Minutes of the expert groups

Brussels, 20 December 2019

Draft Minutes
Meeting of the Medical Devices Coordination Group[1] (MDCG)
13/12/2019, Brussels

1) Approval of the agenda and of the minutes of previous meeting

Agenda and minutes of the following meetings were approved and will be published on the COM website for expert groups:

MDCG meeting with Stakeholders of 30th September 2019

MDCG of 1st October 2019

MDCG of 21st November 2019 extraordinary meeting dedicated to EUDAMED

DE stated they are still not satisfied with the way minutes are presented and that more information should be included. COM reminded that all members are given the opportunity to provide written comments on the minutes and that they should not be too long.

2) Nature of the meeting

MDCG meetings are not public; they are intended only for MDCG members.

3) List of points discussed

Agenda item 3 – MDR/IVDR Implementation

3.1 Update by the European Commission including on MDCG activities:

Corrigendum: formal procedure concluded at the Council level without any objection on 3/12/2019. On the same date, ENVI Committee of the European Parliament voted in favour of the corrigendum with a broad majority. The final step of the process is possible endorsement by the EP at its plenary of 16 December. COM thanked all MDCG members for their cooperation on this specific dossier as this corrigendum will significantly facilitate transition to the new MDR. Once adopted, we will all have to ensure that the relevant changes are effectively communicated to the whole medical device community and notably industry and Notified Bodies. Experience shows that information does not always reach all actors of the system.
EPSCO (Employment, Social Policy and Consumers Affairs) Council meeting: the health part of the Ministerial Council took place on 9/12/2019 and medical devices were included as an AOB item. Commissioner Kyriakides provided a description of the state-of-play and, with regard to Eudamed, confirmed the Commission's commitment to work with Member States on the practicalities of the alternative plan foreseen by the legislation as well as to make

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

available the actor registration module on a voluntary basis. The Commission also highlighted the importance of sticking to the timeline of May 2020 in the interest of patient safety and EU's reputational capital. 22 Member States intervened and in summary all interventions recognised the huge work done till now by all the parties, while pointing to the need for scaling up efforts on both Member States and Commission's side. Furthermore, the Council requested additional concrete engagement of MDCG on implementation monitoring.

MDCG Subgroups: 13 MDCG subgroups operate according to the rules for expert groups, competent authorities have the opportunity to participate in various meetings and teleconferences, in guidance development, and other work produced. Minutes of these meetings are published on the COM website for expert groups. COM informed briefly on main activities of the subgroups except for those which are included in separate agenda items below:

NBO (Notify Bodies Oversight): The guidance on sampling of devices for the assessment of the technical documentation and the Explanatory note of MDR codes have been endorsed by the MCDG few days ago through written procedure and are in the process of being published; many other guidance documents are under discussion. In particular, the group sent for stakeholders' consultation the first version of three documents dealing with transitional provisions and the transition from the MDD to MDR: Guidance on significant changes under Article 120 of the MDR, Guidance on transitional provisions for consultations of authorities on devices containing ancillary medicinal products and on devices manufactured using TSE susceptible animal tissues and addendum on the document MDCG 2019-3 concerning Interpretation of Article 54(2)b. Additional work items are on-going, including the development of a guidance on batch verification for class D for in vitro diagnostic, a new set of Q&A for the requirements for notified bodies as well as un update of the procedure for the designation process.

Standards: the second meeting of the group will take place no later than Q2 2020. Topics for discussion will include latest activities of the Commission and CEN-CENELEC on standardisation issues, the state of play on the Standardisation Request under the new Regulations and the publication of references of harmonized standards in the OJEU under the current Directives and the new Regulation and others.

CIE (Clinical Investigation and Evaluation): last meeting of the group took place on 7-8 November 2019 and discussed in detail the work plan of the group as well as the provision of guidance documents on sufficient clinical data, equivalence, templates for clinical investigation submission and assessment and reporting of Significant Adverse Events (SAE). Dedicated work streams were established for contingency planning covering SAEs and Clinical Investigation submissions.

PMSV (Post Market Surveillance and Vigilance): a Task Force for the development of vigilance guidelines under MDR has been set up. Works will start from January 2020. As regards the development of a Periodic Safety update Report (PSUR), works is ongoing and a face-to-face meeting of the TF is organised by COM on 13-14 February. Next PMSV WG will take place on 20-21 February.

