EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices, Health Technology Assessment

Medical Device Coordination Group - Subgroup on Standards (Working Group 2)

Minutes of the meeting held on 7 June 2021

The meetings of the Medical Device Coordination Group (MDCG)[1] 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 third meeting of the MDCG Subgroup on Standards (Working Group 2), after the first one held on 20 May 2019[3] and the second one held on 19 June 2020[4]. 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.

1. Opening, adoption of the agenda

After a general introduction on the latest key issues in the medical devices sector in the EU – in particular the full applicability of Regulation (EU) 2017/745 as from 26 May 2021 – and on European standardisation, COM presented the draft Agenda for the meeting, as circulated in the relevant CIRCABC interest groups[5] and with the AGM[6] invitations, as well as in the "Register of Commission experts groups and other similar entities"[7]. A presentation by COM was also circulated in CIRCABC, as a general support for the development of the points of the Agenda.

Without any comment, the draft Agenda was adopted.

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[1] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565.

[2] Directorate-General for Health and Food Safety (DG SANTE), Unit B.6 - Medical Devices, Health Technology Assessment. Commission's sectorial website on medical devices: https://ec.europa.eu/health/md_sector/overview; contact: SANTE-MED-DEV@ec.europa.eu.

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

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

[5] MDCG - Standards (CAs): https://circabc.europa.eu/ui/group/40ffa918-04f6-442e-b278-12e596c5e06a, MDCG - Standards (Stks): https://circabc.europa.eu/ui/group/b47c1365-18cf-4015-9bf1-f6a146c72f32.

[6] Advanced Gateway to your Meetings: https://ec.europa.eu/tools/agm/.

[7] https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=25914&fromExpertGroups=true.

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2. Latest activities in standardisation for medical devices and next steps

2.1 Work Programme 2021

COM explained that the 13 MDCG Subgroups (Working Groups) have been requested to prepare annual work programmes to reflect their activities and priorities. For the Work Programme 2021 of the MDCG Standards Subgroup (WG 2), COM prepared a draft that was circulated to the members and observers through the respective CIRCABC interest groups on 23 April 2021. After receiving some comments, a revised version was re-circulated and considered as endorsed by the Subgroup on 12 May 2021. The Work Programme was finally endorsed by the MDCG on 27 May 2021 and uploaded on CIRCABC.

The Work Programme is organised by work packages and tasks with different timelines and priorities:

1) *Standardisation requests*: the Commission Implementing Decision and its periodical updates, when necessary;

2) *Harmonised standards*: publications of references in the *Official Journal of the European Union* (OJEU) for the Directives (the final ones) and for the Regulations (the new ones on the basis of the standardisation request) and their periodical updates;

3) *Guidance documents*: a first one on standardisation for medical devices and its possible revisions, and possibly others on specific aspects of standards.

In the development of these working items, the active participation of competent authority members, stakeholders and other interested parties is explicitly foreseen. Some Member States asked for more opportunities to be effectively involved in the activities, not only in parallel to their development but especially beforehand, as in the case of revisions of the standardisation request in the lists of standards and especially of its Annex III, to provide expert opinions for possible improvements. COM agreed on the need and convenience to further expand such involvement as much as possible, within the applicable legal procedures in each case, in particular those laid down in the Standardisation Regulation (EU) 1025/2012[8] with its Committee on Standards[9]. This could be done by circulating drafts documents, especially for future legislative initiatives on standards for medical devices, for information, comments and contributions of the members and observers of the MDCG Subgroup in their relevant CIRCABC interest groups, before the procedural submission; it is also possible to set up specific remote calls or meetings on a case-by-case basis. Such an early involvement of all the relevant parties would be useful also to ensure a better communication and coordination with the members and observers in the Committee on Standards for the procedures to be developed there.

2.2 MDCG Guidance on standardisation for medical devices

COM presented the background and objectives of the guidance document, and the processes for drafting, discussions, revisions, endorsements and publication. It deals with different issues related to standardisation for medical devices, including in particular the

[8] 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).

[9] https://ec.europa.eu/transparency/comitology-register/screen/committees/C41700/consult.

references to the EU legislative framework for standardisation, the voluntary use of standards, the development and assessment of harmonised standards, the presumption of conformity conferred by harmonised standards the references of which are published in the OJEU, the concept of "state of the art", etc. The idea to develop such a guidance document was presented at the second meeting of the MDCG Standards Subgroup (WG 2) held on 19 June 2020, and on that basis COM prepared a first draft, with the support of a task force in the MDCG Notified Bodies Oversight (NBO) Subgroup (WG 1). The draft was circulated to the members and observers of the two concerned WGs in February 2021 and, after analysing the comments and suggestions received from different parties, a revised version was re-circulated and considered as endorsed in March 2021. Afterwards, the revised draft was endorsed by written procedure by the MDCG on 15 April 2021. The final version of the "*Guidance on standardisation for medical devices*" was published as MDCG 2021-5[10] in April 2021 on the Commission's webpage "Medical Devices - New Regulations - Guidance"[11].

