EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical Devices

Minutes of the expert groups

Brussels, 21 December 2020

Draft Minutes

Meeting of the Medical Devices Coordination Group[1] (MDCG)
7-8 December 2020

Monday 7 December 2020 (10:00 – 13:00)

1) Opening, adoption of the agenda

COM welcomed participants to another audio meeting due to the ongoing development of Covid-19. The agenda was adopted with an addition by the Commission on two additional points of information added under point 3 on Notified Bodies.

The minutes of the MDCG meeting held on 20-21 October 2020 were adopted, and will be made publicly available at the relevant registry for European Commission's expert groups.

2) Implementation MDR / IVDR

2.1 MDCG WGs - short update on their work

MDCG was updated on meetings and main milestones in MDCG working groups in the period since previous MDCG meeting of October, mainly as regards New Technologies, Nomenclature, UDI (Unique Device Identifier), PMSV (Post Market Surveillance and Vigilance), Annex XVI, Market Surveillance, Standards, B&C (Borderline & Classification) and NBO (Notified Bodies Oversight).

2.2 CIE Work Programme

The annual work programme (until end of 2021) of MDCG Clinical Investigation Working Group (CIE) was presented for information and possible comments to MDCG. The work programme was examined and endorsed by CIE and involves some important scheduled deliverables, such as templates for clinical investigation submission, support to Eudamed, exchange of information on serious adverse events (SAE) and others.

2.3 Implementing Acts

COM updated participants on the advancements of various implementing acts.

A new draft MDR/IVDR Standardisation Request is currently under development and internal scrutiny. It contains significant changes with respect to its first edition rejected in June, to take into account the points raised by CEN and Cenelec and feedback from stakeholders, within the

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

legal boundaries of European standardisation. If all goes in accordance with schedule and a positive opinion by the Committee on Standards is reached, the Commission should adopt the new Implementing Decision by March 2021, to address it to CEN and Cenelec for their acceptance by April 2021. On that basis, it would be possible to publish in the OJEU the first lists of harmonised standards in support of the new Regulations.

As regards Annex XVI two implementing acts are being prepared with active involvement of the Task Force operating under MDCG subgroup on Annex XVI: one on reclassification of active devices without an intended medical purpose and one on common specifications.

On the implementing act for electronic instructions for use and further to previous consultations it was concluded that an extension of scope was supported, limited to software and apps for professional users and lay persons.

3) Notified Bodies under MDR / IVDR

3.1 MDCG recommendation on the draft designation of a notified body

Following description of the outcome of the relevant joint assessment process, MDCG issued a positive recommendation for the designation of one notified body 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.

3.2 Joint Assessments Progress Report

COM shared an overview of notified bodies' activities at each stage of the designation process. Currently, a total of 50 applications have been submitted for the MDR and 16 for the IVDR to national authorities. However, COM informed that 4 applicants (3 MDR & 1 IVDR) have withdrawn at various stages in the process. COM encouraged MSs to engage with their notified bodies that have not yet applied, in particular those who plan on applying for the IVDR. In addition, COM highlighted that the joint assessment process is triggered by receipt of the preliminary assessment report (PAR) from designating authorities and informed 7 PARs for the MDR and 4 PARs for the IVDR had not yet been received.

An update in relation to the experience gained to-date relating to the initiation of two joint assessments by remote means at the request of the relevant DAs was provided based on the case-by-case assessments by the COM and MDCG common position. It was noted that the feedback from the JATs and the relevant DAs was positive. The preliminary outputs of the remote assessments will be finalised following on-site assessments that will be conducted in accordance with the process established by the Regulation and prior to the designation of the applicant bodies.

3.3 Update on Joint assessments for designation of notified bodies during Covid-19 circumstances

Following previous exchanges on the same topic and in particular following the extraordinary meeting of MDCG on 14 September, it was noted that:

- Every effort has to be made not to postpone nor delaying any designation process further;
- Possible issues that could come up on the planning of forthcoming joint assessments will be addressed taking a case-by-case approach;

- If needed, alternative solutions such as reducing the number of national experts to be involved or consider the possibility of conducting at least part of the assessment remotely (hybrid solution) may be taken into account.
  As mentioned under 3.2, for two recent cases where the designating authorities asked for the assessment to be initiated by remote means because of exceptional circumstances, it was made possible to accommodate designating authorities' request in order not to create unnecessary delays in the designation process. However, as already outlined at several occasions, the initiation of the assessment off-site constitutes an operative solution for the practical execution of the procedure but the process will be completed only when it will be possible to perform the assessment on-site, in accordance with the process established by the Regulation.
  COM underlined the importance of continue strengthening notified bodies capacity in 2021 and reiterated in particular the relevance for IVDs and they called to all to engage with national experts participating in the joint assessments.