Market Surveillance: a meeting took place on 29 November. Interest in at the vacant co-chair post was expressed by 2 member states and roles will be formalised in the next April 2020 WG meeting. While a number of Task Forces have been set-up (Guidance for Authorised Representatives) and some continuing from the ex-COEN WG (e.g. Class I Manufacturers

WG), a call for volunteers to set-up planned TF projects (e.g. Joint Inspection Groups, Re-packaging & Re-labelling) has been distributed to members. One consultation of a Q&A for Custom-Made & Adaptable devices jointly produced with CAMD Transitional Group is on-going.

B & C Borderline and Classification: the latest meeting took place on 4 December 2019. Two guidance documents will soon be released for stakeholder consultation: borderline with medicines and classification. A guidance document on transitional provisions for consultations of medicines authorities on devices with ancillary substances (for which such a consultation already took place under the MDD) is also being prepared jointly with the NBO group.

New Technologies: two guidance documents have been developed one on clinical / performance evaluation of software and one on cybersecurity – to be presented under following agenda items.

UDI (Unique Device Identification): the last meeting took place on 11 November 2019, where the 4 designated issuing entities were presented to the group for first time. Specifications (e.g. for UDI-DI & Basic UDI) for these 4 issuing entities have now been published on the GROW website. A draft guidance document on the manufacturer's Quality Management System and a list proposing values for certain data fields are currently under consultation of group members. Finally, the request for providing a UDI Helpdesk service by CHAFEA has been launched with a submission date of early January.

International matters: second meeting scheduled for March 2020 before the next Management Committee meeting of IMDRF (International Medical Devices Regulators' Forum); a dedicated Task Force is developing guidance on how NBs may take into account MDSAP (Medical Device Single Audit Programme) reports.

Nomenclature: extraordinary revision of the nomenclature ended in October. Over 500 comments were received and are currently being processed. The technical group processing comments will follow a batch like approach. The batches will undergo translations and will require subsequent validation by MSs for their respective languages. MDCG will be asked to provide their input regarding the translations, especially when the MS is not represented in the Nomenclature WG. WHO is working on establishing an international nomenclature and there are discussions ongoing with them on how to link this to the EU nomenclature.

3.2 Update by CAMD Operational WG on Roadmap progress: The DK MDCG member chairing this CAMD WG informed that in a recent CAMD meeting in Finland the ToR and work programme were adopted. The group, which consists of 31 members, met in Brussels two days earlier and identified the need to monitor closely implementation; the group recognises that the last two years have been difficult and that many tasks have been completed from the existing roadmap (which identifies 145 tasks). They also identified the need for prioritisation, both in the short and long term; this is particularly helpful for the allocation of resources. Transparency was also highlighted as being extremely important and MSs were asked to send comments on the revised Roadmap by 17/1/2020; final version to be endorsed at next CAMD meeting in Zagreb (March 2020). A meeting with MDCG subgroup chairs is foreseen for 31/1/2019.

3.3 Implementation readiness, further coordination and next steps: the Chair stated that this agenda item was added further to the recent discussion at EPSCO and in particular further

to requests by some Member States. There are many ongoing activities such as the work developed in MDCG subgroups and consequently the publication of the documents on guidance development on Commission's website; there is the implementation plan (rolling plan) published on the same website and there is the work done by CAMD. The Chair asked MDCG members to elaborate on the readiness check requested by some Member States in the discussion at EPSCO.

Overall, MDCG members recognised that a lot of work has taken place and is still ongoing but they underlined the need to increase efforts taking into account the limited available resources. Some MDCG members underlined that this should be a joint effort between COM, MS and other involved stakeholders. More importantly, MDCG seemed to agree that there is a need to define certain priorities in order to focus their efforts towards them and seek political approval from a higher level than MDCG in order to bring these priorities to fruition.

Further to the above, COM offered to organise a special MDCG meeting as soon as possible in 2020 with the possibility for participation in addition to MDCG members, of representatives at higher level with the objective to discuss and possibly endorse specific priority areas for the implementation of MDR / IVDR. COM also stated that they will identify a rather limited number of specific priorities based on the work done so far by MDCG and CAMD; any documents for endorsement will have to be sent at least 15 days before the meeting.

