EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate D – Consumer, Environmental and Health Technologies
Unit D4. – Health Technology and Cosmetics

Brussels, 08.05.2018

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 06 March 2018

1) Opening, adoption of the agenda

The meeting was dedicated to the ongoing implementation work with regard to Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR). Following the meeting of the MDCG held the day before (on 5/3/2018) with stakeholders, this session on 6/3/2018 was limited to the representatives of the competent authorities only.

The agenda was adopted with the following additions:

- AT: transition to the new Regulations – second paragraph of Article 122 MDR and the situation following the repeal of the Medical Device Directives;
- FR: authorisations for clinical investigations.

NL emphasised the need to receive the agenda and the meeting documents sufficiently early, in order to allow for internal consultation within MS competent authorities prior to the meeting. Accordingly, the agenda should also indicate the purpose of any point included.

2) Adoption of the minutes of the previous meeting

The minutes were adopted, including comments from IE and part of the comments from DE. The clarifications on the MDCG governance, including the model declaration of interest of MDCG Members, reflected in the remaining comments from DE, will be answered by COM.

3) Follow up to the open session with stakeholders on 5/3/2018

In the first open session of the MDCG the day before, stakeholders emphasised the need to have such meetings more frequently. COM referred to the possibility of organising an open session for stakeholders every second time that MDCG meets. The capacity of notified bodies was considered as a main issue of interest by stakeholders.

SE proposed to hold MS closed session prior to an open stakeholder session in order to prepare for it. DE emphasised the need for set out the agendas for stakeholders meetings by MS and COM jointly.

COM observed that organisation of three subsequent sessions could result in operational difficulties. A very short prior meeting of 1-2h without a translation could be however considered. While a working session to prepare the agenda is not feasible, COM could transmit to the MDCG the draft agenda of the open and closed session before

transmission of the rest of the documents, in order to allow the MDCG to prepare for the meeting and to possibly adjust the agenda as needed.

4) MDCG governance

The main elements were presented during the session of the day before. COM will circulate to MDCG for comments the draft Terms of Reference of the working groups. A call for stakeholders for participation to working groups will be launched.

5) Implementation of MDR/IVDR Implementing Acts (state of play)

The main implementing acts had been presented the day before. To complement this, a PPT presentation was given regarding the progress made on the implementing act on the so called 'Annex XVI products'.

Regarding the abstract 'Level 2': two MS consultations took place in 2017. In the last consultation, 50 out of 59 listed concepts were recommended by COM, and 9 were not recommended. MS agreed, with one exception, to the suggestions made. Thus there is a broad consensus - a 'mainstream' of views. However, the critical comments of the minority views were relevant too, and triggered COM's 'second thoughts', wherefore further concepts should be dropped. The results and comments can be found in a table, which will be sent to MS. MS have submitted further suggestions which merit further consideration. To that end, a third consultation will be sent to MS in the near future. The feedback thereto should be returned by the end of March 2018.

Regarding the product-group specific 'Level 3', the first draft exists for one of the product groups, but not for the others. For the others, some workshops are planned.

The adoption procedure will take more than one year. First drafts will be made available to stakeholders in the summer 2018.

DE pointed out that notified bodies should be involved in the works on the implementing act on the Annex XVI products early on. COM agreed with the need of stakeholders' involvement (including notified bodies). However, the drafting needs to be more advanced to make a stakeholder consultation meaningful.

6) Eudamed (state of play)

a) Outcome of the survey on MS expectations (next step)

COM outlined the outcome of a survey launched at the end of 2017 on MS expectations and details on their data exchange needs related to Eudamed (PPT presentation "6_MDR_Eudamed_MS_Expectations_MDCG_20180306").