3.4 Discussion on conformity assessment performed by notified bodies in Covid-19 circumstances

The topic is a follow up to the discussion in MDCG meeting of 20-21 October, where main concerns relating to the inability for notified bodies to carry out conformity assessment activities in the context of Covid-19 circumstances and consequent travel restrictions were discussed. The need to take action for increased flexibility in this respect in order to avoid delay of certifications under the Regulations and potential shortage of devices was also discussed in detail, taking also into account written feedback received from MDCG members in advance to the meeting. In general, MDCG agreed that the current situation is of concern, implying a risk of delays in certification procedures and a risk of potential shortages. The group also recognised, in principle, that a degree of flexibility may be necessary in some cases as an exceptional measure, including allowing for remote audits under specific conditions but a legally sound solution is necessary.

COM called for caution, reminded about national competent authorities' role in monitoring and enforcing the legislation and recognised the very special conditions created by Covid-19. COM will follow up, according to the outcome of the meeting and consider the most appropriate tool and way forward to address the concerns expressed.

3.5 Consultation of medicines authorities under the MDR for medical devices incorporating an ancillary medicinal substance and interrelation with Directive 2001/83

The topic was added by the COM for information and as a follow up to last MDCG in October, when it was raised by an MDCG member and also by one of the stakeholders at that session of MDCG. Since the MDCG meeting in October COM has been discussing the issue both internally and with notified bodies in order to get a better overview of the issue. A meeting had been held between notified bodies (NB-MED), HMA (Heads of Medicines Agencies) and CAMD representatives. Notified bodies will launch a survey to get a better understanding and if possible quantify the relevant burden for competent authorities for medicinal products.

In parallel, several aspects related to the interrelation between MDR / IVDR with Directive 2001/83/EC are under discussion, some of which are (or intended to be) tackled by the NBO Task Force on Art. 117MDR. The intention is to address some fundamental principles/issues that need clarification. COM invited MDCG members to liaise at national level with their colleagues working on pharmaceutical legislation as they are actively involved - mainly in

collaboration with EMA - on various initiatives concerning medical devices legislation implementation and it would be very beneficial to streamline better national perspectives.

3.6 Request for data on medical devices certifications and demand for EU reference laboratory services

COM informed about a survey under preparation addressed to notified bodies to be launched on certification/application (MDR/IVDR) and demand for EURLs (European Reference Laboratories). The request will be addressed to individual notified bodies and COM invited all designated authorities to reach out to their notified bodies and ensure as many replies as possible.

Similar surveys will be addressed to national competent authorities and industry. It was noted that the survey on certifications/applications is part of a measure discussed within the CAMD Task Force on notified bodies' capacity and is intended to address both medical devices and *in vitro* diagnostics.

4) Expert Panels

JRC gave an update on the ongoing work towards establishment of expert panels with an initial focus on the expert consultation procedures on specific high-risk devices and class D in vitro diagnostics, which support the mechanism for scrutiny under responsibility of competent authorities. JRC presented some key elements:

Expert contracts: JRC summarized the current status concerning expert registration, creation of expert pools and establishment of expert contracts. Expert pools have been created for structuring the around 350experts according to medical fields and expected workload. The expert contracts for panel members are being processed and will be concluded in February 2021.

Training of experts: Experts are offered a comprehensive training program to provide relevant background on legislative and regulatory principles, roles and tasks of panels and individual experts, scope of CECP/PECP procedures, screening decision criteria and operational aspects (including document exchange, handling of commercially confidential information etc.). Recorded versions of 5 training modules and a FAQ document are available on the expert space on CIRCABC and the expert panel website.

Tools and templates: Development of tools, guidance documents and templates required for the operation of expert panels is ongoing. This includes the development of a guidance document for notified bodies concerning the consultation procedures.

Elections of chairs/vice chairs: The elections of Chairs and vice-Chairs of panels has been kicked off and will be concluded in January 2021. This will allow setting-up of the Coordination Committee to adopt the rules of procedure and the proposed sub-group structure. Subsequently, elections of Chairs and vice-Chairs of sub-groups will be held.