This guidance document is rather basic and non-exhaustive, as a first reference to be revised and improved when necessary, for instance to further develop questions on production and assessment of harmonised standards, on presumption of conformity, on the practical use of harmonised standards with specific examples, on the concept and implementation of the "state of the art", on the sound practical implementation of the requirements in Annex III to the standardisation request, etc., as already suggested by some Member States and stakeholders. At the same time, other guidance documents on standardisation could be developed.

According to that, COM proposed to set up a specific task force "*Standardisation guidance*" devoted to the possible revision and improvement of the existing guidance document, as well as to analyse the need for the development of other guidance documents, according to the interest expressed by members and observers. A call for the availability of members and observers to participate in this first task force will be launched right after the meeting, to start the work likely in September 2021.

2.3 Standardisation for the Directives: final publications in the OJEU of references of harmonised standards

COM informed on the final publications in the OJEU of lists of references of harmonised standards to confer presumption of conformity for Directives 90/385/EEC, 93/42/EEC and 98/79/EC, with three Commission Implementing Decisions issued on 14 April 2021 and published on 15 April[12]. They amend the consolidated lists in the Commission Implementing Decisions issued in March 2020[13], by replacing references and adding new ones, with an overall total of 47 harmonised standards for Directive 90/385/EEC, 268 harmonised standards for Directive 93/42/EEC and 43 harmonised standards for Directive 98/79/EC.

These lists are valid until 26 May 2024 to support the implementation of specific transitional provisions on certificates according to Article 120 of Regulation (EU) 2017/745 (MDR) and Article 110 of Regulation (EU) 2017/746 (IVDR), but not to confer presumption of conformity under the Regulations.

[10] https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_5_en.pdf.

[11] https://ec.europa.eu/health/md_sector/new_regulations/guidance.

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2021:129:TOC.

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2020:090I:TOC.

2.4 Standardisation for the Regulations: standardisation request and first publications in the OJEU of references of harmonised standards

COM informed on the entering into application of the standardisation request in support of the MDR and IVDR, with the adoption by the Commission and the acceptance by CEN and Cenelec, the submission of their joint work programme and the preparation of the first publications in the OJEU. After the positive opinion on the draft act delivered by the Committee on Standards on 12 March 2021, the *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* was adopted on 14 April 2021 and published on the Commission's database "Standardisation - Mandates" as M/575[14] (EN version) and on the Commission's webpage "Medical Devices - New Regulations - Topics of Interest"[15], section "Harmonised European standards" (DE, EN and FR versions).

The lists in Annexes I and II include:

- 201 existing harmonised standards to be revised and 27 new harmonised standards to be drafted in support of the MDR by 27 May 2024;

- 46 existing harmonised standards to be revised and 3 new harmonised standards to be drafted in support of the IVDR by 27 May 2024.

The standardisation request was notified to CEN and Cenelec on 15 April 2021 and accepted on 12 May 2021 to make the standardisation request fully applicable. According to its Article 2, CEN and Cenelec submitted their joint work programme to COM on 28 May 2021: after COM scrutiny and further integrations by CEN and Cenelec, the Joint Work Programme will be circulated for information to the members and observers of the Subgroup in their respective CIRCABC interest groups.

The standardisation request will be periodically revised in the lists of standards and possibly other contents when deemed necessary, according to its effective implementation and the inputs by CEN and Cenelec and other interested parties.

On that basis, it is possible to have the first publications in the OJEU of lists of references of harmonised standards to confer presumption of conformity under the Regulations: two Commission Implementing Decisions are under preparation, to be adopted and published in the OJEU likely in June 2021[16]. As in the draft lists circulated in CIRCABC, these publications will include 5 references for MDR and 4 for IVDR, according to the first submissions by CEN and Cenelec and the assessments carried out by COM with the support of the HAS consultants.

This will open a new cycle of publications, to be periodically updated with subsequent amendments each three or four months, to enlarge the lists according to the development of the standardisation work at European and international levels and the correspondent "state-of-the-art" technical solutions for the highest degree of health, safety and performance of medical devices in the EU.

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[14] https://ec.europa.eu/growth/tools-databases/mandates/index.cfm?fuseaction=search.detail&id=599.

[15] https://ec.europa.eu/health/md_topics-interest/overview.

[16] Update: the *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* was published in the OJEU on 19 July 2021: https://eur-lex.europa.eu/eli/dec_impl/2021/1182/oj; the *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* was published in the OJEU on 20 July 2021: https://eur-lex.europa.eu/eli/dec_impl/2021/1195/oj.

3. Cooperation COM - CEN and Cenelec

COM reported on the continuous cooperation and positive dialogue between COM, the European standardisation organisations (ESOs) through the CEN-Cenelec Management Centre (CCMC) and their Technical Committees on relevant issues on harmonised standards for medical devices, both horizontal and specific ones, mentioning for instance the fruitful discussions on EN ISO 14971 on risk management. Members and observers generally appreciated this constructive approach and expressed hopes for solving the current problems and having horizontal standards (such as on risk management, quality management systems, symbols, labelling etc.) harmonised and cited in the OJEU as soon as possible as a matter of priority.

