Minutes of the expert groups

Meeting of the Medical Device Coordination Group - Subgroup on Standards (Working Group 2)[1]

8 June 2022

Nature of the meeting

The meetings of the Medical Device Coordination Group (MDCG) and its subgroups are not public and intended only for MDCG members and observers, chaired by the relevant Commission services (COM) in the field of medical devices[2].

This was the fifth meeting of the MDCG Subgroup on Standards (Working Group 2), after the first one on 20 May 2019[3], the second one on 19 June 2020[4], the third one on 7 June 2021[5] and the fourth one on 28 January 2022[6]. Due to the COVID-19 pandemic, the meeting was held by remote with audio-video connection via WebEx, as timely communicated to all the registered participants.

The minutes of the previous meeting held on 28 January 2022 were approved by written procedure in CIRCABC on 23 March 2022.

1. Opening, adoption of the agenda

The agenda of the meeting was adopted without any change.

2. Standardisation for medical devices: state of play and perspectives

2.1. Development, assessment and publication in the OJEU of references of harmonised standards in support of the MDR and the IVDR

COM informed on the ongoing activities, in particular on:

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1 Published in the "Register of Commission Expert Groups and Other Similar Entities", code number X03565: https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?do=groupDetail.groupDetail&groupID=3565.

2 Directorate-General for Health and Food Safety (DG SANTE), Unit B.6 - Medical Devices, Health Technology Assessment. European Commission's sectorial website on medical devices: https://ec.europa.eu/health/medical-devices-sector_en; webpage on Harmonised standards: https://health.ec.europa.eu/medical-devices-topics-interest/harmonised-standards_en; contact: SANTE-MED-DEV@ec.europa.eu.

3 https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=17334.

4 https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=21190.

5 https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=25914.

6 https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=36074.

- the development of harmonised standards by CEN-CENELEC and their Technical Committees (TCs) after the MDR/IVDR standardisation request[7] issued by COM;
- the assessment by COM, with the support of the HAS consultants, of draft harmonised standards to be cited in the *Official Journal of the European Union* (OJEU) under the Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) to confer presumption of conformity with the requirements of the Regulations the standards aim to cover. A new contract with an external provider to manage the HAS consultants system for COM is going to be stipulated soon, to resume its full operation, including the team of 7 experts in the field of Healthcare Engineering;
- the continuous cooperation and dialogue between COM, the CEN-CENELEC Management Centre (CCMC)[8] and the TCs on relevant issues on harmonised standards, to solve problems on the basis of cooperative and pragmatic approaches;
- the CEN-CENELEC Advisory Board on Healthcare Standards (ABHS) as a forum for extended dialogue with the standardisation experts, referring to their next meeting to be held on 9-10 June 2022.

Then, COM informed on the latest publications in the OJEU of references of harmonised standards: after the first ones in July 2021[9] and in January 2022[10], new ones took place in May 2022[11], reaching overall 16 references for the MDR and 10 references for the IVDR. Consolidated versions of the lists are also available in .pdf and .xls formats on the horizontal

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[7] Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (C(2021) 2406) https://ec.europa.eu/health/system/files/2021-04/c_2021_2406_annex_en_0.pdf.

[8] See https://www.cencenelec.eu/; Healthcare: https://www.cencenelec.eu/areas-of-work/cen-sectors/healthcare/.

[9] Commission Implementing Decision (EU) 2021/1182 of 16 July 2021 on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L 256, 19.7.2021, p. 100) https://eur-lex.europa.eu/eli/dec_impl/2021/1182/oj, and Commission Implementing Decision (EU) 2021/1195 of 19 July 2021 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council (OJ L 258, 20.7.2021, p. 50) https://eur-lex.europa.eu/eli/dec_impl/2021/1195/oj.

[10] Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment (OJ L 1, 5.1.2022, p. 11) https://eur-lex.europa.eu/eli/dec_impl/2022/6/oj, and Commission Implementing Decision (EU) 2022/15 of 6 January 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer and requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (OJ L 4, 7.1.2022, p. 16) https://eur-lex.europa.eu/eli/dec_impl/2022/15/oj.

