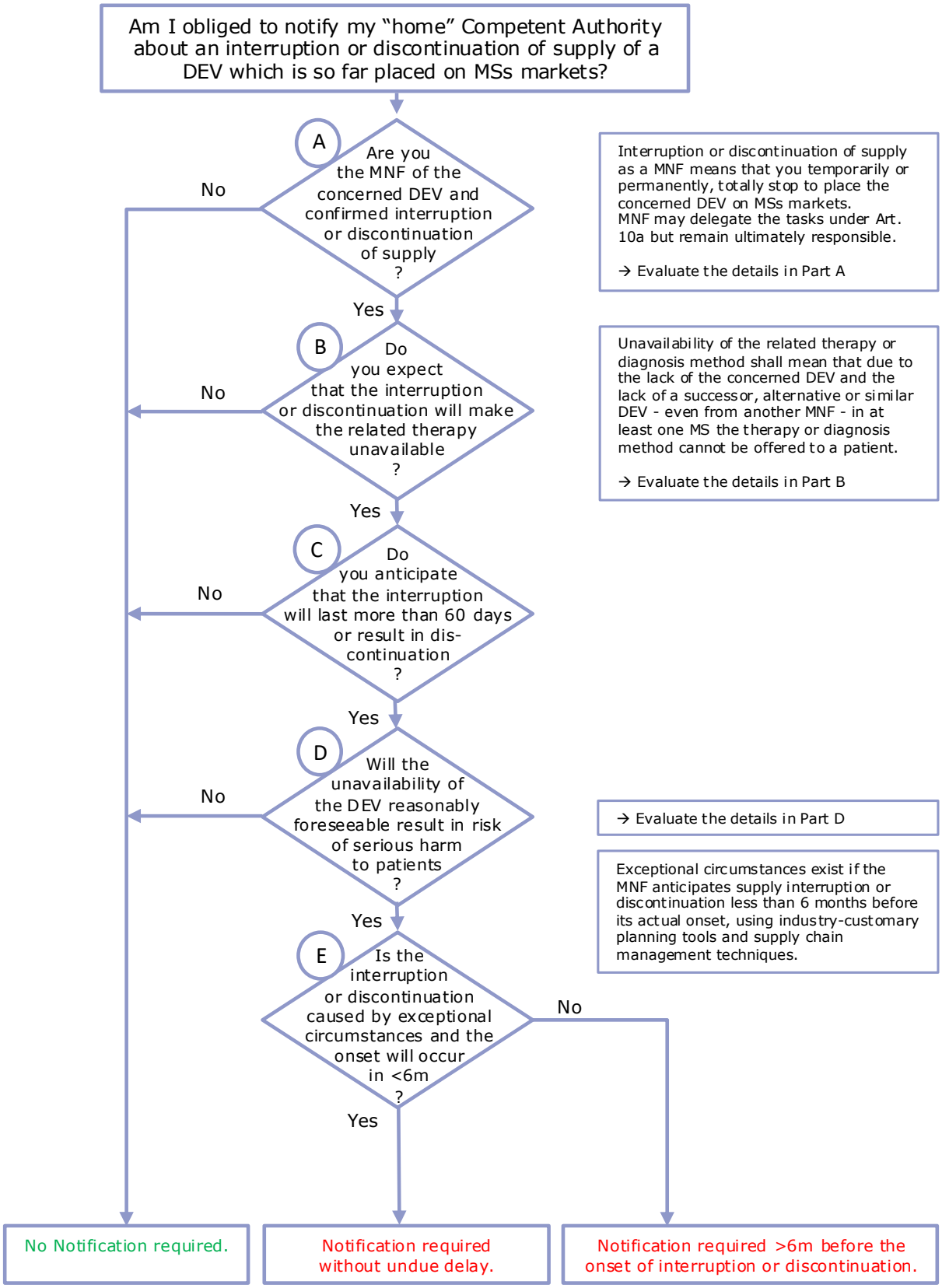
Device Identification Table - MDCG 2024-16 - Annex

