NOMENCLATURE SUB-GROUP OF THE MEDICAL DEVICE COORDINATION GROUP

Terms of reference

1. Tasks and roles

The Nomenclature sub-group ("the working group") of the Medical Devices Coordination Group (MDCG) shall provide assistance and advice to the MDCG on all implementation issues related to the medical device nomenclature with the aim to support the functioning of the future European database on medical devices (EUDAMED).

In particular, the group shall provide relevant advice in matters related to the update and maintenance of the EU nomenclature, which was made available by the Commission, in accordance with Article 26 of Regulation (EU) 2017/745 and Article 23 of Regulation (EU) 2017/746[1].

The group shall also advise on ways to use nomenclature in contexts other than Unique Device Identification (UDI) registration, such as market surveillance.

2. Membership

The group shall be composed of the representatives of Member States' competent authorities who are experts in the particular policy area.

Organisations representing the interests of the medical device industry, other economic operators, healthcare professionals, conformity assessment bodies, hospitals, laboratories, patients and consumers at Union level may be appointed as observers to the working group, as a result of a public call for applications.

Organisations appointed as observers shall nominate their representatives in the working group and shall be responsible for ensuring that their representatives provide a high level of expertise. Organisations shall promptly inform the Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs ('DG GROW') about any changes in the nominations. If the appointed organisation wishes that another person represents the organisation in a meeting other than the appointed representative, it shall inform DG GROW about any such person prior to the meeting.

DG GROW may refuse the nomination of a representative by an organisation if it considers this nomination inappropriate in light of the requirements specified in the above-mentioned call for applications, in particular in view of the level of the required expertise in a particular field. In such case, the organisation concerned shall be asked to appoint another representative.

3. Operation

The group shall act in compliance with the Commission's horizontal rules on the creation and operation of Commission expert groups[2], as well as with the terms of reference of the MDCG.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC
[2] C(2016) 3301.