Minutes of the expert groups

Brussels, 26 November 2019

Minutes
Meeting of the Medical Devices Coordination Group[1] (MDCG)
01/10/2019, Brussels

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

Agenda of the meeting and minutes of the previous meeting were approved. As regards the preparation of future minutes an MDCG member asked for more information to be included in the minutes as regards individual positions of interventions by Member States' experts or that two versions of the minutes should be prepared. COM stated that they are trying on one hand to manage the length of the minutes but on the other hand aiming for transparency and to reflect the discussions taking place as accurately as possible; MDCG members were invited to indicate on a case by case basis when they wish some of their positions to be specifically reflected in the minutes, if not done so.

2) Nature of the meeting

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

3) List of points discussed

a) **Agenda item 3 – Corrigendum**: COM provided information as regards the next corrigendum process and noted it includes at least two points relating to MDR and two points relating to IVDR. A positive outcome of this exercise is of a high importance to correct inconsistencies in the text, alleviation of the current pressure on notified bodies and transition to the new system will be facilitated. COM noted also that they expect all Member States to support this exercise and if necessary assist in providing technical information to new MEPs involved. COM from their side will continue to provide all the necessary support to the two co-legislators.

b) **Agenda item 4 – Notified Bodies under MDR/IVDR**:

4.1 – Joint Assessments Progress Report by COM: Five notified bodies (NBs) are designated under MDR - more will follow in the near future – and the first NB to be designated under the IVDR is expected to be listed in NANDO by mid-October.COM working towards full capacity estimates about 80% of current NBs that have applied for designation under MDR with a slower pace for NBs for IVDR (about half of these have applied at this stage).

4.2 – MDCG recommendations on the draft designation of two NBs: The Dutch designating authority presented their final assessment reports on two applicant notified bodies, and the Commission presented the corresponding final opinions of the joint assessment team. A discussion followed and MDCG issued two positive

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

recommendations under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified bodies should be designated in the scope proposed by the designating authority.

4.3 – Validity of certificates issued according to the Directives after the application date: The Commission highlighted the need to clarify the conditions under which validity of certificates issued according to the Directives can be allowed based on Article 120 of the MDR during the transitional period, covering certificates to be issued and to be valid until May 2024. A draft document was presented to the MDCG for endorsement as a result of previous discussion that took place at the level of NBO (MDCG subgroup). This text focuses on the need for the designating authority to carry out the proper control over the notified body. An exchange of views followed which demonstrated that some MDCG members shared some concerns mainly regarding empowerment of designating authorities – DK, IE, DE, UK and PT. Taking into consideration all concerns expressed, MDCG finally endorsed the proposed text except for DK, who noted that they could not agree and in their view the proposal was potentially creating a two track system for NBs and was against harmonisation of procedures at EU level.

4.4 – Designating authority's final assessment form: Key information (EN): the template was agreed at the NBO meeting of June and the Commission presented the template as a tool to enhance transparency by presenting the outcomes of the joint assessment process in a language commonly understood (English). It aims at giving a picture of all findings identified during the joint assessment and their closing out to all designating authorities. The template will be annexed to the final assessment of the designating authority. The key information document was endorsed by MDCG.

4.5 – Q & A on requirements related to NBs: a new set of nine additional Q&As, agreed by the NBO, was presented. It will complement the document MDCG 2019-6 already published on the Commission website. The new questions tackle various issues. MDCG endorsed eight Q&A; the Q&A referring to fast track services will be revisited in the future.

4.6 – Requirements for NBs – Open topics for endorsement: these points are issues which have been identified during joint assessments of applicant notified bodies as diverging opinions between the joint assessment team and the national designating authority. The proposals presented by the Commission follow discussions at the relevant MDCG subgroup NBO, including written consultation of NBO members. Other services of the Commission have been consulted to consolidate the proposed text, with particular reference to the interpretation of the term "employment", point a) below. All proposals are presented in the form of a Q&A intended to be added to the document MDCG 2019-6, already published in the Commission's website.

