EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical Devices

Minutes of the expert groups

Brussels, 24 March 2020

Meeting of the Medical Devices Coordination Group[1] (MDCG) – 12/03/2020

MDCG meetings are not public and they are intended only for MDCG members. Due to the rapid developments and challenges caused by COVID-19 the meeting was transferred from the originally planned physical meeting to a virtual meeting with video-audio connection.

1) Approval of the agenda, minutes of previous meeting

Agenda was approved.

2) Approval of the minutes

Minutes of MDCG of 13 December 2019 were approved

3) MDR / IVDR Implementation

Commission summarised the High Level meeting emphasising the endorsement of the Joint Implement Plan (JIP) which includes certain priorities, therefore MDCG meetings would have to focus primarily on the priorities identified in JIP.

Main focus of attention was on preparedness and market situation, especially in relation to the compilation of data prepared by COM on availability and market state of play. Overall, situation looked reassuring, however the data is not comprehensive and continuation of monitoring was deemed appropriate. COM asked MDCG members to send national data and information when available, and to liaise with Ministries and other relevant stakeholders in their countries.

COM reminded that one of the main points of discussion was EUDAMED and the gradual approach taken by the Commission to release modules step-by-step, which was generally supported by Member States. COVID-19 was also a key topic of discussion at the High Level with a request by the COM to Member States to share information also in the auspices of MDCG subgroup IVD which organises relevant coordinating teleconferences.

4) Notified Bodies under MDR / IVDR

4.1.Joint Assessments Progress Report

COM presented the state of play on joint assessments (detailed information available on the slides presented). For various reasons, the estimates on the number of bodies are becoming increasingly difficult. Nevertheless, there should be at least 17 notified bodies on NANDO by May, with more to follow in the coming months. One on-site assessment has had to be delayed due to the Coronavirus situation. Due to the slowdown in applications and PARs, no

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

on-site assessments are scheduled in the next (3) months. It is important to continue monitoring the situation, though.

4.2. MDCG recommendation on the draft designation of a notify body

a) Final assessment report of the designating authority and draft designation – summary presentation by the competent authority

b) Final opinion of the joint assessment team – summary presentation by SANTE

c) MDCG recommendation under Article 39(9) MDR

COM indicated that following the issuing of the JAT final opinion on the draft designation of one notified body under Regulation (EU) 2017/745, the relevant draft MDCG Recommendation had been submitted to MDCG on 04 March 2020. Few editorial comments were sent by the DE delegation and changes were incorporated in the text. Further information and all details related to the assessment carried out are, as usual, available to MDCG members in Circa BC. MDCG issued a positive recommendation under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified body should be designated within the scope proposed by the designating authority.

4.3. Transitional provisions

a) Guidance on significant changes [Art. 120.3 (EU) 2017/745] with regard to devices covered by certificates according to 90/385/EEC or 93/42/EEC – <u>for endorsement</u>

MDCG endorsed this guidance, drawn up by the NBO MDCG subgroup. The guidance is part of the Joint Implementation Plan– comments by stakeholders as well as all relevant MDCG Subgroups had been received, reviewed and incorporated as appropriate. COM mentioned that the guidance will continue to be reviewed in cooperation with competent authorities. In particular, concerning design changes related to corrective actions assessed and accepted by the relevant Competent Authority, application of indications provided by the guidance document will be closely monitored in view of a possible revision of the text if needed.

b) Class I transitional provisions in Article 120 (3)(4) – for endorsement

MDCG endorsed the above guidance as a high priority included in the Joint Implementation Plan in an effort to convey a joint clarification to manufacturers as regards interpretation of the second corrigendum in relation to Article 120 (3) (4) MDR.

c) Guidance on transitional provisions for consultations of authorities on devices containing ancillary medicinal products and on devices manufactured using TSE susceptible animal tissues – for information

COM informed MDCG on the ongoing work and that this guidance is currently under consultation with competent authorities in the relevant MDCG subgroups for final agreement and that in the following days MDCG will receive the updated version for their written endorsement.

4.4. Addendum to guidance document MDCG-2019-3 on interpretation of application of Article 54(2)b (EU) 2017/745 – for endorsement

An addendum to the document MDCG-2019-3 was endorsed by the MDCG, providing clarification on procedural aspects for manufacturers and notified bodies. The addendum will be incorporated in the document already published and will be presented as an update (v2) of MDCG-2019-3.

5) Implementing Acts – for information

COM informed MDCG on their ongoing work as regards development of Implementing Acts.

Standardisation: COM is currently working on the draft Standardisation Request for harmonised standards under the new Regulations, with the launch of a written consultation until 20th of March of the horizontal Standardisation committee. At the same time there is work ongoing on the last publication of harmonised standards under the Directives.

Reprocessing: the written procedure has been terminated without results at the request of one committee member; a date will be defined in April for a meeting of the Comitology committee.

Annex XVI: discussions with other COM departments including legal service.

6) Clinical Evaluation

6.1 Guidance on clinical evaluation and performance evaluation of medical device software – for endorsement

MDCG endorsed the guidance which was also previously presented at the meeting of December 2019.