5) EUDAMED update

Roadmap: COM presented the latest EUDAMED roadmap focusing on the different development steps. The Actor registration module is in production since 1st December for voluntary use. The second production release will add the UDI/Devices and Certificates modules in Playground (planned for Q1/2021) and in Production (planned for May-2021). However this is tentative as discussing about requirements and MVP approach are still going on. The target is to deliver a fully functional EUDAMED MVP (Minimum Viable Product) in

May 2022 with all remaining modules. To make this possible, the complete development must be finished by end 2021, taking into account that Q4 2021 will be used to catch up, solve bugs and prepare for the Audit. COM stressed the project technical complexity, particularly for Data Exchange (DTX) and also for testing. DTX requires duplicating features since the user interface features are replicated in DTX and this has an impact on deadlines. COM underlined that they put a lot of effort on DTX and that it is not possible to provide the DTX features before the user interface development is done. COM reminded that requesting machine-to-machine DTX access can be done by the Local Actor Administrators via a form available in EUDAMED Production.

A Member State pointed out that the actor registration in EUDAMED could be considered as fulfilling the national actor registration obligation at the condition the machine-to-machine DTX service for downloading the actor data from EUDAMED is operational.

Another Member State asked for a critical analysis of indicated serious legal challenges with regards to the CA submission of SRN via the voluntary EUDAMED Actor registration module done before the Date of Application and with the submission of SRN to producer of systems and procedure packs claiming that the MDR doesn't provide a legal basis for CA to do so. The MS also offered an active influence of the MDCG on the definition of the MVP of EUDAMED and underlined the need to amend some of the functional specification of EUDAMED to make EUDAMED less complex and better performing in line with the legal provisions of the MDR .

The MVP definition is done in collaboration with national experts from the different MDCG Subgroups and Task forces having the Functional Specifications as the high level basis for the scope definition. COM intends to work with a few identified national experts, to have a quick and agile feedback for clarifying some technical details to speed up the implementation process. For outstanding issues related to the MDR/IVDR interpretations, the horizontal MDCG EUDAMED Subgroup and if needed MDCG will be involved as appropriate (e.g. custom-made manufacturer registration issue). Currently the COM is working in close collaboration with the EUDAMED WGs on Vigilance and Clinical Investigation.

MDCG Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional: further to comments received by some MDCG members prior to the meeting COM informed that small modifications would be made to align the wording with the MDCG Statement of the actor module. The guidance will then be proposed to MDCG for written endorsement.

Implementing Act: an internal consultation with other Commission services is ongoing and a mature draft will be shared with MDCG members for their potential comments. Planned adoption date is Q1 2021.

Monday 7 December 2020 (14:00 – 17:00)

6) IVDR Implementation – exchange of views

This part of the meeting was dedicated to IVDR implementation. In addition to MDCG members, the Commission had invited members nominated by competent authorities to the dedicated sub-group MDCG IVD.

6.1 Report of activities of IVD MDCG Working Group

The chairs of MDCG IVD WG noted that the work of the group is very broad and challenging taking into account the approaching date of application and the Covid-19 pandemic. The IVD

WG has many engaged participants but it is challenging to advance with the resources available. They were looking forward to discussing the allocation of resources and priorities together with the MDCG.

The latest meeting of MDCG IVD took place on 16/11. In this meeting, the group took stock of the work done over the year and examined the joint implementation plan together with a draft work programme for 2021.

Guidance on performance evaluation is in mature draft stage and has recently completed stakeholder consultation. New common specifications have been drafted for Kidd, Duffy, Chagas, syphilis, CMV, EBV. Guidance on classification has been endorsed and published in November.

In addition, work continues on the Covid-19 front. Market surveillance exchanges between competent authorities are ongoing. Guidance on state of the art of antibody tests has completed stakeholder consultation.

6.2 Joint Implementation Plan (JIP)

A discussion on points included in the JIP took place. Representatives from competent authorities expressed their interest in leading or participating in work on specific points. If no leads or participants were available, actions could not be included in the JIP. Volunteers were found for most actions including the summary of safety and performance and in-house devices. The competent authorities suggested to reduce the scope and to reschedule planned work on companion diagnostics.

It was agreed to allow one week for confirmation of interest following the meeting.