i. Tasks to be carried out in accordance to art. 36 MDR / art. 32 IVDR and Section 4.1 of Annex VII of MDR/IVDR – Employment: this issue was already discussed in the past. In particular, a first proposal prepared by the NBOG was presented to MDCG in November 2018 but MDCG did not reach an agreement back then. As regards the proposal brought forward at this meeting, the Commission indicated that there seemed to be a majority of MS supporting direct employment contract including direct paid remuneration. This proposal includes a transitional period of three years (from the date of

notification), taking into consideration that few notified bodies might need some time to fully comply with this interpretation. Five MDCG members (DE, BE, NL, CY and UK) expressed their disagreement with the proposal. Direct payment was deemed problematic for them, as they argued that there can be other ways of demonstrating direct employment between an employer and an employee, such as secondary contracts. Other MDCG members expressed their support to the proposal and finally MDCG endorsed it with the exception of DE, BE, NL, CY and UK.

ii. Re-certification activities: the Commission noted that after failure in MDCG meeting of April 2019 to reach a common position regarding this diverging opinion as recorded in joint assessments, the topic was re-examined in last NBO meeting. The position presented this time represents a compromise proposal. It does not refer to the need to perform individual re-certification audit but it rather focuses on the need for the notified body to assess all relevant Regulation requirements for conducting audits and it also specifies which kind of additional verifications have to be performed prior to the renewal. MDCG endorsed the proposal with an addition to more explicit reference to clinical evaluation as requested by an MDCG member.

iii. Employment linked to internal clinician: MDCG endorsed the proposal presented by the Commission concerning the interpretation of permanent availability of personnel with clinical expertise in accordance to sections 3.2.4 and 3.1.1 of Annex VII. In particular, the person(s) should be employed where possible but the possibility of subcontracting is not precluded.

4.7 – Guidance on sampling of devices for the assessment of the technical documentation, explanatory note on MDR codes and Guidance on interpretation of art. 54(2) b (update): COM informed that these guidance documents are being prepared by various Task Forces operating under the NBO group. Concerning the guidance on sampling and the explanatory note on codes various comments have been submitted both by NBO members and by stakeholders and have been processed by the relevant task forces. IVD subgroup was consulted for the guidance on sampling. MDCG was informed in brief for the progress for all three guidance and more information will be provided when available. The guidance on sampling and the explanatory note on codes are expected to be submitted to MDCG for endorsement by the end of the year.

c) **Agenda item 5 – Qualification and classification of software guideline for endorsement**: the proposed guidance was developed by MDCG subgroup New Technologies based on work initiated in the past by MDEG. The guidance addresses issues of scope and purpose but also qualification and classification criteria in accordance with MDR / IVDR, considerations on placing on the market, classification examples and others. MDCG endorsed the guidance and the Commission thanked the competent authorities for their active participation in the preparation of the document.

d) **Agenda item 6 – Guidance on Class I manufacturers**: the guidance is being currently developed by the Market Surveillance MDCG subgroup and the Commission noted the plan is to send it to MDCG in the near future for written consultation and final endorsement. They also referred to the various stages of consultation that took place: stakeholders were consulted in June, many of their comments were taken into

consideration; the update text which also included comments from competent authorities was sent back to stakeholders for their information and with feedback on their comments; the current draft is now under consultation with two MDCG subgroups Market Surveillance and PMSV. PT chairing the relevant task force also provided more detailed information on the various changes incorporated based on the big number of comments received by stakeholders.

e) **Agenda item 7 – Eudamed**: COM updated on the system development and planning; the responsible team collaborates widely with many MDCG subgroups especially currently on clinical investigation (CIE) and vigilance (PMSV) where a lot of requirements still need to be defined. For UDI and nomenclature most of the requirements have been finalised with the collaboration of the UDI WG. On market surveillance the last WG meeting had to be postponed to further notice due to some issues of availability of people. The Eudamed team is currently working on six modules in parallel, which is quite a challenge, especially knowing that all details have to be defined for the development of IT systems. For actor and Regulation device registration work is almost finalised whereas for legacy devices work is ongoing. A EUDAMED NB & Certificate working group meeting (8th) will take place on 24/10. On vigilance the requirements for MIR (Manufacturer Incident Report) is almost finalised and well advanced for Field Safety Corrective Action (FSCA) and Field Safety Notice (FSN) registration.

Overall, there are many challenges in the development of such complex IT system, keeping in mind that every module must be properly integrated in the whole, with possibly some late readjustments. It is as also essential to consider guidance developed in various MDCG subgroups. Many problems derive from special cases like legacy devices and custom made devices. For the certification module there will be a playground available from next year, while for vigilance not before end Q2 2019, for clinical investigation after Q1 2021 and market surveillance will be last in 2022. The aim is to have fully operational Eudamed by May 2022 before implementation of IVDR.

