EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical Devices

Minutes of the expert groups

Brussels, 20 July 2020

Draft Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG) – 02/07/2020

MDCG meetings are not public and they are intended only for MDCG members. Due to challenges caused by COVID-19, the meeting was organised with video-audio connection.

1) Opening and adoption of the agenda

COM welcomed participants and agenda was adopted. They informed that the responsible unit for medical devices in SANTE has recently changed as a part of organisational restructuring and now includes also HTA (Health Technology Assessment) team; the migration of medical devices website from GROW to SANTE is almost completed, new website https://ec.europa.eu/health/md_sector/overview

MDCG members were invited to replace their personal names and email addresses with those from their national competent authorities when exchanging per email – to comply with new rules of protection of personal data. Finally, it was noted that for most MDCG subgroups more active engagement and participation is required by regulators in national authorities and taking into consideration the challenges caused by COVID-19 in addition to the implementation challenges, closer collaboration may be needed both between national authorities and the Commission and MDCG members and their colleagues attending various MDCG subgroups.

2) COVID-19 related issues

2.1 Regulation (EU) 2020/561 and main consequences

On 23 April earlier this year, the co-legislators adopted under urgency procedure an amendment to the MDR, which deferred by 1 year the dates of application of certain of its provisions in the context of the COVID-19 pandemic. In response to calls from Member States the Commission followed-up with another urgency procedure amending Implementing Regulation 920/2013 to ensure the continuous designation of notified bodies until the MDR becomes applicable in May 2021.

2.2.MDCG guidance and other COM documents published

A great output of documents has been published since the last meeting in March 2020 including guidance documents but also COVID-19 related documents:

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

Some publications related to COVID-19:

- Guidance on regulatory requirements for medical face masks
- Communication from the Commission: Guidelines on Union-wide derogations for medical devices
- Guidance to increase production of safe medical supplies (PPE, hand gel, 3D printing)
- MDCG 2020-9 Regulatory Requirements for Ventilators and Related Accessories
- Communication from the Commission concerning Guidelines on COVID-19 in vitro diagnostic tests and their performance
- Current performance of COVID-19 test methods and devices and proposed performance criteria - Working document of Commission services
- Database of devices and publicly available performance data COVID-19 In Vitro Diagnostic Devices and Test Methods
- Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions
- Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context
- IMDRF Standards Checklist modified in scope of COVID-19
- Conformity assessment procedures for protective equipment
- New lists of harmonised standards made available for medical devices
- A number of European standards for medical supplies made freely available to facilitate increase of production
- Standardisation request in support of the new Regulations on medical devices
- Commission recommendation on conformity assessment and market surveillance procedures

2.3 Market surveillance and derogations

COM updated participants on the activity of the Market Surveillance Working Group, which set up bi-weekly meeting to facilitate discussion and information exchange between Member States on medical devices derogations. As a reminder the intention of COM is to work closely with MDCG to assess whether potential national derogations fulfil the high threshold for the granting of EU-wide derogations, followed by comitology procedure.

3) Joint Implementation Plan – state of play

The Chair reported the endorsement of the Joint Implementation Plan at the High Level meeting of March earlier this year. Since then, almost all the actions included therein have been completed and 14 endorsements relating to the Regulations' implementations have been published, including guidance on basic UDI-DI and changes to UDI-DI, guidance on safety reporting in clinical investigations, on PMCF evaluation report template or on sufficient clinical evidence for legacy devices among many others.

4) Implementation MDR / IVDR

4.1 MDCG subgroups, short update on their work

In parallel with numerous COVID related activities a lot of work has been going on in parallel in various MDCG subgroups. Some MDCG subgroups held recent meetings 25 May IVD, 16 June NBO with NBs and 22 June NBO, 18 June Market Surveillance, 19 June Standards, 25 June the first meeting of EUDAMED MDCG subgroup and 30 June UDI. COM asked for more active engagement of national authorities and committed to share more information on existing task forces in MDCG subgroups.