DE expressed their scepticism to the idea that the COM will do the main preparatory work / identification of priorities in advance of this special MDCG meeting.

Agenda item 4 – Notified Bodies under MDR/IVDR:

4.1 – Joint Assessments Progress Report by COM: COM informed that they have received in total 55 applications for designation (44 under the MDR and 11 under the IVDR), which have resulted in 49 preliminary assessment reports so far. Out of these, 45 on-site assessments have been carried out, and 4 are planned (in 2020). There are currently 9 designations published in NANDO (7 for the MDR and 2 for the IVDR). At the same time, there are 3 more notifications of designation, which are expected to be published in NANDO before the end of the year. There are currently 8 designating authorities' final reports which should arrive in the next months. Based on the average time-span between issuing the JAT CAPA plan review (that precedes the designating authority final report) and the 12 notifications of designation made, the estimate is that there could be a total of 18 notifications of designations by the end of Q1 2020.

4.2 – MDCG recommendation on the draft designation of one NB: the designating authority presented their final assessment report together with additional written information on the applicant notified body, and the Commission presented the final opinion of the joint assessment team. A discussion followed, taking account of the MDCG conclusions as regards requirements for NB designation. 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.

Agenda item 5 – Guidance on Clinical / Performance evaluation of software for endorsement: the proposed guidance was developed in 2018-2019 through multiple meetings and teleconferences of the MDCG subgroup New Technologies and covers the scope of both

MDR & IVDR. Although the guidance was originally foreseen for endorsement at this meeting, COM informed that another round of consultation with IVDR MDCG subgroup deemed appropriate. The intention is to conclude this consultation the earliest possible and forward the outcome again to MDCG for endorsement.

Agenda item 6 – Guidance on Cybersecurity for endorsement: the guidance was developed by MDCG subgroup New Technologies in collaboration with JRC as well as ENISA agency. The term used in the past of "shared responsibility" between manufacturer and user in comparison with the term "joint responsibility" was highlighted by some MDCG members. There was a general agreement that the preferred choice was to use "joint responsibility" and the guidance was endorsed with this change.

Agenda item 7 – Guidance on Class I manufacturers for endorsement: work on this guidance document began 3 years ago under the ex-COEN WG and has continued under the MDCG Market Surveillance subgroup. The aim of this guidance is to assist manufacturers when placing Class I medical devices on the market. PT led the relevant task force and competent authorities plus stakeholders were consulted during the process. MDCG endorsed this guidance.

Agenda item 8 –Eudamed state of play and next steps: COM presented the EUDAMED IT updates and reminded that the Functional Specifications were published in March 2019 and the documentation ready to be shared is progressively available to MDCG Members via CIRCABC.

COM explained that the Actors registration module will be ready to be deployed in May 2020 for voluntary use and the remaining modules will be ready in May 2022. They also provided a detailed state of play of the main EUDAMED milestones for each module, the public site and the data exchange. Currently the Playground is open for Actors registration, UDI/Devices registration and Data exchange for the settlement of access points. Several Playground phases will be opened between 2020 and 2022.

DK expressed their concerns on the possibility to introduce voluntary actors' registration; in their view this would have no added value since it would be a voluntary and not a mandatory action and would probably lead to double registration.

Agenda item 9 – Ongoing Implementing Acts (update):

Standards: The draft Commission Implementing Decision for the Standardisation Request under the MDR is still under internal discussion to clarify some drafting issues in the main text. When such issues are finally solved, the revised and final version should be circulated in written form to the MDCG members, and then presented at the next meeting of the Committee on Standards to be held on 24 January 2020 – in EN and for information only. It will not be possible to submit the text to vote, as the necessary DE and FR translations would not be available due to the time constraints.

Concerning the publication of references in the OJEU, we are working on a new and final publication under the current MDD and AIMDD, in the format of a Commission Implementing Decision. Such publication should include some updates and clean-up from the latest publication in November 2017, and especially the necessary legal clause on the "end date" for the presumption of conformity on 27 May 2024 (ex Art. 120(3) MDR).

