Webinar:

Progress with updating EN ISO 23908 on sharps injury protection

European Biosafety Network, 22 June 2022

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

Setting the scene: harmonised standards in support of the EU Regulations on medical devices

- In April 2021 the **Commission** adopted the **Implementing Decision C(2021) 2406 on a standardisation request to CEN and CENELEC as regards medical devices in support of Regulation (EU) 2017/745 (MDR) and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 (IVDR)** (M/575), in force since May 2021, including:
  - *Annex I*: 201 existing harmonised standards to be revised (Table 1) and 27 new harmonised standards to be drafted (Table 2) for the MDR, by 27 May 2024, and
  - *Annex II*: 46 existing harmonised standards to be revised (Table 1) and 3 new harmonised standards to be drafted (Table 2) for the IVDR, by 27 May 2024

  Regularly updated: draft first amendment, currently in the "Notification system" until 30 June 2022
- **CEN and CENELEC** as the relevant European standardisation organisations (ESOs) **and their Technical Committees** develop harmonised standards on the basis of the MDR/IVDR standardisation request, also in cooperation (by virtue of the Vienna and Frankfurt Agreements) with **ISO and IEC** as the relevant international standardisation organisations (ISOs)
- **The Commission with the support of the HAS consultants** assesses the draft harmonised standards to be cited in the *Official Journal of the European Union* (OJEU) to confer presumption of conformity with the requirements of the Regulations the standards aim to cover

Publications in the OJEU of references of harmonised standards in support of the MDR and the IVDR

- After the first publications in **July 2021**, new publications took place in **January 2022** and in **May 2022**:
  - for Regulation (EU) 2017/745 (MDR): **16 references** so far
    - Commission Implementing Decision (EU) 2021/1182 of 16 July 2021: 6 references
    - Commission Implementing Decision (EU) 2022/6 of 4 January 2022: 8 additional references
    - Commission Implementing Decision (EU) 2022/757 of 11 May 2022: 2 additional references
  - for Regulation (EU) 2017/746 (IVDR): **10 references** so far
    - Commission Implementing Decision (EU) 2021/1195 of 19 July 2021: 4 references
    - Commission Implementing Decision (EU) 2022/15 of 6 January 2022: 5 additional references
    - Commission Implementing Decision (EU) 2022/729 of 11 May 2022: 1 additional reference
- Overall information on the page Medical devices - Harmonised standards; consolidated versions (pdf, xls) on the standardisation pages for Medical devices and for *In vitro* diagnostic medical devices
- **New publications as amendments of the first publications** will continue to take place regularly, to enlarge the lists according to the development of the standardisation work at European and international level, as provided by CEN and CENELEC – next ones, **by the end of 2022**

The standard EN ISO 23908 in the MDR/IVDR standardisation request

- 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* is listed as item 114 in Table 1 of Annex I to the MDR/IVDR standardisation request among the “existing harmonised standards to be revised” by 27 May 2024

- Specific requirements for this standard are laid down in Section 2.3 of Part B of Annex III:

  “*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*”

General safety and performance requirements 11.1 and 22.2 of Annex I to the MDR

- 11. Infection and microbial contamination

  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. 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.

Ongoing activities on the revision of EN ISO 23908

- At international level: ISO/AWI 23908 *Sharps injury protection - Requirements and test methods - Sharps protection features for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration*, under development in the ISO Technical Committee ISO/TC 84 “Devices for administration of medicinal products and catheters”, currently at the stage 10.99 (Proposal – New project approved) since 2021-11-05

- At European level: prEN ISO 23908 rev *Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling* (Work item n° 00205372), under drafting in the CEN Technical Committee CEN/TC 205 “Non-active medical devices”, currently at the stage 10.99.0000 (Decision on WI proposal – Accept); next stage: 20.60.0979 (Circulation of 1st Working Document)

European Commission

Thank you!

European Commission - Directorate-General for Health and Food Safety (DG SANTE)
Unit B.6 Medical Devices, Health Technology Assessment
Mario.GABRIELLI-COSSELLU@ec.europa.eu
SANTE-MED-DEV@ec.europa.eu

European Commission