EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Directorate D – Consumer, Environmental and Health Technologies
Unit D4 – Health Technology and Cosmetics

MDCG (Medical Devices Coordination Group)
Subgroup on Standards

Minutes

Brussels, 20 May 2019

1) Opening, adoption of the agenda

This was the first meeting of the newly created working group. Agenda was adopted. Tour de table followed to introduce representatives of national authorities and stakeholder organisations.

2) MDCG governance – WG on standards

COM presented the governance structure of the MDCG with the focus on the subgroup on standards. The role of the Standards subgroup is to provide technical expertise for positions of the MDCG and opinions of the Committee on Standards (e.g. on formal objections to standards concerning medical devices). The information and communication tools were summarised: Register of the Commission Experts' groups, COM website on medical devices, CIRCABC, AGM.

3) Harmonised standards under MDR / IVDR – overview and discussion

COM presented un update of the legal framework for harmonisation of standards under MDR/IVDR. The focus of COM activities in the field of standards for medical devices is the transition from the Medical Device Directives to the new Regulations, especially completion of the process for issuing a new mandate to Cen/Cenelec. Availability of the relevant mandates is essential for referencing the standards in the OJ, also under the Medical Device Directives. The most recent editions of standards published by the standardisers should be considered as reflecting state-of-the-art, regardless of the OJ referencing. Common specifications play an ancillary role, while harmonised standards remain the principal instrument of the New Approach. The common specifications on reprocessing and Annex XVI products have a special status and COM has a legal obligation to adopt them. Presumption of conformity is a legal instrument facilitating the compliance with the essential requirements, without prejudice to the scrutiny that needs to be applied by notified bodies in the conformity assessment procedures. The need for guidance on the topic, including the role of standards in ensuring compliance with the legal requirements and the implications of the presumption of conformity was flagged. Stakeholders emphasised the importance of standards concerning IVDs, 80% of which will be subject of notified bodies' scrutiny under IVDR. Standardisers recalled the need of OJ referencing of standards under Medical Device Directives.

4) IMDRF activities

Germany debriefed on the IMDRF project concerning recognised standards for regulatory use. Quantitative data are available and a list of recognised standards is updated from time to time. While the number of commonly recognised standards remains fairly low, all participating jurisdictions allow for voluntary use of standards. Standards have a significant potential to facilitate regulatory process, but improvements are needed. Factors preventing formal recognition of standards lay both in the regulatory requirements of respective jurisdictions and the drawbacks in the standards themselves, for instance difficulties in reproducing test procedures or broad referrals to products' dossiers. Larger involvement of regulators in standards development could contribute to formal recognition of standards. IMDRF liaison programme aims at increasing this involvement, and in this context a call for EU liaison officers to participate in ISO technical committees will be communicated to MS competent authorities in the coming weeks.

5) Sharps injury protection (ISO 23908) – presentation of the standard

European Biosafety Network outlined the origin of the project, including inconsistent interpretation of the essential requirements under the Medical Device Directives. The existing EN ISO 23908 should be used as a basis for the future standard development under MDR, and a draft new work item for ISO TC 84 and CEN TC 205 is under way. Built-in safety mechanisms should be required under specified conditions. Implementation of the Sharps Directive 2010/32/EU encounters various challenges, also due to organisation of public healthcare in MS. The need to distinguish between safe medical procedures and essential requirements relating to a specific product was emphasised.

6) General framework for harmonisation of standards

COM recalled its recent Communication on Harmonised standards of 22/11/2018 and outlined the practical guidance in preparation on the subject. The new working methods were explained, including the revised model of a standardisation request, the internal system of assessment of standards and Annexes Z by HAS (Harmonised Standards Consultants) , and the model Commission decision on publication of references to standards. The New Legislative Framework and the Standardisation Regulation 1025/2012 set up the basis for the public-private partnership between COM and the standardisers. According to the definition in Article 2(1)(c) of Regulation (EC) No 1025/2012, a 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation.

Harmonised standards are referenced in the EU Official Journal and provide presumptions of conformity with the requirements of the Regulations covered by those standards, in accordance with Article 8(1) MDR / IVDR (or the corresponding provisions of the Medical Device Directives). Stakeholders recalled that a "transposition" of ISO standards into EU regulatory environment faces particular challenges, as any such transposition can occur only through adoptions to be made in the European foreword and informative Annex Z.

7) Standardisation request under MDR/IVDR

The preparations started in autumn 2017. Following the initial feedback from the stakeholders, the discussion followed in the MDCG meetings in 2018, and most recently

the relevant stakeholders were consulted on the draft mandate, which includes: (i) Commission Decision - draft standardisation request, (b) Annexes I-II - draft lists of standards under MDR/IVDR, (c) Annex III - draft requirements for standards. Inter-service consultation will be carried out in the coming weeks, to be followed by the vote in the Committee on Standards. The draft standardisation request concerning standards on personal protective equipment, which has been the first mandate based on the "blueprint" recently developed by COM, waits launching of a written vote of the Committee on Standards. The mandate on standards relating to medical devices will depend on this process.

8) AOB

The meetings of this subgroup will take place 1-2 times/year. The date of the next meeting will be shared *via* CIRCABC once the date is set.

List of participants:

Competent authorities:
AT, BE, CZ, DK, DE, EE, IE, EL, ES, FR, HU, NL, PT, RO, SL, SK, FI, SE, CH.

Organisations:
AESGP, APPLIA, CEN-CENELEC, COCIR, EAAR, EBE, ESC, Euromcontact, European Biosafety Network, European Council of Optometry and Optics FIDE (Federation of the European Dental Industry), HAS Consulting, MedPharmPlast, MedTech Europe, NB-Med, Team NB

European Commission:
GROW/D4 and GROW/B3