MDCG 2018-2
Future EU medical device nomenclature
Description of requirements

Introduction

According to Article 26 of the Regulation 745/2017 on medical devices and Article 23 of Regulation 746/2017 on *in-vitro* diagnostic medical device, the Commission is required to make available a medical device nomenclature to support the functioning of the future EUDAMED.

This document intends to provide a detailed description of requirements and criteria that the future nomenclature is expected to fulfil. This is expected to serve as a reference basis throughout the decision process and will also ensure that all legal and technical issues associated with the future EU medical device nomenclature are properly mapped.

1. Description of legal requirements

It arises from the text of the new Regulations (namely Article 26 of Regulation 745/2017 and Article 23 of Regulation 746/2017) that the future EU medical device nomenclature will have to comply with certain defined requirements.

First of all, the future nomenclature shall be available free of charge to manufacturers and other natural or legal persons required by the Regulation to use that nomenclature, this meaning that no manufacturer or natural/legal person should be subject to fee or suffer from any discrimination, compared to other operators, in relation to the use of the nomenclature under the new Medical Device Regulations.

It shall be therefore ensured that relevant names and codes are accessible (in full) in EUDAMED to all operators that are requested to provide the relevant UDI submissions.

Provisions in Chapter III and Annex VI of the new Regulations, and in particular the combination of Article 28(3) of the Regulation 745/2017 on medical devices and point 8 of part B of Annex VI, provide that moreover names and codes are publicly available in the UDI database (in EUDAMED).

By virtue of Article 26, the Commission shall also endeavour to ensure that the nomenclature is available to other stakeholders free of charge, where reasonably

practicable. The public availability of terms and codes in EUDAMED is in itself an ideal vehicle to provide sufficient access of all stakeholders.

Finally the nomenclature shall be internationally recognised at the time of the date of application of the Regulations. In this context, global harmonisation principles and orientations followed and adopted by the International Medical Device Regulators Forum (IMDRF) and the World Health Organisation, are taken into particular account.

Without prejudice to the fulfilment of requirements described in previous paragraphs, the European Commission and the Competent Authorities from EU Member States shall benefit from the full access to the most up to date nomenclature system and its hierarchies free of charge. They shall not be charged for any service received from the nomenclature provider, which is necessary for them to exert their supervisory role over the nomenclature and the fulfilment of their obligations under the new Regulations.

2. Description of other relevant criteria

In order for the system to leverage further the potential of the future EU nomenclature, some other essential requirements that the nomenclature shall fulfil have been identified.

While those requirements are not explicitly mentioned in the texts of the two Regulations, they are essential to guarantee the good functioning of the future EUDAMED and to the fulfilment of some of the regulatory objectives set in the new Regulations, namely facilitating effective market surveillance operations and facilitating device traceability throughout the supply chain.

Policies/rules for update, removal and creation of names and descriptions in the nomenclature are to be sound and must reflect regulators' and the wider healthcare economy needs. An EU regulatory team on nomenclature composed of regulators, to be established possibly as an MDCG sub-group, will review, determine (preferably within a global perspective) and validate those rules prior to designation decision and will continue to hold an advisory role on these matters. On a periodic basis, in accordance with a pre-defined procedure, and in consultation with the nomenclature provider, that group shall also provide feedback and advice on the governance of terms and descriptions, based, inter alia, on the requests received from economic operators and other stakeholders.

In the context of activities mentioned in the previous paragraph, it shall be aimed to ensure that the terminology structure used for it should not be unnecessarily granular and should not contain names that are only used by only a few economic operators

or stakeholders, unless it is proven to be advantageous to regulators or the wider healthcare economy.

The structure and design of the future nomenclature should facilitate the establishment of links with the codes defining Notified Bodies competence (designation scope) , the scope of medical devices QMS (Quality Management System)/QA (Quality Assurance) certificates, and product portfolios in the mandate of Authorised Representatives.

The nomenclature should have hierarchies by which terms and codes could be meaningfully grouped into categories and subcategories

The future nomenclature system shall adequately support the functioning of the EUDAMED database and the functioning of the new Regulations as a whole. In this context, EUDAMED shall make available the most updated names/codes related information, to the benefit of operators and general public. Therefore, the nomenclature provider will need to have procedures and services in place that shall allow EUDAMED to be kept up-to-date at any time. When setting the procedure, in particular the frequency, related to the periodic review of nomenclature terms and descriptions, this shall be taken into account.

For enforcement purposes, in relation to its obligations vis-à-vis the Commission and the EU economic operators, the nomenclature provider shall have a legal entity in either one of the EEA countries or Switzerland or Turkey[1] with an exception being foreseen for international organisations in which the EU is one of the members.

System/processes shall be in place to periodically review the terminology structure and content to incorporate learning from ongoing experience with real-world use of device nomenclature (ex. EUDAMED, GUDID, registries) as well as from technological innovation.

Availability of names and descriptions in all the official EU languages is recognised as of being of high importance.

All copyrights associated with the nomenclature shall be secured.

[1] Indication of these countries is based on current situation with the applicable directives on medical devices as a result of the combination of the legal text of those Directives and relevant currently applicable international agreements. this list of countries might be subject to change in the context of the new medical device framework.