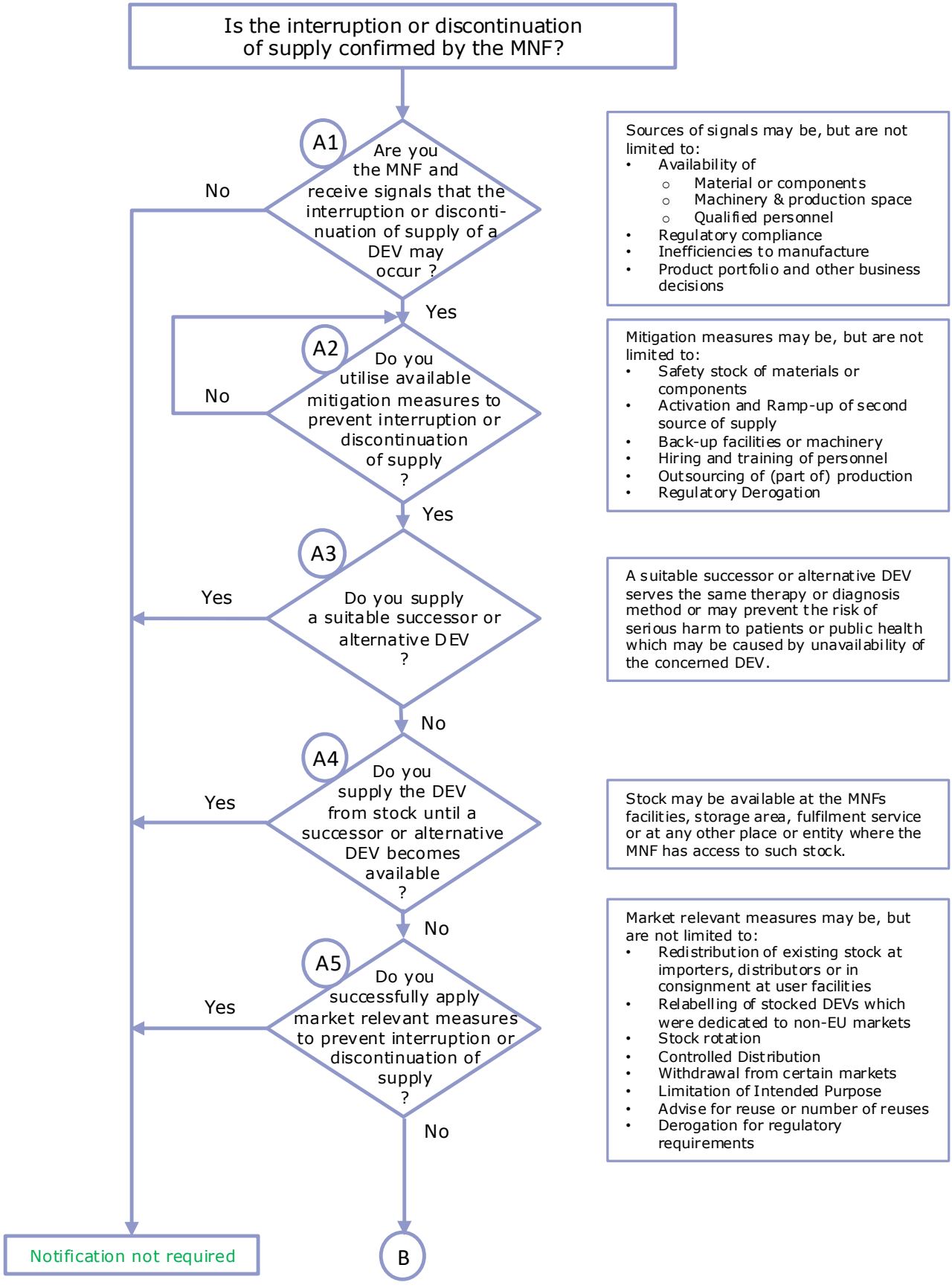
MDCG 2024-16 – Annex 1: Device Identification Table

