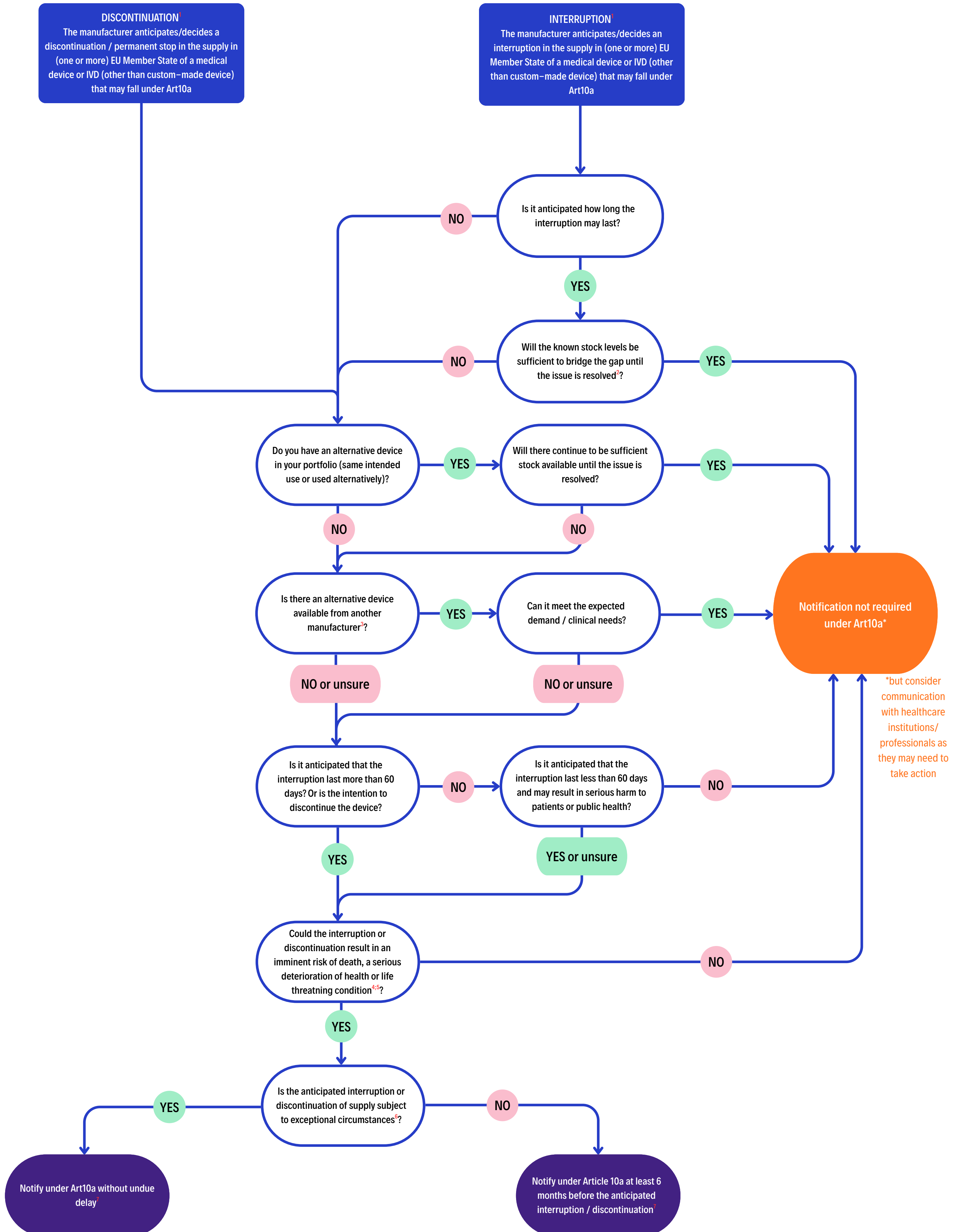


# Article 10a Decision tree

This decision tree aims to outline the key points to consider in the assessment of an interruption or discontinuation of supply of a device falling under Article 10a (Regulation EU 2024/1860) affecting one or more Member State.



## Notes:

1: 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 (refer to question 7 of the Q&A)

2: refer to questions 7 & 9.2 of the Q&A

3: If alternative device(s) are not available in the manufacturer’s own portfolio, the interruption / discontinuation of supply should be assessed with regards to its impact on the possibility to provide care. This may include considering information available to the manufacturer on whether alternative options (i.e device(s) from another manufacturer or suitable methods of diagnosis or therapy) are available. If an alternative device(s) / method(s) is identified, the following aspects may be considered, as relevant (not exhaustive) :

- if it is readily available
- if it can meet the expected demand / clinical needs in the markets concerned
- if it requires any particular infrastructure or any training (in some cases, recourse to the alternative may be limited)

4: refer to questions 9.1 & 9.2 of the Q&A

5: The manufacturer may consult with physicians, medical societies or healthcare facilities to gather any further information which determines to be necessary for assessing the impact that interrupted supply or discontinuation may have on patient safety and health (refer to question 9 of the Q&A)

6: refer to question 6 of the Q&A

7: Manufacturers should inform:

- the competent authority of the Member state where the manufacturer or authorised representative is established
- the economic operators, healthcare institutions and healthcare professionals to whom the manufacturer directly supplies the device

***Disclaimer:*** This decision tree has been developed by the competent authorities within a task force under the Competent Authorities for Medical Devices (CAMD).

*This decision tree is intended to complement the Q&A document aiming to facilitate the application of Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending the 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 decision tree is of general nature and not intended to address specific circumstances of any particular case; it 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. In case of discrepancies, the official text of Article 10a of the MDR/IVDR will take precedence over this decision tree.*