DG Internal Market, Industry, Entrepreneurship and SMEs

# Guidelines for Member States on the use of Data Exchange solutions

## MDR EUDAMED

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# Contents

1 INTRODUCTION 4

1.1 Purpose ..... 4
1.2 Requirements for the different modes of data input ..... 4
1.3 Assessment for Competent Authorities for Actors and Certificates data ..... 6
1.4 Assessment for Economic Operators for UDI and Basic-UDI data ..... 7
1.5 Assessment for Notified Bodies for Certificates data ..... 8

# 1 INTRODUCTION

## 1.1 Purpose

The purpose of this document is to help Competent Authorities, Notified Bodies, as well as all Economical Operators (Manufacturers, Authorised Representatives, Importers, and System/Procedure Pack Producers) in assessing the most cost-efficient solution for their needs to comply with the Medical Devies Regulation.

Although Eudamed offers multiple ways of inputting/downloading data, there are several parameters to take into consideration before making a decision. The different entry points include:

1. The User Interface: this option implies manual input of data through the application.
2. The XML upload/download: this option is a semi-automated one, where the data can be uploaded by means of XML files. The XML data must be validated agains the provided EUDAMED DTX service and entity model XSDs. The generation of the files can be automated, but the action of uploading/downloading the files remains manual.
3. The Data Exchange Machine – to – Machine (M2M) system: this option allows for automatic data exchange between an external backend system and Eudamed backend services (in bulk as well). The End User enters information in the external system, and the data is automatically transmitted to Eudamed, in XML format following the same conditions as previously mentioned without any human intervention. However, the connection of two systems in a fully automatic way may be too costly considering many architectural, technological and operational aspects (e.g. local application readiness, interoperability, infrastructure, security, support, etc.) if the frequency and/or volume of transmission remains low.

This document covers only the assessment on data related to Actors, UDI, and Certificates module. It will include Vigilance and Clinical Investigations at a later stage.

The Security requirements mentioned in Section 1.2 will be published at a later stage.

## 1.2 Requirements for the different modes of data input

We provide here, a brief description of the requirements for the three already mentioned data input methods:

*The User Interface*

This option is the simplest one from data handling / manipulation / implementation point of view. The User only needs a PC with Internet connection and a browser to connect to Eudamed.

*The XML upload/download trough EUDAMED UI*

In addition to the requirements to connect to Eudamed, the User will need to provide (***upload***) the data in XML format to Eudamed. This will allow bulk upload of existing information by uploading the XML files through the User Interface. It is advisable to produce the XML format data in an automatic way to avoid validation errors of the data. Some implementation effort by an IT team will be required taking into consideration the complexity of the data format (XSDs) and validation rules (e.g. field sizes, tags positions, mandatory / vs. not mandatory, etc.).

Similarly, the User will only be able to bulk ***download*** the data in XML format. This format, although understandable, is not easy to be read. A software that displays this information in a more readable structure should be considered.

This solution could be useful when Eudamed goes live, where a high volume of data needs to be input, but where subsequent updates can be done through the User Interface. In this situation, the set up of a data exchange connection would not be justified, as it would be a one-off upload.

*The Data Exchange*

In this case, the data will be automatically transmitted between an external system and Eudamed. To achieve this, the external system must be extended in order to convert its data into the XML format requested by Eudamed DTX and implement a specifi data exchange protocol.

Furthermore, in order to establish the connection through eDelivery, there is a need to link the external system with an Access Point. This Access Point needs to be installed on specific hardware on premises, and maintained (support, versions updates, configuration, etc.).