[11] Commission Implementing Decision (EU) 2022/757 of 11 May 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for quality management systems, sterilisation and application of risk management to medical devices (OJ L 138, 17.5.2022, p. 27) https://eur-lex.europa.eu/eli/dec_impl/2022/757/oj and Commission Implementing Decision (EU) 2022/729 of 11 May 2022 amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for quality management systems and for application of risk management to medical devices (OJ L 135, 12.5.2022, p. 31) https://eur-lex.europa.eu/eli/dec_impl/2022/729/oj.

standardisation pages for medical devices[12] and for *in vitro* diagnostic medical devices[13]. The number of available harmonised standards is still limited, but there already are very significant standards such as those for quality management systems (EN ISO 13485), risk management (EN ISO 14971), symbols (EN ISO 15223-1), etc. New publications again 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 levels, as provided by CEN-CENELEC; next ones should take place by the end of 2022.

To address the request expressed by Member States and stakeholders for more timely and updated information on the development of harmonised standards and the timing for publication of their references in the OJEU, COM circulated and presented a "Consolidated list of references" between the MDR/IVDR standardisation request and the CEN-CENELEC Joint Work Programme. More detailed information could be provided from the submission of draft harmonised standards by CEN-CENELEC to the HAS consultants for assessment: COM and CEN-CENELEC will check the feasibility of this information when the HAS consultants will be fully operational again.

Some Member States asked for clarification on the standardisation items reflected in the "Consolidated list of references", in particular on those to be removed from the MDR/IVDR standardisation request in the amendment under preparation (see item 2.2 of the Agenda). COM and CEN-CENELEC explained the reasons why some standardisation items are considered no longer relevant to be developed under the MDR and IVDR, on the basis of the information coming from the concerned TCs; however more detailed justification for each case will be provided soon. This will be useful also to adequately support the procedure for the adoption of the amendment in due time.

2.2. Draft amendment to the standardisation request

COM recalled that the MDR/IVDR standardisation request is intended to be periodically updated, when necessary to remain fully in line with the continuously ongoing standardisation work at European and international levels. On the basis of the inputs provided by CEN-CENELEC and their TCs through their Joint Work Programme in response to the standardisation request, and subsequent discussion and clarifications, COM prepared and presented a first draft amendment, with the list of standardisation items to be added and to be removed in Tables 1 and 2 of Annex I (for the MDR) and in Table 2 of Annex II (for the IVDR), as a draft Commission Implementing Decision amending C(2021) 2406, under the procedure according to the Standardisation Regulation (EU) No 1025/2012[14]. In parallel to the circulation and consultation among the members and observers of the MDCG Standards Subgroup, the draft is currently submitted to public consultation and feedback in the

[12] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en.

[13] https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en.

[14] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

Commission's "Notification system"[15] until 30 June 2022. COM also described the whole procedure for the adoption of the amendment, in principle the same as for the standardisation request as such, but shorter, in particular by using a written procedure to submit the draft to the Committee on Standards and ask for their opinion. In this sense, it is important for the members and observers to liaise with their representatives in that Committee to ensure coherent and effective communication. The exercise should be completed by the end of 2022.

CEN-CENELEC referred to ongoing similar exercises in other sectors, in particular the Personal Protective Equipment (PPE) Regulation (EU) 2016/425, with some proposed changes also in the structure of the standardisation request. COM mentioned the ongoing horizontal exercises on standardisation for the improvement of the current procedures (see item 4 of the Agenda) and ensured that the different sectors will keep coordination also in possible changes in the structure of standardisation requests, to be taken into account for medical devices in future amendments.

3. Reports on the activities of the task forces

3.1. TF#1 "Standardisation guidance"

COM recalled the activities carried out so far in the task force on "Standardisation guidance" (TF#1), but currently paused due to other urgent priorities. The work will be retaken hopefully in September 2022 with a new meeting to consider proposals for the improvement and update of the guidance document published in April 2021[16], with respect in particular to the "state of the art" and to Court cases related to standardisation. A revised version should be submitted to the consideration of the members and observers of the MDCG Standards Subgroup at the next meetings in 2023.

3.2. TF#2 "'Cookbook' for standards"

COM and CLC/TC 62 presented the activities carried out so far in the task force on "'Cookbook' for standards" (TF#2) and the documents circulated in CIRCABC, with the final draft version of the "Cookbook" as well as a draft list of "Legally relevant terms of EN 60601-1", as a first step for the practical implementation. The next one would be the definition of the table on the relationship with the requirements of the Machinery Directive 2006/42/EC (taking into account the ongoing developments towards a new Machinery Regulation), also in close cooperation between COM, CLC/TC 62 and the task force.

