EBN webinar on preventing sharps injuries, MDR and safety mechanism in medical devices

Point 7: MDR/IVDR standardisation request, new harmonised European standard and interpretation of 11.1 and 22.2 Annex I MDR

Directorate-General for Health and Food Safety (DG SANTE)
Unit B.6 Medical Devices, Health Technology Assessment

Sharps injury protection in the new EU legislation on medical devices

- **Regulation (EU) 2017/745 on medical devices (MDR)**, Annex I - General safety and performance requirements:

- 11.1: *Infection and microbial contamination* (further developed from Annex I, 8.1 of Directive 93/42/EEC)

11.1. Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,

(b) allow easy and safe handling,

(c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and

(d) prevent microbial contamination of the device or its content such as specimens or fluids.

- 22.2: *Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons*

22.2. Devices for use by lay persons shall be designed and manufactured in such a way as to:

— ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training and/or information,

— reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries, and

— reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

The MDR/IVDR standardisation request

- Positive opinion on the draft act delivered by the Committee on Standards on 12 March 2021
- **Commission Implementing Decision on a standardisation request to CEN and Cenelec as regards medical devices in support of Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746**, adopted on 14 April 2021 and published on the Commission's database "Standardisation - Mandates" as **M/575** (EN version) and on the Commission's webpage "Medical Devices - New Regulations - Topics of Interest", section "Harmonised European standards" (DE, EN and FR versions), including:
  - 201 existing harmonised standards to be revised and 27 new harmonised standards to be drafted in support of Regulation (EU) 2017/745, by 27 May 2024
  - 46 existing harmonised standards to be revised and 3 new harmonised standards to be drafted in support of Regulation (EU) 2017/746, by 27 May 2024
- Notified to CEN and Cenelec on 15 April 2021 and accepted on 12 May 2021 to make the **standardisation request fully applicable**
- CEN and Cenelec submitted the **joint work programme** to the Commission on 28 May 2021
- Standardisation request to be **periodically revised** in the lists of standards and possibly other contents when deemed necessary

European Commission

First publications in the OJEU of references of harmonised standards for the Regulations

- Two **Commission Implementing Decisions for harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746**, under preparation, to be adopted and published in the OJEU likely by June 2021
- First publications of lists of references of harmonised standards **to confer presumption of conformity under the Regulations**, including:
  - 5 references for Regulation (EU) 2017/745
  - 4 references for Regulation (EU) 2017/746
- A new cycle starting: publications to be **periodically updated** with subsequent amendments, each three/four months, to enlarge the lists according to the development of the standardisation work at European and international level and the correspondent state-of-the-art technical solutions for the highest degree of health, safety and performance of medical devices in the EU

Standardisation on sharps injury protection

- **EN ISO 23908:2013** ***Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling***:
  - harmonised for Directive 93/42/EEC under mandate M/295, but not cited in OJEU (thus not conferring presumption of conformity)
  - included in the **MDR/IVDR standardisation request** in its Annex I, Table 1 among the existing harmonised standard to be revised, with 27 May 2024 as deadline for the adoption
  - Requirements specified in its Annex III, point 2.3: "*The existing standard EN ISO 23908:2013 shall be modified by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which are intended to be used for administration and/or extraction of body/blood fluids and/or medicinal substances*"
  - To be developed by the Technical Committee *CEN/TC 205 - Non-active medical devices* by 27 May 2024, as per the CEN-Cenelec Joint Work Programme

Requirements 11.1 and 22.2 of Annex I MDR – interpretation, guidance?

- Legal interpretation, possible only by the Court of Justice of the European Union
- Possible guidance on the sound implementation of the requirements, by the sectorial working parties:
  - the Medical Device Coordination Group (MDCG) and its Subgroups (in particular on Standards – WG 2 – and on Notified Bodies Oversight (NBO) – WG 1)
  - the group of Competent Authorities for Medical Devices (CAMD)
  - others? (notified bodies, sectorial entities, etc.)
- Practical steps to be followed:
  - collection of information from different sources (associations, experts, etc.)
  - drafting of a text (Commission, working groups, task forces…)
  - procedures for discussion, revision, endorsement and publication

Thank you!

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