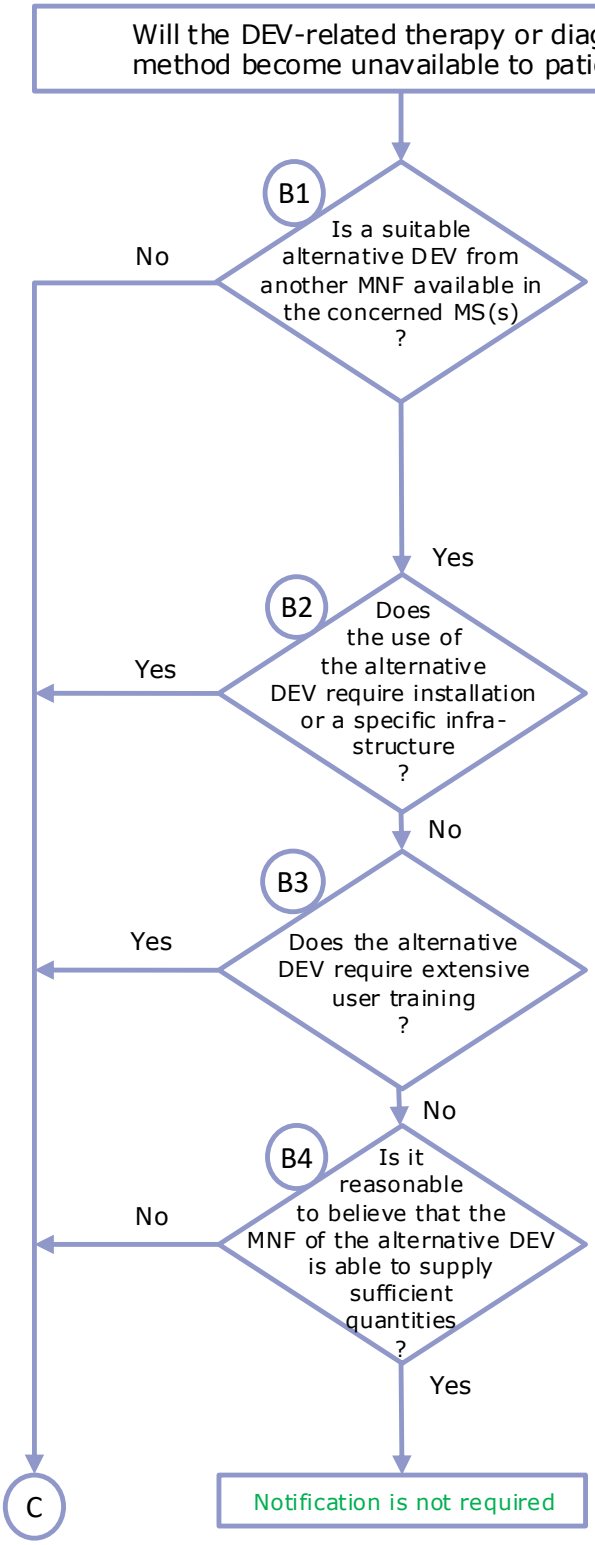
BVMed additional guidance

CMS Hasche Sigle legal opinion

The flowchart comprises a one-page main flowchart, accompanied by three sub-flowcharts, along with various comments, recommendations, and explanations.




Is the interruption or discontinuation of supply confirmed by the MNF?
A1
Are you the MNF and receive signals that the interruption or discontinuation of supply of a DEV may occur ?
No
Yes
A2
Do you utilise available mitigation measures to prevent interruption or discontinuation of supply ?
No
Yes
A3
Do you supply a suitable successor or alternative DEV ?
Yes
No
A4
Do you supply the DEV from stock until a successor or alternative DEV becomes available ?
Yes
No
A5
Do you successfully apply market relevant measures to prevent interruption or discontinuation of supply ?
Yes
No
Notification not required
B
Sources of signals may be, but are not limited to:
• Availability of
○ Material or components
○ Machinery & production space
○ Qualified personnel
• Regulatory compliance
• Inefficiencies to manufacture
• Product portfolio and other business decisions
Mitigation measures may be, but are not limited to:
• Safety stock of materials or components
• Activation and Ramp-up of second source of supply
• Back-up facilities or machinery
• Hiring and training of personnel
• Outsourcing of (part of) production
• Regulatory Derogation
A suitable successor or alternative DEV serves the same therapy or diagnosis method or may prevent the risk of serious harm to patients or public health which may be caused by unavailability of the concerned DEV.
Stock may be available at the MNFs facilities, storage area, fulfilment service or at any other place or entity where the MNF has access to such stock.
Market relevant measures may be, but are not limited to:
• Redistribution of existing stock at importers, distributors or in consignment at user facilities
• Relabelling of stocked DEVs which were dedicated to non-EU markets
• Stock rotation
• Controlled Distribution
• Withdrawal from certain markets
• Limitation of Intended Purpose
• Advise for reuse or number of reuses
• Derogation for regulatory requirements



A suitable alternative DEV serves the same therapy or diagnosis method or may prevent the risk of serious harm to patients or public health which may be caused by unavailability of the concerned DEV. Does the MNF have evidence that such alternative DEV is supplied ?