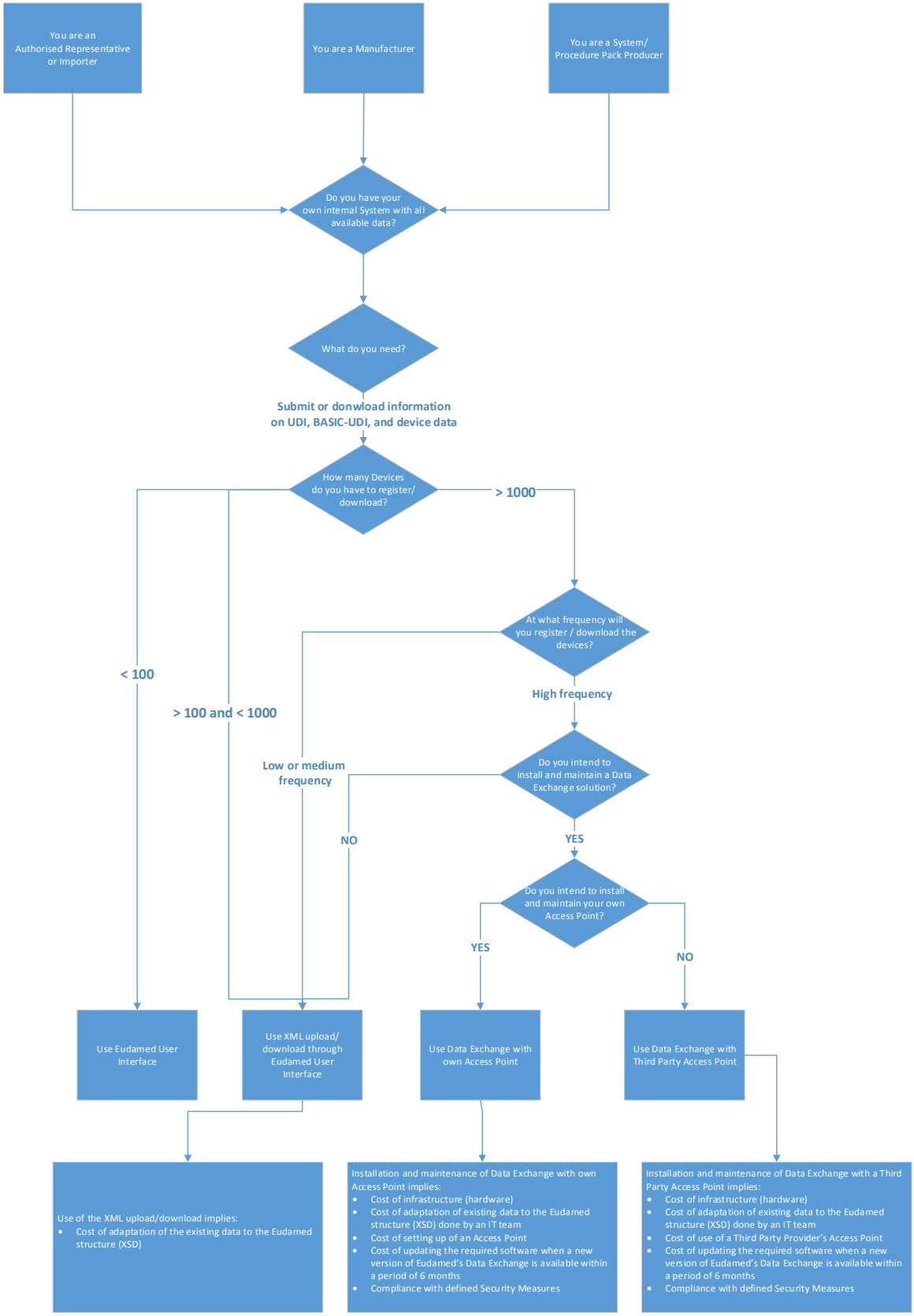
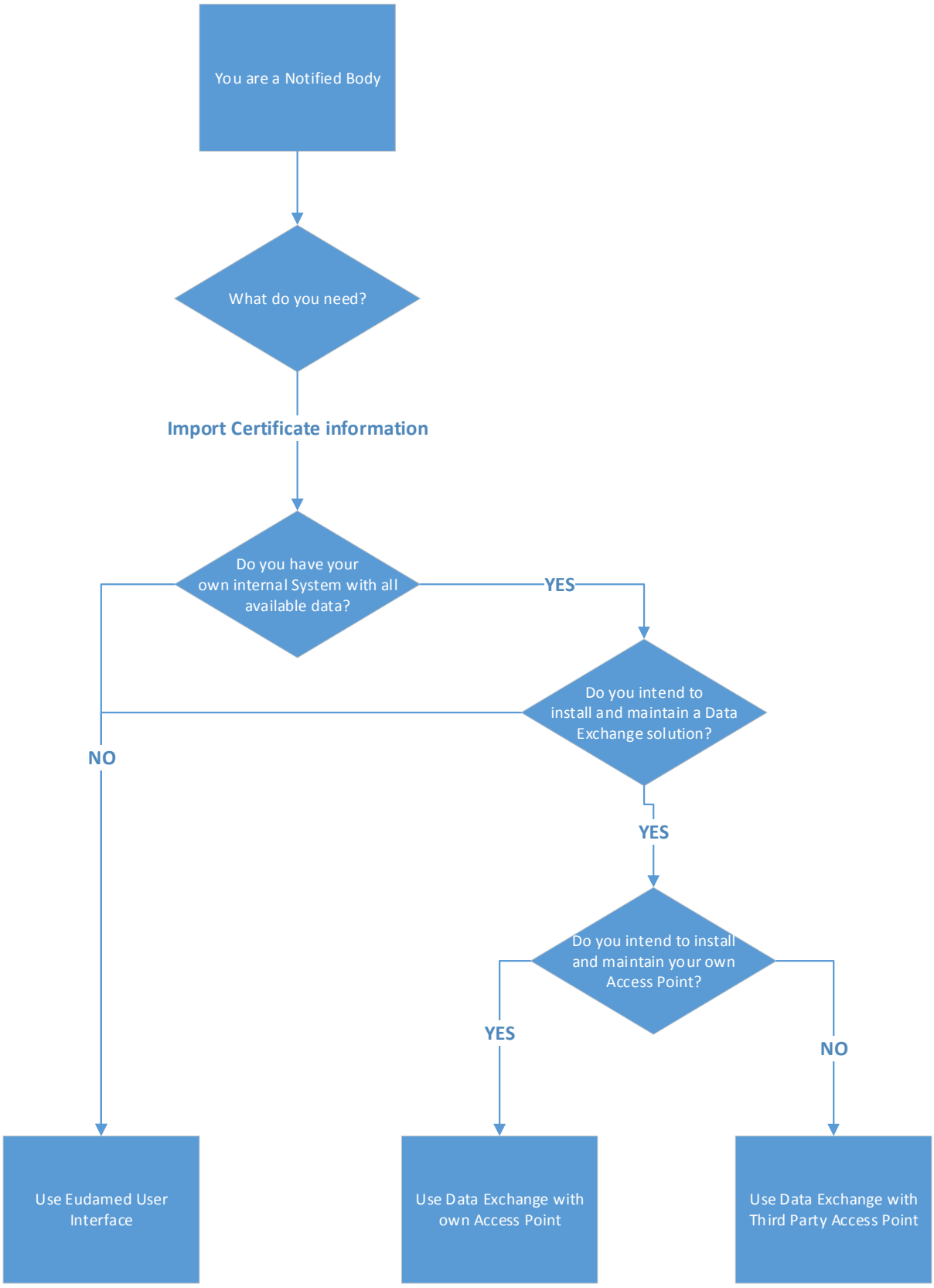
Because this mechanism allows bulk download of sensitive data in a fast way, the application connected to Eudamed will also need to comply with a series of security requirements, in order to preserve the defined security level.

The data exchange may be updated in future releases, e.g., when there is a new field, or a new value of a label, or a new functionality. Whenever there is a new release, all systems connected through the data exchange system will have a 6 months period to be updated in order to adapt to the new changes.

Overall, this is the most complex and costly solution, which should only be considered under the following conditions:

- the amount of data to be uploaded/downloaded cannot be entered manually
- there will be frequent exchanges of information between systems
- the cost of manual input outweights the cost of automation
- there are available resources for implementation and maintenance

## 1.3 Assessment for Economic Operators for UDI and Basic-UDI data



## 1.4 Assessment for Notified Bodies for Certificates data