On that basis, COM proposed to the members and observers of the MDCG Standards Subgroup to reflect in the minutes of this meeting that the "Cookbook" is recognised as a useful internal tool for CLC/TC 62 to improve the development of harmonised standards and to prevent problems in the assessment by the HAS consultants and COM. This would be useful also for other TCs and later on, with possible further developments according to the experience, for the sound and effective implementation of the MDR/IVDR standardisation request, in particular for some of the provisions in its Annex III.

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[15] Single market and standards > European standards > Notification system - Possible future standardisation requests to European standardisation organisations https://ec.europa.eu/growth/single-market/european-standards/notification-system_en#future.

[16] MDCG 2021-5 Guidance on standardisation for medical devices https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2021_5_en_0.pdf.

The proposal was generally supported by the attendees and will be reflected in the minutes of the meeting accordingly.

4. European and international standardisation: horizontal ongoing activities

COM informed on the ongoing activities related to European and international standardisation, in particular on the adoption of the new EU Standardisation Strategy on 2 February 2022[17], including:

- Commission Communication "An EU Strategy on Standardisation: Setting global standards in support of a resilient, green and digital EU Single Market"
- Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 1025/2012 as regards the decisions of European standardisation organisations concerning European standards and European standardisation deliverables
- Report from the Commission to the European Parliament and the Council on the implementation of the Regulation (EU) No 1025/2012 from 2015 to 2020
- The 2022 annual Union work programme for European standardisation

COM reported also on the continuous horizontal work with the European and international standardisation organisations, to agree on clear procedures for the whole cycle of developing and implementing standardisation requests and harmonised standards, as in the "Brainstorming group ISO-IEC-CEN-CENELEC-COM" to address cases of negative assessments and agree on solutions, the "Joint Task Force ESOs-COM on timely delivery and citation in the OJEU of harmonised standards", the COM inter-service group on standardisation, the international dialogues with the USA (TTC WG 1 TSC) and other countries also in the framework of the IMDRF, etc.

5. AOB

The European Biosafety Network (EBN) reported on the ongoing development of the draft international standard ISO/AWI 23908[18] on safety mechanisms in the design and manufacture of medical devices and the prevention of sharps injuries, and the related draft European harmonised standard prEN ISO 23908 rev[19]. EBN confirmed that an online webinar will be held on 22 June 2022[20] to inform and discuss on the latest updates, and invited the members and observers of the MDCG Standards Subgroup to participate and provide their contributions. The invitation and agenda have been circulated in CIRCABC.

6. Next meetings

[17] See the press release https://ec.europa.eu/growth/news/new-approach-enable-global-leadership-eu-standards-promoting-values-and-resilient-green-and-digital-2022-02-02_en.

[18] https://www.iso.org/standard/83582.html.

[19] https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:75149,6186&cs=12D526A0D7ED78EDFE5998050B7E94C6E.

[20] See https://www.europeanbiosafetynetwork.eu/ebn-webinar-on-preventing-sharps-injuries-mdr-and-safety-mechanism-in-medical-devices/.

COM informed on the planning for the next meetings: the two annual meetings of the MDCG Standards Subgroup in 2023 should be held in January/February, and in June; for the task forces, the next meeting of TF#1 should take place in September/October 2022, and the next meeting of TF#2 should take place in June/July 2022. All the dates and modalities will be confirmed as soon as possible.

List of participants

Members - National competent authorities:
Belgium (BE), Czech Republic (CZ), Germany (DE), Estonia (EE), Greece (EL), Spain (ES), Croatia (HR), Italy (IT), Hungary (HU), Netherlands (NL), Austria (AT), Portugal (PT), Romania (RO), Slovenia (SL)

Observers - National competent authorities:
Turkey (TK)

Observers - Stakeholders' organisations:
APPLiA (Home Appliance Europe), Biomedical Alliance in Europe (BioMed Alliance), European Committee for Standardization (CEN) – European Committee for Electrotechnical Standardization (CENELEC), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), European Association of Authorised Representatives (EAAR), European Association of the Contact Lens and Lens Care Products Manufacturers (EUROMCONTACT), European Biosafety Network (EBN), European Council of Optometry and Optics (ECOO) – EurOptom, MedTech Europe (MTE), Notified Bodies Coordination Group Medical Devices (NBCG-Med), European Association for Medical Devices of Notified Bodies (Team-NB)

European Commission:
SANTE B.6 Medical Devices, Health Technology Assessment
HAS consultants