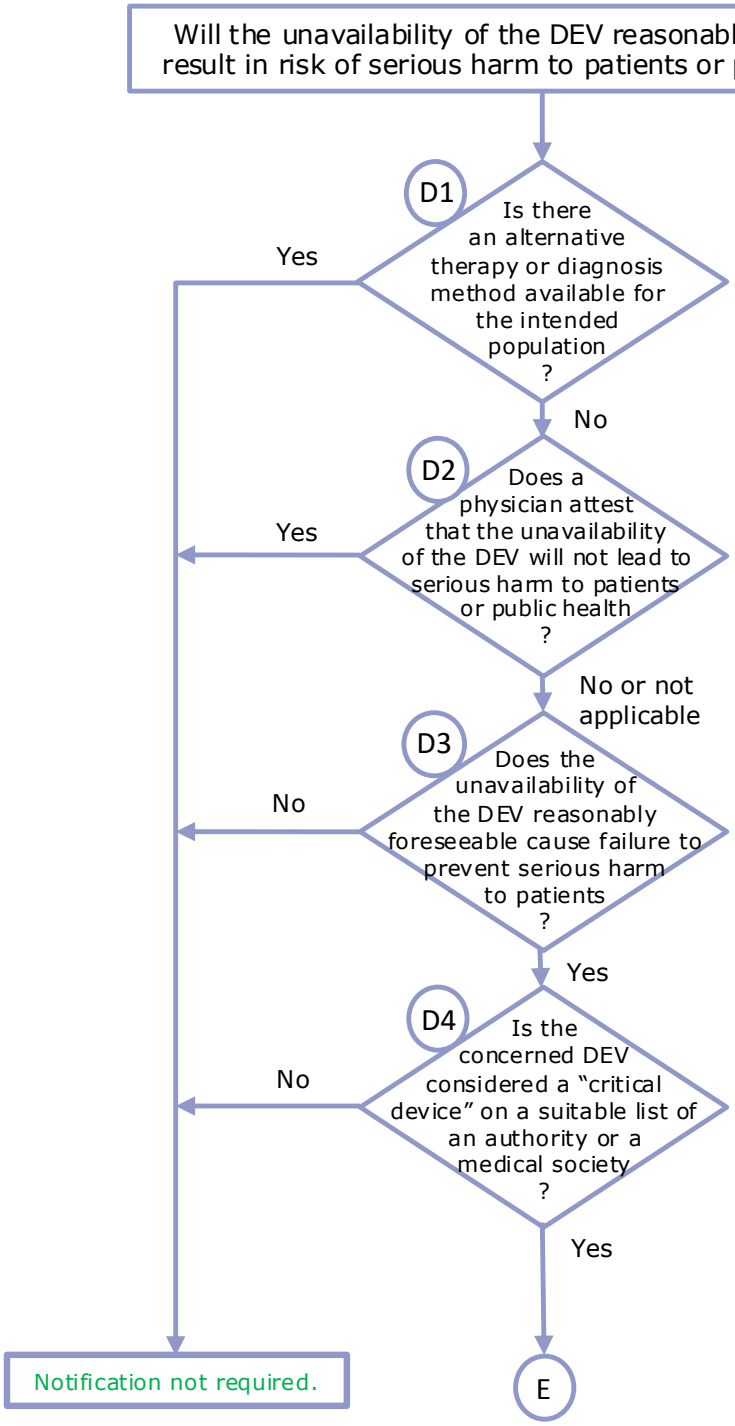
In addition:
Sometimes DEVs are not available in the member states but another market. This may be due to economic reasons or due to missing certification. The MNF may initiated a procedure in accord. with Art. 59 with his home Competent Authority to make such DEV available in the MSs.

Certain DEVs require
- installation of measures which are related to the building or the supplies within the building, or
- a certain infrastructure such as properties of the used room, or
- other DEVs or related accessories,

which may not be achieved or supplied in less than 60 days.

Some complex DEVs require extensive training of the user, which – even in best case circumstances - is not achievable in a few weeks.

In mono- or oligopolistic markets it may be unrealistic to believe that the inter-ruption of supply at a major MNF can be compensated by other MNFs with an alternative DEV.



Alternative therapies or diagnosis methods include any type or style, whether DEV-based or not.
It includes pharmaceutical therapy.

The MNF may seek advice from a physician, a healthcare institution, an ethics committee or medical society for its individual case of interruption of discontinuation to substantiate his notification decision or lack thereof.

The unavailable DEV per se does not cause harm. It is rather the DEV's unavailability which does not prevent the progression of the patient's disease, injury or disability.
In context of the intended purpose of the DEV and the intent of Art. 10a, patient populations who are facing an imminent risk of death, a life-threatening condition or - to a certain extend - a serious deterioration of patient health are to be assessed.

Authorities and Medical Societies have started to work on lists of critical DEV after the COVID19 pandemic. There may be lists considered suitable where the inclusion criteria match the intent of Art. 10a and which follow a respective methodology driven by an all-stakeholder expert group.
Example could be a threat-unspecific European list of critical devices similar to the US HHS Critical Medical Devices List (CMDL).