Medical Device Coordination Group

15 October 2024

Agenda Point 11.a: AOB – Standardisation state of play

European Commission
Directorate-General for Health and Food Safety (DG SANTE)
Unit D.3 Medical Devices

Most recent achievements in standardisation for medical devices

- Adoption, acceptance and entering into force of the **MDR/IVDR standardisation request** (M/575) with its amendments (M/575 Amd 1, M/575 Amd 2), valid until December 2028, listing a total of 277 standardisation items for the MDR and 49 for the IVDR
- **Publications in the OJEU** of references of harmonised standards to confer presumption of conformity:
  - under the MDR: 26 harmonised standards (9% of the requested)
  - under the IVDR: 15 harmonised standards (31% of the requested)
- Endorsement and publication of the revised and improved **guidance document** MDCG 2021-5 Rev.1 Guidance on standardisation for medical devices

State of play and perspectives

- Even if their use is generally not compulsory, the **lack of an adequate number of harmonised standards** has been recognised as one of the most significant problems in the implementation of the MDR and IVDR, especially for manufacturers and notified bodies
- **Reasons** for the still limited number of harmonised standards:
  - on the Commission: difficulties in the implementation of certain aspects of the EU standardisation system (HAS consultants, “eNorm” platform…), long and complex procedures for publications in the OJEU
  - on the European standardisation organisations (CEN and CENELEC): lack of adequate resources and availability of experts in the Technical Committees, long and complex procedures for drafting and adopting standards
  - on other actors: interplay with international standardisation (ISO and IEC), impact of rulings of the Court of Justice of the European Union

Ongoing actions to improve the situation

- By the Commission:
  - Adoption and implementation of the "EU Strategy on Standardisation", including more active presence at international level
  - Ongoing evaluation of the horizontal Regulation (EU) No 1025/2012 on European standardisation for a possible revision to adequate it to present and future needs
  - Development of the "eNorm" platform as informative hub on European standardisation
  - Development of "readability platforms" to implement the ruling of the Court of Justice of the European Union on access to standards (Case C-588/21 P)
  - Increased cooperation with the CEN/CENELEC Technical Committees to pragmatically solve problems detected in the development of standards
- By the European standardisation organisations:
  - Increased cooperation with the Commission to improve and streamline the procedures for the adoption and publication in the OJEU of harmonised standards
  - Activities to upgrade transparency and participation in the standardisation process
  - Organisation of specific training and information initiatives for standardisation professionals

Interplay between harmonised standards and guidance documents: role of the MDCG

- Article 105 MDR “Tasks of the MDCG”: among others,
  - (c) to contribute to the **development of guidance** aimed at ensuring effective and harmonised implementation of this Regulation…
  - (e) to contribute to the **development of device standards**…
- Suggestion to launch a **mapping / matching exercise** between the CEN-CENELEC Technical Committees and the harmonised standards they develop in support of the MDR and IVDR, and the work of the MDCG and its Subgroups in developing guidance documents, in order to:
  - keep always informed each other on the respective initiatives
  - avoid duplications and overlaps in working on the same or very similar topics
  - optimise resources and stimulate participation of experts in the respective works
- The Commission will make available the **basic information** to develop the idea

Thank you!

More information on standardisation for medical devices:

Horizontal webpage: Single market and standards > European standards https://single-market-economy.ec.europa.eu/single-market/european-standards_en

Sectoral webpage: Public Health > Medical Devices - Topics of Interest > Harmonised standards https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en

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