The survey was very successful with a high rate of replies (more than 80%). The essential expectations are first to have Eudamed with harmonised Regulations' requirements, which can be used as the main tool for collaboration/cooperation and exchange of information between all stakeholders, which is the main source of information on medical devices, with advanced interoperability features and search functionalities. However, in view of the deadlines imposed by the Regulations and the MS expectations on Eudamed, priorities must be determined and the implementation must and can only be done step by step (not everything in the 1st release). The first priority must be to have harmonised Regulations' requirements met, the second to have the necessary high quality data, and finally, to have the level/scope of the interoperability, search and cooperation functionalities implemented step-by-step

(determine essential ones for the 1st release and less essential and/or more advanced ones for later).

FR questioned the chronology of the 2nd and 3rd level of priorities.

CH emphasised that it was crucial for Eudamed to have a good interface to national systems. This appears from MS replies to questionnaires. Are the upload and download functions sufficiently considered?

IT stressed the need for the download function in the context of the actor registration validation. IT reiterated its request to check the data using their national system; e.g. IT uses data from chambers of commerce, which should continue to be possible.

DE expressed concerns with the proposed prioritisation, in particular as regards the interoperability – there is no data upload – why 3rd level of priority then? It is crucial to both upload and download data. The deadlines are not possible to be met. The upload should be possible already in the 1st phase of Eudamed. DE needs the upload and download function for timely workflow. Which status will be provided in May 2018 and where does October 2018 date come from?

COM explained that the level of priority is related to the order of importance for the implementation. COM agrees that the three are of high importance, but for the 3rd level, a distinction must be made between the levels/scopes of implementation. Very advanced features in this area take much time and need first a system having enough maturity (not possible at the very beginning). There is a need to decide which functionality has to be taken into account, whereas some functionalities are extremely ambitious and may not always be feasible. It needs to be decided case-by-case which data could be handled in that way. The upload function will be available from the beginning as long as it is about data owned for the initial entry. For instance, the market surveillance information will be possible to upload by the competent authority owning the data. The impact of the need for actor registration as requested by IT has to be assessed. Knowing that this feature has only a reason for a short period at the beginning for few MS, the necessary investment must be taken into account and the burden needs to be decreased as much as possible into a workable solution easy to implement. The October 2018 date for having all specifications totally determined in details is set because the Eudamed development team, the industry (who asks for 18 month time for adaptation) and MS need enough time for the implementation. March 2020 deadline for Eudamed 'go-live' is determined by Article 34 MDR.

b) Review comments on the functions specifications for 1st set of module (next step)

COM presented the main outcomes of the comments received and clarifications on the functional specifications for the first set of modules: Actors, UDI & Devices, NB & Certificates (PPT presentation "6_MDR_Eudamed_Functional_specifications_MDCG_ 20180306"). Limited feedback was received. The main outcome is clearly the wish for more detailed information in general about the functional specifications and explanations on the priorities. COM explained that at this stage, it is necessary to keep level high enough in order not to be lost in details, but just to have enough information and the priorities for making the implementation plan before 26/5/2018. For the details that will be provided after as process overviews, data models, business rules and wireframes, they can be finalised by October 2018. COM also explained different priorities and the need to distinguish between legal priority and timing priority (order of implementation - first

release or the next ones), because the two are not necessarily the same, and for the implementation plan it is mainly the timing priority that matters.

DK referred to its comments submitted and to the readiness to provide feedback again. These were mainly technical and functional issues.

IE indicated its interest for a timely plan considering prioritisation. Is the budget foreseen enough for the implementation, also after the 1st release?

DE explained that it had some fundamental difficulties with implementing features which the stakeholders would need to use without a legal obligation. It is important to consider in the design of Eudamed to have a transparent vision on the categorisation of data that the users enter (public, confidential, etc.).