Reprocessing: Ahead of the meeting, COM had shared the final draft of the IA, which includes the revisions resulting from the public consultation and the comments that were provided in the written consultation with the MDCG (closed on the 2nd of December). COM thanked Member States that provided comments as the text has improved substantially with these comments. Following the previous rounds of revisions, it is considered that consultation with MDCG has been completed on this consolidated version. The vote of the text in the Comitology Committee will take place as soon as possible.

Annex XVI: COM informed that the draft text on common specifications of Annex XVI devices is currently being reviewed by other Commission services. This process will still take some time, due to the complexity of the topic. The main points under discussion are the definition, and inclusion in the text, of the specific MDR requirements that need to be addressed with common specifications and the scope of these common specifications. The text will be then published on the Commission website for stakeholders' feedback. Responding to questions, COM clarified that a transitional period for Annex XVI devices is not intended to be included in the current corrigendum.

In addition COM informed that a call for expression of interest for observers will be published early in January 2020 in order to give them the opportunity to attend the MDCG subgroup on Annex XVI provided that they will fulfil the selection criteria.

Agenda item 10 – IVD specific topics (update): COM updated on latest activities of IVD MDCG subgroup: a meeting took place on 29/11/2019. Key work items included the guidance on classification, common specifications, guidance on performance evaluation and EU reference labs, as well as qualification of assays used in clinical trials. A workshop on performance evaluation took place on 12/12/2019. New task forces are being set up for summary of safety and performance and in-house devices. There are volunteers from MS but no leaders – COM strongly encouraged delegates to put themselves forward as leaders to avoid blocking various work items and they promised to support organisational / logistic aspects.

10.1 – EU Reference Laboratories: the Implementing Act (IA) was developed during the year and IVD MDCG subgroup was consulted. The acts on (1) tasks and criteria and (2) on fees have been developed with the assistance of JRC and consultations of the task force on scientific bodies and the IVD WG. Mature versions were circulated for consultation of the MDCG between the 27/11/2019 – 9/12/2019. Next steps are the COM interservice consultation which can, lead to changes and a vote in the Comitology Committee.

The call for application is in preparation and has been subject to a consultation of the IVD MDCG subgroup. It will be presented to the MDCG in early 2020. It will be launched following the adoption of the acts. It was clarified that it is up to each MS to decide which appropriate entity is responsible for nominating EU Reference Labs at national level.

10.2 – Common specifications: CTS on self-tests: translations and linguistic check completed, vote of MS to be launched on 16/12/2019. Following adoption, the transposition of CTS (Common Technical Specifications) into CS (Common Specifications) will be launched.
Common specifications: CS for Chagas and syphilis as well as Kidd and Duffy blood groups have been developed. This is intended to be included as part of the transposition of CTS into CS. Now that the classification guidance is mature, COM did a survey to prioritise the

development of CS for other class D devices and has drafted a roadmap which was discussed in the last IVD meeting. The first agents are CMV and EBV.

Agenda item 11 – Expert panels (update):

11.1 Applications received for the Call of Expression of Interest: the Call for experts on medical devices and IVDs was published in the Official Journal and on relevant Commission websites. It was also disseminated to relevant stakeholders and professional organisations. 696 applications were received before the deadline. Following a completeness and first eligibility check 556 of them were included in the Selection Procedure. Most candidates have a medical degree, but also have a wide range of other expertise. The majority of candidatures are from Germany, Italy, Spain, France and Portugal. The main steps of the selection procedure are the complete eligibility assessment, the scoring of candidates against the selection criteria, the screening of their declarations of interest followed by their appointment. Every applicant submitted a Declaration of Interest as part of their supporting documents and management of these declarations is a substantial part of work. A conflict-of-interest management policy has been developed based on the applicable rules for other EU bodies, Commission expert groups and in close alignment with the corresponding European Medicines Agency policy. According to COM's estimation, the appointments of the expert panels will be concluded before 26 May 2020.

Responding to questions, COM reassured that MDCG will be closely involved in the selection procedure as stipulated in MDR; MDCG will receive short-lists of candidates for expert panels for their review to ensure that the distribution of expertise and nationalities are appropriate. Trainings of experts after their appointment will be scheduled in due course.

