Guidelines on Data Exchange with EUDAMED

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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 Devices Regulation.

Although EUDAMED offers multiple ways of inputting/downloading data, there are several parameters to take into consideration before making a decision.

The different data input methods are:

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 against 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 (DTX) 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 of data related to the EUDAMED modules that are available and can be used on voluntary basis: Actors registrations, UDI/Devices, and NBs & Certificates modules.

2 Requirements for the different modes of data input

Brief description of the requirements for the three data input methods:

2.1 The User Interface (UI)

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

2.2 The XML bulk upload/download through 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. Software that displays this information in a more readable structure should be considered.

2.3 The Machine-to-Machine Data Exchange (M2M-DTX)

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

Furthermore, 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.).

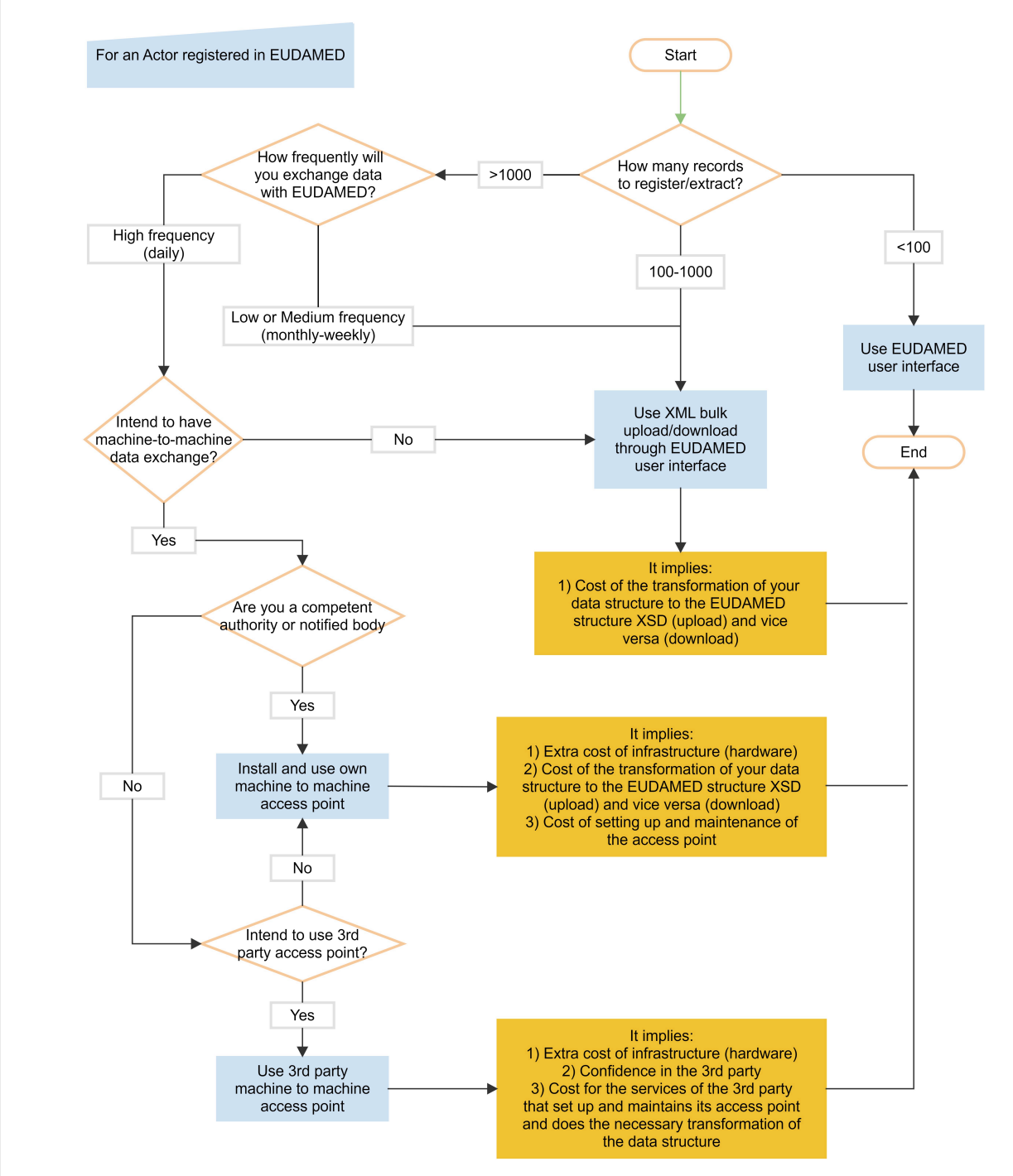
When EUDAMED is fully functional, in the event of a change being implemented that requires a change to the DTX (for example new functionality or a change to the validation

rules for a field), there will be a period (usually 6 months') of notice and both the old and new XSD will work for that period. After that period, all systems connected to EUDAMED will need to have been updated to continue to work for data exchange. During EUDAMED development phase, i.e. before it is fully functional, any DTX changes will be communicated 4 to 6 weeks prior to a new release.

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

- The Actor that needs to exchange data with EUDAMED has a database outside EUDAMED for these data.
- The amount of data to be uploaded/downloaded is too important for being entered/ extracted manually (would be too burdensome and too long).
- There will be frequent exchanges of information with EUDAMED.
- The cost of manual input outweighs the cost of automation.
- The Actor has enough available and necessary resources, competence and infrastructure for implementation and maintenance.

3 Assessment on the way to provide data and to obtain data from EUDAMED

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