COM explained that the Eudamed team did not receive DK comments and therefore asked for resubmission. The timing priority will be added in the functional specifications and reviewed based on comments received before further dissemination. The budget is clearly enough for 1st release and will have to be determined for the next releases depending on the functionalities to be developed. The Eudamed team relies on highly skilled experts in the field for each dedicated Eudamed WG, not just representatives. COM agrees with DE Germany that the purpose of the data entry should be clear. It is foreseen to have all the information necessary displayed for a field for the user to enter the right data. The search function within a document is difficult, it is important to have enough (meta-)data without having possibly too many meta-data associated to a document.

c) Questions addressed to the MDCG Members from the Eudamed WGs

COM presented the main questions identified by the Eudamed *ad hoc* WGs on Actor registration, NB & Certificate, Vigilance and Market surveillance for follow up discussion in the MDCG (PPT presentation "6_MDR_Eudamed_Questions_MDCG_20180306"). These are mainly questions about the assembler, the harmonisation of the actor registration validation among MS, the communication of the SRN, post-market surveillance and market surveillance data for the public, the language issue, and the need for templates and guidance from the COEN. COM emphasised the need for prompt MDCG feedback.

AT reiterated that within COEN, a task force has been set up for the validation of actors in Eudamed, trying to develop a guideline. Inspection reports and language issues were not addressed yet. Additional members are needed. Caution need to be applied as to what information will be available to the public.

IT mentioned that the members in the task force need to be experts of COEN and market surveillance. Answer on the questions in the presentation: 1. Assembler issue must be considered and a solution found. 2. Templates are important for the market surveillance - these can be in English language. 3. Information to the public need to be in all languages.

ES enquired about the background to the last presentation. What is the task of the MDCG as compared to the Eudamed WG? Answers on the questions in the presentation: 1. A protocol for harmonisation of the validation is needed. 2. All documents and information for the public need to be in all languages. 3. Inspections reports should be included in a standard protocol in English language. 4. An internal translation system may be relevant.

COM explained that ideally, the participants to the Eudamed WG are experts of the related domain and therefore, are also part of the high level group for this domain (COEN for market surveillance, vigilance WG for vigilance, CIE for Clinical Investigation). The Eudamed WG is the main discussion forum to determine what should be implemented for Eudamed, and in case of a major issue for which there is no common agreement, it will be brought to the MDCG for settlement. MDCG feedback is needed to agree on the working groups' outputs, especially on important aspects, such as the language. Moreover, all documents shared by the different Eudamed WGs are available in CIRCABC also to all MDCG members. An internal automatic translation tool should be available in Eudamed, but it will be far from perfect as any such tool. The answers from the MDCG Members can be sent by mail to COM.

7) Joint assessments of notified bodies

COM presented the state of play of joint assessments (JAs), in particular the number of applications considered to be complete and preliminary assessment reports (PARs) that have been received. Reference was made to the best practice guides (BPGs) endorsed at the previous MDCG meeting, which are an essential element that would allow applications and joint assessments to progress smoothly; the BPGs are available on NBOG + Europa pages. COM noted that some fine tuning of some of these BPGs have become apparent once they have been tried and that they will be presented to MDCG in time. On 19/1/2018, an access to documents request concerning the list of JA National Experts was received. The list of National Experts is now available to MDCG Members via CIRCA BC; it was reiterated that the list has been communicated in reply to an access to documents request, but that all personal data have been redacted, in accordance with the requirements of the relevant EU legislation on protection of these data. The second session of training for the National Experts participating in JA (many of whom are new to the exercise) will take place on 7-9/3/2018.

COM took the opportunity to explain the process for the appointment of JA teams, emphasising that such appointment is triggered by the reception of the PAR (Preliminary Assessment Report), but not linked to the assessment of the PAR.

DE raised a number of issues:

i) the need to ensure the quality of PARs and applications; in particular, DE considered that some PARs are not of good quality and do not contain enough information;

ii) the potential consequences of Brexit, and the need to anticipate them; DE noted the potential difficulty that will be posed by the fact that an important number of certificates are held by notified bodies (NBs) based in the UK;

iii) the timing of the JA team appointment decisions, for which DE expressed concerns about the legal robustness of the approach for the joint appointment of JA teams;

iv) the transparency of the decision-making process, where comments are raised by delegations and DE felt that these are not always shared;

v) in case of objections, the need to obtain the explicit endorsement by other MDCG Members to the JA team proposal, for which 15 positives votes would be needed; DE noted in particular that silence should not be construed as a positive vote;

vi) a procedural matter, whereby DE questioned whether the current practice for the appointment of JATs was in accordance with the rules of procedure of the MDCG; in that sense, DE emphasised the need for a sound process, to avoid legal challenge.

ES referred to the already received proposals for JA teams. ES wonders about the need to comment on those, and on whether they should expect feedback from COM, in case of doubts of the team's composition. ES also wondered if a video-conference would suffice in order to confirm JA team appointments.

FR signalled that they would neither have time not interest in voting, systematically, for JA team proposals.

IT noted that there was a need to ensure the timely feedback from national experts, since some of their replies are produced too late (albeit within deadlines).

On the quality of the PARs and applications, COM explained that it is not possible to draw any conclusion on a given application having a look only at the PAR. The PAR should elaborate only on issues for which there is a need for clarification (usually during the on-site assessment). At that stage (prior to the appointment of the JAT), the preliminary judgement on whether an application could result in a timely JA or not can be made only by COM, as it is in a position to examine both the PAR and the application. For that purpose, COM oversees some key elements of the application, in order to reasonably confirm that it is in good shape. Nevertheless, the final assessment on the application belongs to the JA team, which is a fundamental argument against delaying its appointment. COM underlined that it is legally mandatory to appoint a JA team within the 14 days following COM's reception of the PAR. COM could work though, on the scheduling of the JA (at a later date), should the assessment of the application make it advisable. In the event of such re-scheduling, COM would be liaising with the MDCG (as set out in the corresponding BPG), given that it would constitute a deviation from usual practice.

On the timing of the JA team appointments, COM indicated its conviction that the process is legally sound; it was noted that the Regulations do not attribute 14 days to the MDCG for discussion on the appointment (or for the scrutiny of the PAR). The Regulations set out that within 14 days of the submission of the PAR, the Commission, in conjunction with the MDCG, is to appoint JA team. COM acknowledged the time constraints for the comments of MDCG members, but noted that the primary reason for these constraints stems from the Regulations. In addition, it is essential to ensure that JAs are organised in a timely fashion, for which it is necessary to confirm the availability of the corresponding National Experts, the latter being a time consuming exercise. The COM expressed hopes that the efficiency of the process will increase in the future, and it will be able to come back earlier to the MDCG with a proposal.

On the transparency of comments made by MDCG members, COM indicated that substantive comments are always shared with all MDCG members. In any case, COM will ensure that all comments (no matter their nature) are made available to all MCDG members.

On the endorsement of JA team proposals, COM emphasised that consensus is the basic decision making procedure of the MDCG. If a given delegation is dissenting from this approach, the onus is on this delegation to explicitly request a vote on the matter if they see it fit. COM took the opportunity to underline that whereas at this point in time, the Commission is to appoint a JA team in conjunction with the MDCG, the MDCG will have a more fundamental role at a later stage in the process, notably in the issuing of

a recommendation with regards to the draft designation of the notified body. For that purpose, the MDCG will be provided with the final opinion of the JA team regarding the assessment report prepared by the national designating authority.

On procedures, COM indicated that it will work to provide clearer formalisation to the appointment of JA teams. That said, COM noted that no joint assessment team has been appointed without the agreement of the MDCG.

On the need to encourage National Experts to swiftly produce their comments or reactions, COM committed to reiterate the point in its dealings with these experts, but noted that it has no control on the matter.

In the closing remarks, the Chair indicated that he was in favour of maintaining a relatively simple procedure for the appointment of JA teams, which is working fine for the time being. He underlined that given the constraints in resources that affect all services, it was in nobody's interest creating a complicated procedure whose management would require more resources and bureaucracy.

8) UDI: Analysis and possible endorsement of the revised version of guidance

COM presented to the MDCG a revised guideline on UDI. The title has changed, an explanation has been added, the structure has been adjusted to make it clearer, terminology has been adjusted, and the format of some fields was changed slightly. COM hopes that the changes will be found acceptable.

SE: What does basic UDI group and secondary DI mean?

ES: The product is with two UDIs in Eudamed? Why will the document be published? Can you explain the secondary DI? Does the same product require an additional DI? Which DI needs to be on the product, if there are two DIs?

PT: How can one product get two different UDIs?

FR: Are we talking about the guidance? Why only the latex is distinguished and other materials not?

DE: We cannot accept the documents guidance and the presentation because these are not detailed enough.

COM: If the manufacturer decides to change the issuing entity for the same product or may want two issuing entities for the same product, in this case a secondary DI is used. The product needs to be registered with both UDIs in Eudamed. A connection to these two products is needed. COM works together with the FDA on this issue. For the UDI working group the comments on the document are important. This is the reason to publish the document. Only latex has been discussed in the working group, no other materials were mentioned in the annex. It is proposed to the MDCG to acknowledge this document which would be then subject to further elaboration, and could be endorsed once finalised.

9) Harmonised standards - alignment to MDR/IVDR – process for the standardisation request to the European Standardisation Organisations (the "mandate")

As follow up to the same item on the agenda of the previous meeting on 28/11/2017, COM outlined the process for issuing the standardisation request. While the role of

harmonised standards will not change under MDR/IVDR, the majority (about 230) of the existing standards will need to be aligned to the new Regulations. This workload will affect primarily the technical committees of the standardisation organisations. In addition, the formal requirements for citation of standards in the EU Official Journal are increasing. The process for issuing the standardisation mandate likewise requires a number of formal conditions to be met. Based on feedback received from the standardisation organisations and representations of the medical device industry and notified bodies, COM will prepare a draft mandate, where the most pressing standardisation needs will be prioritised according to the timelines for revision. In the meantime, while the adoption of the mandate is pending, COM has been encouraging the standardisation organisations to start the alignment work.

DE emphasised the need for the standardisation request to be specific and precise. The working group on standards needs to be involved in the process. COM confirmed that in accordance with the horizontal requirements for various standardisation sectors, the new mandate will need to specify each single standard according to the number/title. Pending the setting up of the new "architecture" of the working groups, and in view of time constrains, it is important to start the process already now, whereas, according to the stage of the development of the mandate, it could be discussed at any future meeting of the relevant working group.

IT pointed out to the need to develop a harmonised symbol for identification of a product as a medical device. COM agreed to this need.

10) Introduction to the roles of the new scientific bodies

COM's PPT presentation gave an overview of the general roles and tasks of the scientific advisory bodies, with a focus on the set up of expert panels, their work load, need of expertise, reimbursement and next steps. A dedicated working group may need to be established.

FR stated that we do not need expert panels covering all functions detailed in the legislation from the beginning. The priority should be the clarification on the compulsory procedure for the clinical evaluation assessment that needs to be delivered in full. FR has some ideas and expresses its availability to help.

DE is willing to help this system with experts. According to the recently published HTA proposal of the COM there will be an interaction with the MDR expert panels. Is this proposal already considered during the design of the expert panels? The second problem will be to establish the EU reference laboratories. Establishment of reference laboratories requires resources which must be planned just now. According to a German analysis of the IVDR there are more than 10 essential questions which must be answered before starting the establishment of an EU reference laboratory.

COM clarified that there are different estimates about the number of expert panels that would be needed to cover all the functions under the legislation and there is a need to prioritise. It may be difficult to find the best mix of experts for instance because of the conflict of interest. The HTA proposal is not yet approved by European Parliament and Council. Therefore it is far too early to answer the question on possible future interactions.

UK expresses is willingness to help in finding the right experts.

11) Corrigendum to MDR/IVDR (state of play)

This topic was discussed the day before. The proposed corrections on the text will be transferred to the Council.

ES stated that comments about the Spanish version have been sent. ES asked if comments were received from stakeholders, when will the corrigendum be adopted, and whether it will be at the same time available in all language versions.

COM: The deadline for the comments was 1/12/2017. Most stakeholders' comments concerned EN language version. In 2018, all language versions should be completed.

12) Full refurbishing of medical devices in the context of policy on circular economy

The presentation of COCIR was held the day before.

AT, UK, ES and DE expressed concerns about the approach proposed. Among others, it was pointed out that most refurbishment relates to x-ray equipment and ultrasonic units and that there are in principle two companies in Europe doing refurbishment. MDR does not refer to "second-hand" equipment, and, usually, the refurbishment is not done by the original manufacturer. The proposed approach could be considered as a bypass of the existing local rules and guidelines.

COM agreed that all requirements for new medical devices need to be met also for refurbished equipment. COM will provide feedback to COCIR.

13) Choice of nomenclature under the Regulations: possible endorsement of the draft requirements for publication

Thanks to the members of the task force, the draft requirements on the nomenclature have been provided.

Two levels of requirements have been reflected in the document:

1) regulatory: contrary to the requirements of FDA, both relevant names and codes needs to be fully accessible, in order to enable sufficient access of all stakeholders;
2) other criteria to be taken into account: stability; well-functioning EU nomenclature; policies for updates and removals of entries and key role of the regulators.

According to ES, all languages need to be included, and this aspect should be addressed in the future contract with the provider.

In DK and SE view, clarifications on the considered MDCG working group are needed.

DE expressed concerns with regard to the requirement that the future nomenclature should be available in all languages. This might be impossible to be delivered when the nomenclature should be available for free. However, any future contract with the provider should duly take into account the feasibility for the provider to comply with the proposed terms.

COM: A task force with a focus on the nomenclature could support further work. The issue of languages is complex, costly, and needs to be further discussed. The question

about establishing such a task force could be clarified at a later point, and it is not part of the current document.

The document was accepted with minor adaptations.

14) IVDR; update on the implementation preparation of some Working Groups

The presentations were held in the meeting between MDCG and stakeholders the day before. No further comments were provided by the MDCG.

15) AOB

a) AT - transition to the new Regulations: In view of the second paragraph of Article 122 MDR, difficulties may arise from unavailability of the Medical Device Directives following their repeal. COM proposed for consideration textual transposition of the Directives into national legislation.

b) FR - authorisations for clinical investigations; COM proposed to address the issue in working groups.

c) CH - inquiries about registration of Class I devices in Eudamed: COM explained that such registration is not possible as long as there is no corresponding Eudamed functionality.

d) Next MDCG meeting is planned on 2 or 3/5/2018, subject to confirmation.

List of participants

No	MDCG Member/ Observer	Institution/Organisation
1.	AT	Federal Ministry of Health and Women's Affairs
		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.	DK	Danish Medicines Agency
6.	EE	Estonian Health Board
7.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
8.	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
9.	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
10	GR	National Organisation for Medicines (EOF)
11	HU	National Institute of Pharmacy and Nutrition
12	IE	Health Products Regulatory Authority (HPRA)
13	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
14	LV	Ministry of Health
15	LU	Ministère de la Santé - Direction de la Santé
16	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
17	NO	Ministry of Health and Care Services
18	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
19	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
20	RO	National Agency for Medicines and Medical Devices (ANMDM)
21	SK	State Institute for Drug Control
22	SI	Agency for Medicinal Products and Medical Device

		(JAZMP)
23	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
24	SE	Medical Products Agency (MPA)
25	CH	Swissmedic – Swiss Agency of Therapeutic Products
26	TR	TMMDA – Turkish Medicines and Medical Devices Agency
27	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- JRC
- DG SANTE F5
- DG GROW D4