With respect to the CEN-Cenelec Advisory Board on Healthcare Standards (ABHS), the latest meeting (the 27th) was held on 30 November 2020 and the next one (the 28th) is planned on 22 June 2021, to discuss on the different topics of interest and the ongoing activities. Updated information will be provided by COM and CCMC in due course.

COM also informed on the activities of the HAS consultants for Healthcare Engineering, referring to the upcoming changes in the composition of the team, to replace at least one consultant leaving the team. More specific information will be provided as soon as the related procedures are completed. In the meantime, periodical coordination/alignment meetings between COM, the EY managers and the HAS consultants take place regularly, now in particular to coordinate on the upcoming work in the second half of 2021. COM also confirmed that additional funding for the HAS consultants project was recently granted to ensure the full functionality of the system: this should allow the HAS consultant to retake their activities in full, including participation in meetings.

Representatives of the Cenelec Technical Committee CLC TC 62 "Electrical equipment in medical practice" presented an initiative for a "*'Cookbook' for writing harmonized standards under MDR/IVDR by CLC TC 62*", with practical indications to develop harmonised standards for electrical medical equipment, for information and possible comments and contributions. COM expressed interest in the initiative as well as some members and observers. The presentation given and the latest draft version of the text will be circulated in CIRCABC.

COM proposed to set up another specific task force "*Cookbook for standards*" to analyse and discuss in detail the initiative, for possible further developments, improvements and even extension to other types of standards, also taking into account the horizontal aspects involved and the already existing guidance documents on standardisation[17]. A call for the availability of members and observers to participate in this second task force will be launched right after the meeting, to start the work likely in September 2021.

4. European standardisation: ongoing activities

COM informed on the "Strategy on Standardisation" to be developed within the initiative for "*Updating the 2020 New Industrial Strategy*", as from the Commission Communication of 5 May 2021[18]. It will include including considerations on the role and

[17] In particular, the Commission's "Vademecum on European standardisation" https://ec.europa.eu/growth/single-market/european-standards/vademecum, the CEN and Cenelec's procedures and guidance, etc.

[18] https://ec.europa.eu/info/sites/default/files/communication-industrial-strategy-update-2020_en.pdf.

activities of the EU in international standardisation, the standardisation needs in industrial ecosystems, possible amendments to the Standardisation Regulation (EU) 1025/2012, etc.

Internal and external dialogue and discussions on standardisation is going on at different levels with meetings between COM and the European and international standardisation organisations, a Joint Task Force between COM and the ESOs, a COM inter-service group on standardisation, etc.

Furthermore, COM informed on the final steps in the ongoing revision of "*The 'Blue Guide' on the implementation of EU product rules*"[19], including the contents on standardisation and others related to.

Members and observers expressed interest in being informed on such initiatives and in possible participation. COM explained that where interested parties are not directly involved, they might always address comments and contributions to COM and the ESOs to be taken into account.

On a request about the effective availability of standards and the participation of professional associations in standardisation, COM briefly described the functioning of the system and referred to CEN and Cenelec for more specific information, from their websites and contact points[20].

5. AOB

No other business were proposed for discussion.

6. Next meetings and close

The next annual plenary meeting (members and observers) of the MDCG Standards Subgroup should take place in May or June 2022 – to be defined and confirmed as soon as possible in its timing and modalities.

Additional meetings could be possible if necessary, for instance a second annual plenary one by the end of 2021 or beginning of 2022, likely in remote mode, as well as for possibly ad-hoc meetings and/or for the task forces "*Standardisation guidance*" and "*Cookbook for standards*" to be set up. COM will send a message in CIRCABC asking for the opinion of the members and observers at that respect, and possible dates.

[19] https://ec.europa.eu/docsroom/documents/18027/.

[20] https://www.cencenelec.eu.

List of participants

Members - National competent authorities:

Belgium (BE), Czech Republic (CZ), Greece (EL), Spain (ES), France (FR), Cyprus (CY), Hungary (HU), Netherlands (NL), Austria (AT), Portugal (PT), Slovakia (SK), Finland (FI), Sweden (SE)

Observers - Stakeholders' organisations:

APPLiA (Home Appliance Europe), Association of the European Self-Medication Industry (AESGP), Biomedical Alliance in Europe (BioMed Alliance), European Association of the Contact Lens and Lens Care Products Manufacturers (EUROMCONTACT), European Association for Medical Devices of Notified Bodies (Team-NB), European Association of Authorised Representatives (EAAR), European Biosafety Network (EBN), European Committee for Standardization (CEN) – European Committee for Electrotechnical Standardization (Cenelec), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), European Council of Optometry and Optics (ECOO) – EurOptom, European Plastics Converters Association (EuPC) – MedPharmPlast Europe (MPPE), European Society of Cardiology (ESC), Federation of the European Dental Industry (FIDE), MedTech Europe (MTE), Notified Bodies Coordination Group Medical Devices (NBCG-Med), Small Business Standards (SBS)

European Commission:

SANTE B.6, HAS consultants