11.2 Preparatory work on a guidance document for consistent interpretation of criteria in Annex IX, point 5.1(c): MDCG was informed on the preparatory work done so far concerning a guidance document for expert panels. This guidance is about consistent interpretation of the criteria in order to decide whether to develop an opinion in the context of the clinical evaluation consultation procedure (CECP). There is a legal obligation: COM after consultation with Member States and relevant scientific experts shall provide guidance for expert panels for consistent interpretation of the decision criteria (as specified in MDR Annex IX Section 5.1) before 26 May 2020. As preparatory steps, JRC organized two events in 2019. A meeting of the MDCG TF on scientific bodies took place on 27 June in Ispra. It was followed by a workshop on novelty and innovation in MDs and IVDs (9-10 October, Ispra) with the participation of clinicians, industry and notified body representatives. Following input by participants, JRC developed a draft guidance document. Regarding the consultation phases, the draft guidance has been sent out to the MDCG TF on scientific bodies for consultation (15 November–4 December 2019). JRC received comments from Ireland, Germany, Portugal and Spain. A revised version will be circulated. A consultation with clinical experts present at the workshop is planned early next year (10-24 January 2020). It should be followed by a consultation of the relevant MDCG subgroups (e.g. PMSV, NBO, NT, CIE) in February 2020 prior to review / endorsement by MDCG plenary. Some MDCG members suggested that a simplification of the draft document may be needed.

Agenda item 12 – AOB:

12.1 CAMD – (Competent Authorities for Medical Devices): update on activities by CAMD Chair:

Preparation of agenda for the next CAMD meeting in Zagreb in March 2020 is ongoing

Publication of an open letter to share the CAMD concerns on the EUDAMED delay; another publication on Brexit may follow soon;

Meeting on CAMD Operational Working Group in Brussels on 11/12/2019

JAMS meeting on 12/12/2019 in Brussels – Joint Action in Market Surveillance; a pilot on joint inspections will be launched under MDCG subgroup Market Surveillance. Preparations for any application for a new Joint Action would need to be launched soon.

12.2 Communication campaign, COM informed on the following:

- Offers are currently being evaluated for the next phase of the communication campaign which will start from June 2020 to December 2021;

- A webinar is under preparation on patients' rights under the new regulations on medical devices. The webinar should be made available on the Commission website with subtitles in all EU languages;

- In November the communication campaign was at Medica, a major medical devices trade fair. A digital banner on the communication campaign was projected on a big screen at the entrance of the fair and a full page advertising of the campaign was part of the paper visitor guide. Main objective was to inform manufacturers about the existence of information material on the requirements of the new regulations available on DG GROW website;

- MDCG members were reminded that they are always welcome to communicate any specific needs they may have as regards communication in order to make an effort to incorporate them into the communication campaign.

4) Next meeting

Next MDCG meeting: the date of next meeting will be communicated to members as soon as possible.

5) List of participants

No	MDCG Member/ Observer	Institution/Organisation
1	AT	Austrian Federal Office for Safety in Health Care/Austrian Agency for Health and Food Safety (BASG/AGES)
2	BE	Federal Agency for Medicines and Health Products (AFMPS)
3	BG	Bulgarian Drug Agency

4	HR	Agency for Medicinal Products and Medical Devices (HALMED)
5	CH	Swiss Agency for Medicines and Health Products
6	CY	Cyprus Medical Devices Competent Authority
7	CZ	State Institute for Drug Control
8	DK	Danish Medicines Agency
9	EE	Estonian Health Board
10	FI	VALVIRA – National Supervisory Authority for Welfare and Health
11	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
12	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
13	GR	National Organisation for Medicines (EOF)
14	HU	National Institute of Pharmacy and Nutrition
15	IE	Health Products Regulatory Authority (HPRA)
16	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
17	LI	Office of Public Health, Lichtenstein
18	LU	Ministry of Health Luxembourg
19	LT	State Healthcare Accreditation Agency, Ministry of Health
20	LV	Ministry of Health – EXCUSED
21	MT	Ministry of Health
22	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
23	NO	Norwegian Ministry of Health and Care Services
24	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
25	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
26	RO	National Agency for Medicines and Medical Devices
27	SI	Agency for Medicinal Products and Medical Devices
28	SK	State Institute for Drug Control – EXCUSED
29	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)

30	SE	Medical Products Agency (MPA)
31	TR	TMMDA – Turkish Medicines and Medical Devices Agency
32	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- GROW D4
- SANTE F5
- JRC F2