As regards the EUDAMED Implementing Act the Commission thanked for the input and informed that the text is in consultation with other relevant Commission services, in particular the Legal Service; further information will be provided at the MDCG meeting of December 2019.

Responding to questions by MDCG members, COM clarified that for clinical investigation/performance study (CI/PS), the relevant EUDAMED working group decided to have the Serious Adverse Event registration functionality later, together with CI/PS application registration functionality for consistency and efficiency reason, meaning that it is not before May 2022 something will be available for CI/PS; for actor registration, validation will have to be done by a person through user interface with the possibility of manual XML bulk upload (not possible by machine to machine data exchange). COM clarified as well that the registration of the competent authorities and their first Local Actor Administrator will be done by the Commission not necessarily at the beginning through the user interface.

Finally, COM reiterated that more information will be provided at the next MDCG.

f) **Agenda item 8 – Update on Annex XVI products**: COM informed that the draft text on common specifications of Annex XVI devices is currently being reviewed by other internal services including the Legal Service of the Commission. This process will still take some time, due to its complexity. 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 relevant questions, COM clarified that transitional period for Annex XVI devices is not intended to be included in the current corrigendum.

g) **Agenda item 9 – Transparency - exchange of views on consistent approach**: MDCG was informed on the outcome of first discussions that took place in the vigilance transparency task force (TF) as regards access by the public to Manufacturers Incident Report (MIR) in Eudamed. The Task Force led by IE is part of PMSV (Postmarket Surveillance & Vigilance) subgroup and various discussions took place examining which parts of MIR could be disclosed. In addition, further consultation took place between stakeholders and at the level of subgroup CIE (Clinical Investigation and Evaluation). A MIR transparency document, still under discussion was sent to PMSV and after all these exchanges identified possible challenges and solutions. The following general orientations emerged following the work of the TF:

- EUDAMED should provide as much possible information for public access
- There should be no traceability back to patients nor to health facilities
- Special handling of commercially confidential information
- Favour for a gradual approach with further extension of the release based on experience gained

Next steps: TF to finalise the MIR transparency document and present it for endorsement at a next MDCG meeting. Other vigilance reports will also be examined by the TF in order to decide what kind of access would be given to them. Collaboration with other subgroups is planned, already started with CIE (Clinical Investigation and Evaluation). In addition to the horizontal approach and consultation with other MDCG subgroups the Commission asked MDCG to consider sharing national experiences and legislation where available.

h) **Agenda item 10 – Common specifications under IVDR and CTS under IVDD**: issues of CTS and CS were covered at the meeting of MDCG & Stakeholders the previous day. More generally regarding the IVD MDCG subgroup, the Commission encouraged greater involvement of competent authorities and investment of technical expertise in particular in the topics of performance evaluation and common specifications. In addition MDCG members were asked to start reflecting which would be the entity nominating the candidate EU reference laboratories in their Member State and to begin identifying possible candidates. It was clarified that laboratories which are linked to national regulatory agencies may be proposed as candidates as long as there is no conflict of interest.

i) **Agenda item 11 – Remaining issues discussed in the meeting between MDCG and stakeholders of 30/9/2019**: Following a request by some MDCG members at previous meetings concerning enhancement of coordination of activities between MDCG subgroups and in order to support more transparency on activities, Commission sent

prior to the meeting two draft documents to MDCG members: an overview of all guidance endorsed until now and a non-exhaustive list of the ongoing guidance development in the various subgroups. It was clarified that stakeholders are consulted regularly as they participate directly in most subgroups; for those that do not, they are also consulted when there is development of guidance. Further to MDCG input the Commission will adapt these drafts which will be published on its website; this information will be updated at regular basis, at least after each MDCG meeting.

j) **Agenda item 12 – AOB**:

- Update on activities by the Chair of CAMD – Competent authorities for Medical Devices: updating of their website and coordination of the various groups including transitional groups and implementation task forces; a major challenge is to engage more with MDCG and MDCG subgroups and allocate the necessary resources.

- Commission informed that they are in contact with EMA (European Medicines Agency) as they are working on a minor update of the guideline concerning Article 117 MDR. MDCG members are encouraged to liaise with their colleagues in medicines agencies as they will be examining this update soon.

4) Next meeting

Next MDCG meeting: scheduled for 13 December 2019.

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