6.3 Discussion of specific IVDR transition issues

In previous meetings, the MDCG expressed its support to focus on finding solutions and mitigating risks to availability of devices, by means of an MDCG-level forum mentioned in the JIP. To support this work of the MDCG, the Commission consulted members and observers of MDCG IVD WG in November to collect input on identification of specific transition issues and possible solutions. Members of the group were encouraged to share their comments since only one competent authority provided comments until now. On the contrary there was considerable input provided by the observers of the group.

Input received by COM was shared with MDCG in advance of the meeting.

The issues included those related to expert panels, EU reference laboratories, notified bodies, general conformity assessment and consequences of Covid-19 pandemic. A preliminary discussion of the issues and possible solutions took place. As the participation in the discussion was limited, it was agreed to continue review of these points in future meetings.

6.4 Draft IVD MDCG WG Work Programme

The draft WP for 2021 was presented as an information point for MDCG members. It includes items in the JIP as well as other items the group considers a priority notably Covid-19 related work items under the Directive. MDCG members were invited to share any comments on the work programme in writing following the meeting.

7) Covid-19 and IVDs

As regards conformity assessment of Covid-19 devices under Directive 98/79/EC, following a reflection process on possible tightening of the procedures, the Commission carried out a survey of the Member States as to whether any of them is considering submitting a request to the Commission under Article 14 (1) (a) or (b) of the Directive. The Commission reported that to date 11 Member States had responded to the survey, of which none was considering submitting such a request. The remaining Member States were encouraged to respond to the survey.

The Commission also informed the MDCG that the IVD WG is working on common specifications for SARS-CoV-2 devices under Regulation (EU) 2017/746.

Tuesday 8 December 2020 (10:00 – 13:00)

8) Custom made devices

The Q&A document was originally developed by a task force established under the CAMD group. In order to facilitate consultations with relevant experts, this work was brought under the remit of the Medical Device Coordination Group and in particular the Market Surveillance working group (MSWG). Consultations took place in December 2019 (MSWG only) and February 2020 (MSWG and MDCG Stakeholders). Comments received have been processed and reflected within the revised text sent to MDCG. It was noted that among comments received there was a call from the Market Surveillance Working Group for a more elaborate guidance on Custom-Made Devices.

The main objective of this Q&A was to address the most pressing questions where clarity on the status of custom-made devices, adaptable devices and so-called intermediate products and a common understanding of the changes in the relevant definitions introduced with the MDR is needed. As identified on the Market Surveillance Working Group work program, further guidance will be developed, as appropriate.

MDCG members expressed different views, among others on the understanding of what is mass-produced. Members also pointed to the need to finalise the document as soon as possible, and it was proposed that the Commission will launch an ad hoc Task Force with MDCG nominations to reach a final decision, following this meeting.

9) Draft MDCG Position Paper on UDI assignment rules for ophthalmic lenses and ready readers – for information

This position paper aims at explaining the UDI assignment rules for ophthalmic lenses and ready readers in order to ensure relevant regulatory information is captured in EUDAMED. There was a general discussion of the document and it was agreed to proceed to written endorsement of the document by 14 December.

10) AOB

10.1 European Health Union – information from the Commission

COM informed briefly on the European Health Union Package, which is a part of the Commission's response and lessons learnt to the crisis and consists of three proposals for Regulations: Strengthening the mandate of European Medicines Agency (EMA), strengthening

the mandate of the European Centre for Disease Prevention and Control (ECDC) and a revision of Cross Border Health Threads Decision.
The proposal on EMA includes amongst others that EMA would - on behalf of the Commission - provide support for the work of the expert panels and monitor and mitigate potential and actual shortages of medical devices considered as critical in order to address a given public health emergency. No regulatory changes are proposed neither for MDR / IVDR or EMA founding Regulation. A few MDCG members expressed views on the proposals but as the proposals are currently under examination by co-legislators, MDCG members were encouraged to liaise with their colleagues in Council for more detailed comments on the proposal.

10.2 CAMD (Competent Authorities for Medical Devices) – Update on activities by the Chair of the CAMD Executive group

The Chair of the CAMD Executive group, presented their latest activities since last MDCG meeting in October. These focused mainly on distribution of work initiatives and work allocation between competent authorities and update of the Roadmap by the CAMD Operational working group. It was also noted that there is no support for any further MDR / or IVDR postponement.

Next meeting

The next MDCG meeting is scheduled for 4 and 5 March 2021. More information to follow.

List of participants

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

Observers: CH, IC, LI, NO, TR.

Commission: SANTE B6, SANTE F5, JRC F2, SANTE A4.

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