4.2 Q&A on Clinical Investigation under MDR

MDCG was informed on the ongoing work for the development of a Q&A document on clinical investigations under MDR. The Clinical Investigation MDCG subgroup will submit the document to MDSG in autumn.

4.3 Implementing Acts – for information

COM shared with participants the latest updates on implementing acts:

Reprocessing: the written procedure for voting in the Medical Devices Committee will be launched shortly;

Annex XVI: there are ongoing exchanges with COM Legal Services on the development of common specification; as soon as there is an agreement on a draft this will be examined by MDCG Subgroup on Annex XVI;

Standardisation: COM adopted the Standardisation Request in support of the new Regulations on 15 May 2020, but it was rejected by CEN/CENELEC on 16 June. Therefore it is necessary to relaunch the procedure for a new Standardisation Request, checking the extent and feasibility of a revision. Until the new procedure is completed (likely not before Q1 2021) there is no legal basis for the publication in the OJEU of references to harmonised standards for the new Regulations. Concerning the current Directives, new lists of references to harmonised standards were published in the OJEU on 25 March 2020. Another publication should take place by the end of 2020;

Electronic instructions for use: in relation to Regulation (EU) 207/2012 and Directives 90/385/EEC & 93/42/EEC establishing certain requirements concerning instructions for use in electronic form there have been in the past some exchanges between the Commission, regulators and industry and these led to a draft IA. Due to minimal input received by the Medical Devices Committee and heavy workload, this topic has not moved further but there is currently relevant reflection on moving this forward where further engagement from Regulators would be necessary. Participants were invited to comment on whether there is an interest to move this forward.

5) Implementation MDR / IVDR

5.1 Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under MDR / IVDR (MDSAP: Medical Device Single Audit Programme) – for endorsement

MDCG members endorsed the guidance document.

5.2 Update on various issues

COM updated on various ongoing work streams: IMDRF different working groups with strengthened EU representation, MRA with CH, Turkey customs agreement, MRAs with Australia and New Zealand.

6) EUDAMED

6.1 Update on various issues

COM's IT team presented the latest progress made in the development of EUDAMED. MDCG members are reminded that the key target in releasing EUDAMED modules is providing a Minimum Viable Product: delivering what is necessary first, and add more "nice to have" later as deemed necessary. The development is composed of 6 modules, each including parts with public and with restricted access to information. In line with earlier communication, the COM confirmed that is stands ready to deploy the actor registration module by end of Q4 2020 as agreed by the new EUDAMED Subgroup. However, the COM has no legal basis to require the use by Member States and other parties before EUDAMED is fully functional. The COM confirmed that all modules will encompass both MDR and IVDR requirements.

6.2 MDCG position paper on requiring the use of the EUDAMED actor registration module in the Member States – for endorsement

A number of MDCG members commented on the guidance and expressed doubts on the legal feasibility of requiring at national level actors to use the actor registration module. Participants therefore advised a rewording of the text, replacing 'require' with 'strongly encourage' to soften the latter. The COM took note of this request, but also stressed to participants the importance of avoiding a disharmonised approach toward the use of the module and the SRN across Member States. The gradual release of the different module only yields added-value for all parties concerned, if aspects such as double reporting obligations are avoided as much as possible. The MDCG members agreed to endorse the text by written procedure once amended accordingly.

7) Notified Bodies under MDR/IVDR

7.1 Joint Assessment Progress Report

Commission update on the state of play of joint assessments under MDR/IVDR. At the time of the meeting there were 46 applications for MDR and 15 for IVDR while 53 preliminary assessment reports had been completed. Three onsite assessments were conducted to-date in 2020 and four more were pending to be performed. At the time of the meeting 18 designations under MDR / IVDR (14 + 4) were published in NANDO. Finally, the Commission noted the vital role of national experts for the performance of joint assessments and asked MDCG members for their support in ensuring availability of experts from their administrations.