6.2 Guidance on clinical evidence requirements needed for medical devices previously certified under Directives 93/42/EEC and 90/385/EEC (legacy medical devices) – for information

6.3 Guidance on Equivalence – state of play

Both guidance documents under 6.2 and 6.3 are included in the Joint Implementation Plan and they have been discussed in various meetings in the MDCG subgroup CIE (Clinical Investigation and Evaluation). MDCG members were asked to provide any possible comments in the following days in addition to various consultations that took place with competent authorities and other relevant stakeholders.

7) Expert Panels

Following publication of the Implementing Act in September 2019, the call for expression of interest for expert panels on medical devices and IVDs was published in the Official Journal and on relevant Commission websites. The Selection Procedure was aimed at appointing up to 246 experts to 12 different expert panels and creating a central list of available experts for replacements and temporary assignments.
697 applications were received before the deadline. 556 eligible applications were included in the Selection Procedure, a total of 360 candidates passed and were considered suitable for the work of the expert panels or inclusion in the central list.
Next steps: written consultation of the MDCG on the ranked shortlists, followed by appointment of the experts by COM. Subsequently, panels need to be made operational (election of chair/vice chair, formation of coordination committee, adoption of rules of procedure), followed by expert introductory meetings and expert training (workflow, guidance, use of IT tool, templates).

8) Information Note on Transparency obligations – state of play

COM noted that this is another priority included in the JIP and the intention is to come up with a short factual note with references to transparency obligations stemming from the legislation. COM asked for input from MDCG members on whether it should cover only

EUDAMED related aspects or horizontal issues. Taking also into consideration contributions to be received, COM will create the first draft of such document.

9) EUDAMED – conclusions and next steps

COM shared with participants the conclusions from the High Level MDCG meeting on the previous day. It also informed about agreed next steps and priorities, notably those set out in the endorsed Joint Implementation Plan.

- The COM confirmed the high priority of EUDAMED project and pledged to ensure that the development process will be as transparent as possible, and that all relevant parties are kept updated until and beyond May 2022.
- The COM will roll-out the six EUDAMED modules on a gradual basis, making each module available to Member States as soon as it is operational. The first module will facilitate actor registration and be launched in May 2020.
- It is important that until May 2022 the EUDAMED development focuses on the essential aspects to ensure the establishment of a basic functional system, which enables all parties concerned to meet their obligations under the MDR/IVDR. To support a strategic and streamlined approach, COM recently launched a new MDCG Subgroup on EUDAMED to help steer the work of the various ad-hoc technical working groups. There is an intention to comprise the group of both national authorities and stakeholders. In light of current circumstances, a first meeting (with national authorities only) most likely would have to take place via video-conference.
- A MDCG guidance document on harmonised administrative practices and technical solutions until EUDAMED is fully functional is currently being drafted. The document will focus on solutions and practices that bring 'added value' (in terms of collection and use of data) while at the same time ensuring that any potential additional burden on concerned parties stays as little as possible.
- An MDCG position paper is being drafted with the intention to set out a common approach of Member States to use the Actor Registration Module and to issue unique Single Registration Numbers in the EU.

10) Exchange of views on market situation in the EU

COM encouraged MDCG members to continue sharing information as regards availability issues in their respective markets including derogation requests and potential measures to be taken. COM proposed to facilitate regular monitoring.

In addition and in relation to Article 113 (EU) 2017/745 on notification of national penalties to the Commission, MDCG members were reminded to notify any national measures put in place.

11) IVDR specific topics (update)

11.1. EU Reference Laboratories

COM is in internal consultation regarding the implementing acts on tasks and criteria and fees for EU reference laboratories. COM noted that, while it is aiming at rapid adoption of the acts in the coming months, according to Article 113(d) of the IVDR the application date of those acts will be 25 November 2020. Work is ongoing in parallel on the call for application to be issued to the Member States. It should be opened as soon as possible after the adoption of the

acts and close after 25 November 2020. Designation of the labs can be estimated to take place early 2021.

11.2. Common Specifications

COM announced that the last amendment to Common Technical Specifications under the IVD Directive has been adopted and published. The focus is now on developing Common Specifications under the IVDR. The IVD WG is working on several new additions to be incorporated in these Common Specifications.

11.3. COVID-19

COM encouraged cooperation between competent authorities of Member States and within MS to share information and national measures taken to tackle the outbreak. Collaboration in this respect is fostered in the MDCG subgroup on IVD with technical exchanges and regular teleconferences. COM also referred to the conclusion from the high level MDCG that the development of COVID-19 needs to be considered in the implementation of the joint implementation plan.

12) International matters

12.1 EU Participation in the IMDRF (International Medical Devices Regulators Forum)

COM noted that COVID-19 has affected the work of the IMDRF (cancelling of the meeting in Singapore). COM invited competent authorities to submit names of suitable candidates from their administrations to follow IMDRF work items.

12.2 Developments with regard to guidance on MDSAP (Medical Device Single Audit Programme)

EU has undertaken to make use of these reports in line with EU legislative requirements, work is ongoing in the task Force set up in the MDCG subgroup International matters.

13) AOB

- CAMD (Competent Authorities for Medical Devices) – Update on activities by the Chair of CAMD;
- CMD meeting is Croatia is postponed due to COVID-19 situation, hoping to reschedule;
- Planned election of the executive group to be discussed further;
- France is setting up a taskforces to tackle shortages and handle them.

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

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, LI, TR

Commission: SANTE B6, SANTE F5, JRC F2, EMA (European Medicines Agency)