WHO concept note and collaboration proposal for International Nomenclature, coding and classification of medical devices (ICMD)

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Interest in ICMD: The Unit “Health Technology and Cosmetics” is responsible for the implementation of the medical device framework within the EU

General comment on the concept note, especially on the principles:

The European Commission welcomes the project undertaken by WHO. We note that that concept note builds on the same principles/objectives pursued by the EU in relation to the definition of a future EU medical device nomenclature.

- State-of-play within the EU:

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 database. The European Commission has set 1st quarter 2019 as the deadline for making available that nomenclature.

A document recently endorsed by the EU Medical Device Coordination Group (a EU regulators ‘group tasked with an advisory role on all matters related to the implementation of the EU medical device framework) provides a detailed description of requirements and criteria that the future nomenclature is expected to fulfil. This document will serve as a reference basis when engaging with possible nomenclature providers. The paper indicates that, the future EU 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”. Therefore, the EU is keen to establish the necessary link between the process for designation of nomenclature within the EU and the WHO work on establishing of an International Nomenclature so that deviations could be avoided.
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If you would like to propose your nomenclature /coding or classification system from your institution/country, in order to support the development of an international system for medical devices, ICMD, please provide your information below:

Name of the system:  
Website  
Owner  
Country  
Language  

Please feel free to explain your proposal Reasons why your system can be used to support the development of an international system that could be used by all medical devices stakeholders. (You would be contacted in September, once the responses are analysed)

Kindly send this form to medicaldevices@who.int before 24 August - thank you.