MDCG 2024 – 16

Manufacturer Information Form on Interruption or Discontinuation of Supply of certain medical devices and certain *in vitro* diagnostic medical devices (as per Article 10a of Regulation (EU) 2024/1860 amending Regulation (EU) 2017/745 and Regulation (EU) 2017/746)

Note: this form should be completed where reporting on individual or several devices of the same manufacturer. For reporting on several devices, only one form should be completed and see section 6 for further instruction. See also Q.11 and Q.12 of 'Q&A Obligation to inform in case of interruption or discontinuation of supply'. For the purposes of this form, no personal data should be submitted or collected, including contact details.

1 Administrative information
Name of National Competent Authority (NCA) to which this report is sent
Type of information ◯ Initial information ◯ Additional information (voluntary)* ◯ Follow-up information (voluntary)*
***Please specify modified sections of the form (if additional or follow-up information):**
Date of information
Reference number assigned by the manufacturer (if any)
Reference number assigned by NCA (as applicable)

2 Information on submitter of the report
Status of submitter ◯ Manufacturer ◯ Authorised Representative (if mandated to act on behalf of the manufacturer) ◯ Other entity (if acting on behalf of the manufacturer)

3 Manufacturer Information	
Manufacturer organisation name	
Single registration number (if filled here and already EUDAMED registered, please leave following fields in this section 3 open)	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country**

4 Authorized Representative Information (if applicable)	
Authorised representative organisation name (if mandated to make this report on behalf of the manufacturer)	
Single registration number (if filled here and already EUDAMED registered, please leave following fields in this section 4 open)	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country**

5 Other entity (if applicable)	
Organisation (if completing this report on behalf of the manufacturer)	
Address	
Postcode	**City**
Phone	**Fax**
E-mail	**Country**

6 Medical device information

Risk class of device

MDD/AIMDD

- ○ AIMD Active implant
- ○ MDD Class III
- ○ MDD Class IIb
- ○ MDD Class IIa
- ○ MDD Class I
- ○ MDD Class I sterile
- ○ MDD Class I measuring function

IVDD

- ○ IVD Annex II List A
- ○ IVD Annex II List B
- ○ IVD for self-testing
- ○ IVD general

MDR

- ○ Class III
- ○ Class IIb
- ○ Class IIa
- ○ Class I
- ○ Class I sterile
- ○ Class I measuring function
- ○ Class I reusable surgical instruments

IVDR

- ○ Class D
- ○ Class C
- ○ Class B
- ○ Class A
- ○ Class A sterile

Device Identification

Please fill this section when reporting on an individual device.
Where reporting on several devices, complete the 'MDCG 2024-16 Annex - Device Identification Table'.
Reports on several devices should be for the same manufacturer, the same interruption or discontinuation and same associated reason (See 'reasons' in section 7).

Unique Device Identification (UDI-DI)/EUDAMED ID (if applicable)	
Basic UDI-DI/Eudamed-DI (if applicable)	

If the above UDI section is completed and the device is already registered in EUDAMED, please leave the following fields blank and go to 'Intended use' field.
If filling out the following fields for devices without UDI-DI/ EUDAMED DI, please complete all mandatory fields.

Model	**Catalogue/reference number**
Nomenclature system (e.g. EMDN)	**Nomenclature code**
Nomenclature text	
Commercial name/ brand name / proprietary or common name	
Intended use according to the IFU or add IFU in attachment (voluntary)	

7 Description of the Interruption or discontinuation of supply (information requested as per Art 10a)

Specify if the report concerns an interruption or discontinuation

- ◯ Interruption
- ◯ Discontinuation

Reason for the Interruption or Discontinuation of Supply

please select:

- ◯ Regulatory issue
- ◯ Supply chain issue
- ◯ Manufacturing issue
- ◯ Other

Specify other:

Additional information on reason for the interruption or discontinuation of supply (voluntary)

Information on the assessment of the situation (If available)

- ◯ Device used in a serious, acute or chronic pathology, life- sustaining or life-saving device or accessory
- ◯ Intended for a specific population (e.g., vulnerable populations such as paediatric or geriatric patients)
- ◯ Disruption or interruption limiting / preventing the patients from accessing treatment
- ◯ Device without or with limited available alternatives, or consumable device not replaceable by any other type/ brand Major market share in one or several members states
- ◯ Other

Additional information on the assessment of the situation (if available)

Duration

When is the interruption/discontinuation of supply estimated to start?

When is the interruption estimated to end (if available)**?**

Note: Where the estimated start date differs in case of reporting on several devices, please complete the dedicated field in the 'MDCG 2024-16 Annex - Device Identification Table'. The same applies for interruptions where end date is provided.

Additional information about the estimated duration, if the start date and the duration is disclosed (voluntary)**:**

Estimated point in time for resumption of supply of the devices (where known and appropriate)

The medical device is usually marketed and supplied to the following countries: (voluntary)

☐ All EEA, Turkey and Northern Ireland

☐ AT ☐ BE ☐ BG ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GR ☐ HR
☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT
☐ RO ☐ SE ☐ SI ☐ SK ☐ TR ☐ XI

Others:

The code XI is used for Northern Ireland

The countries that are impacted by the interruption/discontinuation:

☐ All EEA, Turkey and Northern Ireland

☐ AT ☐ BE ☐ BG ☐ CY ☐ CZ ☐ DE ☐ DK ☐ EE ☐ ES ☐ FI ☐ FR ☐ GR ☐ HR
☐ HU ☐ IE ☐ IS ☐ IT ☐ LI ☐ LT ☐ LU ☐ LV ☐ MT ☐ NL ☐ NO ☐ PL ☐ PT
☐ RO ☐ SE ☐ SI ☐ SK ☐ TR ☐ XI

Others:

The code XI is used for Northern Ireland

Information Notification(s) regarding the interruption or discontinuation of supply have been sent:

Notification to HI/HCPS	☐ **Yes**	☐ **No**	☐ **Not Applicable**	**Date Sent (DD/MM/YY)**
Notification to AR	☐ **Yes**	☐ **No**	☐ **Not Applicable**	**Date Sent (DD/MM/YY)**
Notification to importers	☐ **Yes**	☐ **No**	☐ **Not Applicable**	**Date Sent (DD/MM/YY)**
Notification to distributors	☐ **Yes**	☐ **No**	☐ **Not Applicable**	**Date Sent (DD/MM/YY)**

Attached files (Voluntary)

8 Additional information on Interruption or Discontinuation of Supply (voluntary)

This section allows manufacturer, on voluntary basis or on the request of a competent authority, to share additional information

Possible mitigations measures: *to reduce the impact of the interruption or discontinuation of supply.*

Is the redistribution of EU or Global stocks an option? ☐ **Yes** ☐ **No**

Do you manufacture a similar alternative product with a similar intended purpose? ☐ **Yes** ☐ **No**

Details of the remaining inventory / existing stock level at EU level

If applicable, please provide information in attached file

Progress update on the interruption or discontinuation of supply