7.2 MDCG recommendation on the draft designation of a notified body

The German designating authority presented their final assessment report on an applicant notify body, and the Commission presented the corresponding final opinion of the joint assessment team. A discussion followed and MDCG issued a positive recommendation under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notify body should be designated in the scope proposed by the designating authority.

8) Expert panels – state of play on the setting up of Expert Panels

Commission presented the ongoing work towards establishment of expert panels as required under the MDR. Various milestones have been achieved including the expert selection (February), MDCG consultation (April/May) and formal nomination of shortlisted candidates for possible membership of the panels (June). Their final appointment will depend on whether their renewed Declaration of Interests (DOI) is still compatible with membership. Renewed DOIs are currently collected from experts and scrutinized by Commission. Successful experts will be formally appointed within the summer to the panels and the central list. Commission also presented other elements such as the elections of chairs and vice chairs (a prerequisite for the establishment of the Coordination Committee and the adoption of the Rules of Procedure), the training of panel experts on 6 defined modules with a view of providing adequate background on the scope and procedures of their engagement, the fine-tuning of internal secretariat workflows and secure data exchange/storage via CIRCABC, the setting-up of an internal monitoring database of dossier progression and expert engagement per dossier, training of internal staff.

9) Information Note on Transparency obligations

COM shared a factsheet on transparency which covers key information related to the actors, the devices including their UDI and their certificates and some specific information related to Vigilance and post-market surveillance, Clinical evaluation and market surveillance. It also provided the list of information to be made publicly available outside EUDAMED either by COM, Member States, Notified bodies or manufacturers as foreseen by specific MDR requirements. It was noted that it would be for Member States to decide which additional information (incident reports, FSCA, PSR etc) could be made accessible to the public when there is not a mandatory requirement for disclosing and pursue a common approach in MDCG.

10) EU Reference Laboratories (EURLs, update)

COM updated the group on the state of play and expected timelines with regard to implementing acts on (1) tasks and criteria for the EURLs and (2) on fees they may levy, and on the call for application, to be sent to the Member States. Both acts are undergoing internal consultation in COM. MDCG Members were encouraged to engage in informal dialogue with possible candidate EURLs.

11) AOB

11.1 *CAMD (Competent Authorities for Medical Devices) – Update on activities*

The Chair of CAMD thanked participants for their continuous collaboration since the last MDCG meeting, and particularly during the COVID-19 pandemic. The latter has forged more political attention to medical devices and has shed the light on the need to increase capacities at EU and national levels. The CAMD will present its new strategic focus on the year to come in October.

11.2 Other information by the COM

Proposal for a new Health Program EU4Health for the 2021-2027 period, aiming to invest €9.4 billion in various projects for strengthening health systems. The proposal is currently examined by co-legislators.
Pharma Strategy: a COM initiative aiming for a holistic approach for ensuring safe and affordable medicines and support of the European pharmaceutical industry; MDCG members were invited to contribute to the ongoing public consultation by 15 September 2020.
REACH Regulation and ongoing discussion for banning certain CMR substances (carcinogenic, mutagenic and toxic for reproduction substances): MDCG members were informed and invited to liaise with colleagues at national level that participate in the relevant REACH committee.

Next meeting

Next MDCG meeting: to be communicated to MDCG members as soon as possible but under the circumstances it will probably be another virtual meeting in October 2020. COM suggested that (part of) this meeting will focus on state of play /implementation of IVDR.

List of participants

MDCG members: AT, BE, BG, HR, CY, CZ DK, EE, FI, FR, DE, GR, HU, IE, IT, LU, LT, LV, MT, NL, PL, PT, RO, SI, SK, ES, SE.

Observers: CH, IC, NO, TR

Commission: SANTE B6, SANTE F5, SANTE A4, JRC F2, ENV B2 and GROW D1