MDCG 2018-7

Provisional considerations regarding language issues associated with the UDI database (Annex VI, Part A Section 2 and Part B of the Medical Device Regulation (EU) 2017/745 (MDR) and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR))

October 2018

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

General principles

In consideration of the following:

- In accordance with Article 28(3) MDR and Article 25(3) IVDR, the core data elements to be provided to the UDI database shall be accessible to the public,

- Annex VI Part C of the MDR and IVDR on the UDI System requires explicitly in its section 5.10 that *the user interface of the UDI database shall be available in all official languages of the Union* and that *the use of free- text fields shall, however, be minimized in order to reduce translations,*

- one of the main declared purposes of the European database on medical devices (Eudamed) as per Recitals 43-46 and Article 33(1a) of the MDR and Recitals 40-43 of the IVDR is to enable the public (including the healthcare professionals) to be adequately informed about devices placed on the market,

it is essential that the information in the UDI database is publicly available and easily understandable by any European citizen.

Use of free-text and translation

Among the UDI core data elements of Part B of Annex VI of the MDR and IVDR, only three data elements ("Additional product description", "Storage and handling conditions" and "Critical warnings or contra-indications") are expected to have a free-text format, while a fourth data element (nomenclature term) is associated with a text allowing to understand the meaning of the associated code (description).

As to the nomenclature, ideally, all the terms/description associated with the nomenclature codes should be translated in the different Union official languages. However, it could be also considered having terms available only in English, particularly taking into account that the nomenclature will have a code. Appropriate budget and legal verifications will be made on this matter, in the context of the designation procedure for the new nomenclature.

Among the three data elements that use free-text, one is an optional field: "Additional product description". It should be provided in English as well as in the languages of those countries where the device is made available. A data field will be available for each relevant language.

For the data elements "Storage and handling conditions" and "Critical warnings or contra-indications", relevant information (as per Annex I Section 23.2 of the MDR and Annex I Section 20.2 of the IVDR: (k) "any special storage and/or handling conditions" and (m) "warning or precautions to be taken") should be provided in

English as well as in the languages of those countries where the device is made available. It shall be noted that, as laid down in the provisional guidance related to formats and definitions of UDI data elements, only storage/handling conditions and critical warnings or contra-indications, that are required to be on the label, shall be transmitted to the UDI database. With respect to those two data elements, the possibility to use (in EUDAMED) – as an alternative option - symbols and/or list of reference that can categorise and provide enough information understandable by anyone is currently being explored.

Indication of hazardous substances (only applicable for MDR)

For CMR substances, the Commission intends to explore the feasibility for EUDAMED to provide the list of official CMR[1] substances (from CLP Regulation[2]) available in the ECHA[3] database. The CAS number[4], EC number and/or official chemical name could be used to identify those substances.

With regard to endocrine disruptor substances, pending verification that an official database managed by the Commission containing these substances is available, a solution is currently being explored.

Information to be provided is known by the economic operator in charge of the submission as it shall be displayed on the device label (Annex I Section 23.2 (f) of the MDR).

[1] CMR stands for carcinogenic, mutagenic, or toxic for reproduction
[2] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the 'CLP Regulation')
[3] The European Chemicals Agency
[4] A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature