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, 20 November 2018

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 24-25 September 2018

1) Opening, adoption of the agenda

Following the morning session of the MDCG on 24/9/2018 with stakeholders, the afternoon session on 24/9/2018 and the session on 25/9/2018 were limited to the representatives of the competent authorities.

IT, ES and PT emphasised the need to ensure translation during the meetings of the MDCG. DK and SE emphasised the importance of dispatch of the documents early enough, with indication which documents would be submitted to the MDCG for endorsement.

2) Adoption of the minutes of the previous meeting

The minutes were adopted, including MS comments submitted prior to the meeting.

3) Implementation of MDR/IVDR (state of play)

a) Overview

The rolling plan, complementary to the CAMD roadmap, sets out the essential elements of implementation, primarily under Commission's responsibility. It will made publicly available in the coming days on DG GROW website on medical devices.

b) Reprocessing of single use devices

No additional comments were provided after the presentation given to the stakeholders.

c) Annex XVI products

Following the intense discussion (including three rounds of consultations with MS) held on level 2 (i.e. horizontal requirements applicable to all or at least to 5 out of the 6 product groups referred to in Annex XVI) and inputs received from MS on level 3 (product-specific requirements), COM prepared a first draft text of the Implementing Regulation (IR) on the Annex XVI products (Implementing Regulation on Common Specifications for certain products without an intended medical purpose to which the Regulation on Medical Devices applies) to be published soon for informal consultation with stakeholders. Stakeholders will be given around 4 weeks for comments and suggestions. MS will be as well given the possibility to raise additional comments. All comments received will be processed. Decision on feedback received will be taken by MS and COM jointly. A two-day meeting should be held before the end of the year in order to finalise such decisions.

MS will be also given an extensive version of the Q&A document. A number of questions and concerns raised by MS has been collected, with particular reference to the process for the development of the IR.

As already mentioned during the meeting with stakeholders in the morning, in order to keep the application date indicated by the legislator and taking into account that notified bodies claim a need for at least 9 months for certification, the formal application procedure should start early 2019 and will include the public formal consultation stage.

NL asked about the scope of the text to know whether also the draft Annexes will be provided to stakeholders and about whether the alignment of level 2 and level 3 requirements will still take place. NL wanted also to know if MS will be allowed to receive the draft text before the publication.

DE highlighted that the draft should be shared with MS before public consultations. Should the draft be published without a further consultation of MS, given the many not yet answered questions, there is no guarantee of success.

COM explained that the timelines are crucial and that it is a pioneering work in which all parties should be able to bring knowledge and experience. That is why we should go ahead with an informal consultation.

NL asked again for the possibility to see the draft before the informal consultation, wishing the opportunity of a meeting to discuss open points.

UK expressed surprise about the decision to consult stakeholders without first informing MS of the plans after so much collaborative work. It did not object to going ahead with the informal consultation but, at the same time, recognised an issue related to the process.

PT supported NL, as it would be a good idea to share the documents with MS before the informal consultation in order to allow for consolidated opinions and ensure support for common ideas. MS are not aware of the content of the text.

COM recognised that the consolidated text was not yet transmitted but reassured MS that the document precisely reflects what have already been discussed. In particular, all concepts reported in the Articles are only a copy-paste of the table already disseminated as a result of the last round of consultation.

DE pointed out that at the end a qualified majority is needed for adoption. Although COM believes that there will be no surprise in the text compared to what had been discussed, there are still many concerns related to level 2 and level 3 requirements. Then, if the COM wants to have time advantage, qualified majority needs to be ensured. The work on Annex XVI products was one of the first examples of how to collaborate together but results are still far from being positive.

COM replied that the text does actually reflect the view of majority, as recorded in the table already circulated. COM acknowledged that the draft is not necessarily meeting everyone’s expectations but the decisions were taken on the basis of majority views. In addition, the draft doesn't have to be understood as a final text. MS will still have the opportunity to provide any additional comments. All proposals will be considered when taking final decisions by COM and MS jointly.

ES emphasised the issue that MS have not yet seen a complete document. MS have different representatives in groups working on level 3 requirements and thus are not aware of the big picture.

COM stressed that the issue is related to difficult process and subject. The work is not perfect but it is anyhow a compromise and we are facing a crucial timeline. It is the state of play where we are. In addition, it is important to have in mind that the consultation is going to be launched informally, as the official one will have to take place at a later stage.

ES did not feel confident with the procedure and asked to have communicated to stakeholders that the text has not been agreed with MS and it is not a consensus document.

FR supported ES about the need to make the status of the document clear. In addition, it also raised doubts about the scope of the IR and borderlines products (e.g. sunbeds).

IE highlighted the need for engagement of MS. It would be better to delay the consultation by one week or so rather than sending a message that MS do not agree upon.

NL re-iterated the need for a short round of consultation with MS before the transmission of the text to stakeholders.

COM committed to provide MS with the consolidated draft text soon, in advance to the informal publication to be possibly launched before the end of the year. It will investigate again into the timing issue. With reference to the informal consultation stage, a disclaimer will be put on the text and the consultation will be presented as an initiative of COM, specifying that the text has not been endorsed by the MDCG.

4) New scientific bodies (JRC)

The JRC presented the key findings from the surveys on expert panels and European Reference Laboratories. In addition to points already discussed in the open session, the JRC indicated that a majority of the responders are of the opinion that the maximum working days an expert is involved in the clinical evaluation consultation procedure (CECP) should be kept below 30 or even below 20 days per year, which has to be considered when defining the number of experts are appointed to panels. The size of the panels should be adapted to the expected workload, composed predominantly by clinicians. Responders had big expectation concerning the use of Eudamed for future retrieval of incident rate data. Also the necessity was expressed that the Commission should provide a secured electronic document management system. The data on the number of performance evaluation consultation procedure (PECP) dossiers to be expected is poor. Concerning the EURLs reasonable workload estimates could be derived. Also the selection criteria for EURLs deserve further consideration.

The next meeting of the task force on scientific bodies is scheduled for 26 September.

5) Eudamed (state of play)

COM presented state of play as regards implementation of Eudamed (see PowerPoint presentation MDR Eudamed – State of Play – MDCG 24.9 2018 (7_MDCG_Eudamed_State_Play_MS_20180924.pptx).

The Eudamed team is currently working on the 6 modules (Actor, UDI/Device, NB & Certificate, Clinical Investigation/Performance Study, Vigilance and Market Surveillance) of Eudamed in parallel.

The 1st set of modules (Actor, UDI/Device and NB & Certificate) is well advanced and even if we have a delay between 3 and 5 months there is no doubts these modules will be well implemented and ready in due time.

For the second set of modules (Clinical Investigation/Performance Study, Vigilance and Market Surveillance) there is still work to do. The gathering of the requirements takes more time than expected because many things have to be determined and agreed with a common solution by the MS. However, thanks to the involvement of the different WGs work is well progressing but it will be clearly more challenging to be on time with these modules. It will be essential to determine priorities for having the essential needs fulfilled at the beginning. All other features can and will have to be implemented in further releases. For the time being, even if still much to do and some clear delay, we can remain optimistic. We are climbing the mountain in a steady pace with no impassable obstacle yet.

IE asked about the transparency issues for disclosing data to the public and if there is any news.

PT wanted to know about vigilance data model, when it would be ready and what search criteria will be available, as if training for National Competent Authority and the other actors is foreseen and for the possibility of mixed process during the transitional period.

NL asked on clinical investigation whether MS will be responsible for providing the single identification number of clinical investigations submitted by sponsors and if this will be indeed MS responsibility.

COM answers:

About the public access of data, no news, for vigilance it is still only the Field Safety Notice (FSN) that is foreseen for the public. For Clinical Investigation/Performance Study (CI/PS), the Eudamed team works with the CIE WG to determine what may be accessible to the public. The general rule is that nothing would be for the public before authorisation but that from this moment some information of the CI/PS application should be available to the public.

The Eudamed team is working on the vigilance data model, at least for the serious incident reports, but it will not be before the next Eudamed vigilance WG meeting (18th October) that this data model could be available. For the search criteria, it is something we will tackle later, as for the time being we are focusing on what data we need to have in Eudamed. Training for the NCA will be provided by the COM but for the other actors it will be not really possible due to their number. However, user guides and appropriate documentation will be provided like possibly online training tools. A notification system will be in place for informing all actors/users. There should not be any mixed process during the transition period.

The CI/PS identification number will be generated by Eudamed (as required by the MDR (Art 70(1)/IVDR (Art 66(1)) and directly available to the sponsor from beginning of the registration process for CI/PS application submission in Eudamed. It is therefore not a responsibility of the MS.

6) UDI (state of play)

In the context of the written consultation on 5 proposed guidelines on UDI which followed the meeting of 17 July 2018, comments have been received by the Spanish and Swedish delegations. Most of those comments have been incorporated in the revised versions of the 5 documents, which have been circulated prior to the meeting. Detailed feedback has been provided to the two commenters ahead of the meeting.

COM indicated that guidelines 1, 2 and 4 are proposed as final MDCG documents. Guidelines 3 and 5 are proposed as EU UDI Work Group documents, positively received by the MDCG.

SE pointed out that one of the data elements of document 2 – "additional product description - (list of UDI data elements for systems/procedure packs) is indicated as mandatory while the Regulation considers that as optional.

DE indicated that there is no need to have different status for MDCG docs. There will be a lot of MDCG documents having preliminary character. Nevertheless those documents are the best guidance available, at the time when publication occurs.

In reply to the comment from SE, COM indicated that the list of data elements contained in the Regulation refers to general devices and needs to be adapted to specific situations, such as systems/procedure packs. The field "additional product description" can be extremely important for systems/procedure packs as it could provide some information on the individual components of the system/procedure packs.

In relation to the comment from DE, COM expressed its agreement indicating that the proposed different "status" for MDCG documents was meant to only reflect the results of a discussion which took place at the MDCG level in March 2018. If and since there are no objections, all MDCG documents can be published in the same form and this is without any prejudice to the possibility to update them when needed.

7) The standardisation request (the "mandate") to the European Standards Organisations (state of play)

The outcome of MS consultation (MDCG and NBOG) on the first draft list of standards to be included in the first standardisation mandate under the new Regulations was presented. Majority of MS supports prioritisation approach, i.e. selection of priority standards to be included in the first mandate. These include very few standards of key importance for the industry, which should be available for the starting date of the application of MDR, i.e. 26/5/2020: 13485 (QMS), 14155 (GCP), 14971 (risk management), 15223/ 15986 (symbols), and some important standard families which could be aligned progressively: biological evaluation, sterilisation, horizontal standards for medical electrical equipment.

An updated list of standards has been prepared on the basis of feedback received. Any additional comments on the draft list can be submitted until 15/10/2018. To this end, the updated list will be also shared with NBOG in the next days. A draft standardisation mandate will be circulated for comments to the MDCG and NBOG in the course of October.

8) Joint assessments of notified bodies (progress report by SANTE)

COM provided updated information on the state of play of the joint assessment process. This was done on the basis of the presentation that had been delivered the previous day during the meeting with stakeholders, which was duly enlarged and included information on:

- the number of applications received (also per country) and the overall applied-for scope,
- the number of preliminary assessment reports received (also per country),
- the average number of days elapsing from the submission, at national level, of the notified body's application, to the COM receipt of the preliminary assessment report,
- the scheduling of joint assessments, including the number of national experts participating in them,
- the activities following the on-site assessment completion, and
- the challenges found in the process.

In relation to the number of on-site assessments, COM recalled its earlier commitment to do its best to ensure that the completion of joint assessments did not became a bottleneck step in the process of designation of conformity assessment bodies. COM can confirm that joint assessments are not being a limiting factor and that, on the contrary, more joint assessments could have been carried out if there had been additional requests. Unfortunately, there were not enough requests and a number of available scheduling slots have been left empty.

In relation to the challenges found in the process, the first one concerns the involvement of national experts in joint assessments, and the issue is twofold:

a) There is a significant discrepancy between the nomination of national experts and their declared availability. As a result, there is a need to make a repeat search for potentially available national experts (as opposed to the original plan, whereby the experts had indicated already their availability and the contacts would have been a mere confirmation of their potential membership of the joint assessment team – JAT). Since there are well-known time constrains linked to the necessary consultation of the proposal for a JAT with the MDCG and the respect of legal deadlines, the COM's role of coordinating the appointment of JATs has become particularly demanding and subject to a certain level of uncertainty.

   COM encouraged Member States to confirm if all experts nominated will participate in joint assessment and to provide the expert's availability for the specific slots allocated to schedule joint assessments.

b) A number of national experts are leaving the designating authorities, which creates difficulties if these experts were part of a JAT. When these experts are no longer available prior the organisation of the on-site assessment, the matter is explicitly covered in section 2.6 of the MDCG BPG 2017-1, which envisages that the designating authority concerned has to propose a substituting expert.

   However, if the expert ceases to be-available after the on-site assessment took place, the matter is not contemplated in the above-mentioned BPG and, in reality, is much more difficult to manage. This is because of the existence of obvious constraints linked to the fact that the national designating authority concerned will be, automatically, more stretched in resources (in a context where all designating authorities are already struggling to make national experts available at the start of the joint assessment process), including that other experts in this authority will see that their workload is increased. Therefore, it is doubtful that a new, overworked,

member would make a meaningful contribution to the work of the JAT at that stage, considering that the new expert did not participate in the on-site joint assessment.

For the above reasons, COM proposed that in those cases where a national expert ceases to be available as JAT member after the on-site assessment has been carried out, the joint assessment process continues with the remaining members of the JAT.

c) Another challenge relates to the level of preparation of the conformity assessment bodies. This relates, for instance, to the fact that some new requirements are not yet entirely understood by the conformity assessment bodies. In addition, JATs are consistently facing situations where documents and procedures are updated several times prior to the on-site assessment and even during the course of it, which increases significantly the workload to be carried out. Although BPG 2017-1 introduced some theoretical limitations to the updates that could be accepted, JATs always trying to be flexible in this respect.

d) The third challenge refers to the legal interpretation of some of the requirements, on which the national designating authorities and the JATs are not in agreement, i.e. the diverging opinions. From the onset it must be emphasised that the level of cooperation between the national designating authorities and the JATs is being remarkably good. In addition, and to put this challenge into context, the number of diverging opinions raised during on-site assessments is quite modest, with a maximum of 5 diverging opinions and some assessments not resulting in any single one.

In this regard, COM has been working with a draft document on Questions & Answers (Q&A), focusing on the issues where there has been a divergence of views, with the aim of discussing it with all the designating authorities in the framework of an NBOG meeting. It is expected that this Q&A will allow reaching a common position on the issues at stake.

Finally, COM brought to the attention of the different Member States, that the next step in the process will be the issuing of MDCG recommendations on the designation of some conformity assessment bodies.

DK took the floor to indicate satisfaction in relation to the absence of capacity issues in the organisation of joint assessments. This delegation expressed some concerns at to carrying out joint assessments with less than two national experts.

COM emphasised that on-site joint assessments will continue to involve, always, two experts, with no intention whatsoever in converting the exercise into a COM solo operation. The proposal is circumscribed to a situation where one expert leaves the designating authority (and therefore the JAT) after the on-site assessment has been completed. Under those circumstances it is proposed that the joint assessment process continues with the remaining of the JAT, for pragmatic reasons and for efficiency, since we run the risk otherwise of not being able to complete the process.

DK was satisfied with this explanation.

UK expressed its agreement with COM's proposal in this respect, since the involvement of a new JAT member would be quite challenging for her/him, and this participation would be of limited value.

No other views were expressed on COM proposal. Therefore it was considered accepted, by consensus, that in those cases where a national expert ceases to be available as JAT member after the on-site assessment has been carried out, the joint assessment process will continue with the remaining members of the JAT.

UK and NL indicated that they would like to discuss how the diverging opinions would be resolved, and that this should be done as soon as possible.

DE indicated that diverging opinions should not be discussed at the very stage when the MDCG should issue its recommendation, since this would be too late. On the contrary, they should be solved before, for which there might be a need to settle legal interpretation, in order to avoid disputes between the national designating authorities and the JATs. If we leave these issues to be resolved by voting, we may end up in a situation where Member States which are not particularly affected by a given matter could have a majority.

UK indicated that a possible way forward could be to define what are the diverging opinions and, in advance of the meeting where the MCDG opinion would have to be issued, to organise a separate meeting for the MDCG members to express their views on these diverging opinions.

NL supported the UK's position, noting that some diverging opinions have been raised in more than one on-site assessment and that some of them seemed to relate to issues which are critical. They also indicated that diverging opinions make it difficult for the conformity assessment body to proceed with their corrective and preventive action (CAPA) plan.

COM agreed that some of the diverging opinions are common to several on-site assessments and that they need the adoption of a common position. COM indicated their hope that this will be done via the discussion of the draft Q&A document.

FR enquired about one of the challenges noted in terms of preparation of the notified bodies, in particular that their qualification matrix did not cover new codes, and whether this was just a documentation issue or a more complex one.

COM clarified that conformity assessment bodies are in general applying for the entire scope of application, even when they do not avail of the expertise in certain devices codes. Whereas in some cases the cause of the deficiencies in the qualification matrix could relate to gaps in the documentation of authorisation of staff, in others the issue could be a real lack of expertise.

9) Corrigendum to MDR/IVDR

The scope of the corrigendum under preparation by the Council and the process for its adoption was outlined and discussed. COM presented the outcomes of the written consultation – which followed the 17.07 meeting - on a few revision proposals (to be possibly made in the context of the corrigendum) to the text of the two Regulation. Based on replies received, consensus was provisionally reached only for 2 points. COM also provided some clarifications requested in relation to the proposed modification to Article 54 of Regulation 745/2017.

On the proposals concerning Annex VII, point 4.5.2 a), 4th indent of Regulation 745/2017 and Regulation 746/2017 and Annex X, point 3 (a) of Regulation 745/2017 (and corresponding provision of Regulation 746/2017), IT and IE indicated their

openness to reconsider their negative stance. In particular, IE pointed out that some of their views were mostly aimed at obtaining additional clarification as to the rationale of the proposals suggested.

COM also presented the five additional issues which were described in a separate document circulated ahead of the meeting. Member States showed openness to discuss the proposed changes, while generally pointing out their need for additional time to consolidate their internal position. COM indicated that this will be followed-up through a dedicated meeting.

10) MDCG governance – establishment of working groups (state of play)

Based on comments received after the MDCG meeting on 2/5/2018, and the internal review in the Commission, new versions of ToR of the working groups have been prepared. The Q&A document provides additional explanations on the functioning of the working groups. The call to stakeholders for participation as observers to the working groups should be published in the next days. As the next step, the new WG structure will be reflected in Register of Commission Expert Groups and Other Similar Entities.

By the end of November, MDCG Members should communicate to GROW D.4 national experts participating in respective working groups. A reminder in this respect will be also passed in each WG, but collection of information will take place via the MDCG. MS can nominate as many alternates in the WGs as needed, and all of them will be included on the relevant Circabc, while the reimbursement remains limited to one expert per country.

The communication between WG is very important and it is the role of the WG Chair to share the information with another relevant WG. The MDCG may not be best placed to play this role, because it would not follow closely the work of all WG. While a MDCG can be established by the MDCG in relation to specific coordination needs, it would be more appropriate to await more time to reflect on any such needs, in particular until the new WG structure of the MDCG is fully established.

11) Evaluation of EU legislation on blood, tissues and cells – implications for MD (SANTE)

DG SANTE presented the evaluation exercise on the EU legal frameworks on blood, tissues and cells. This exercise includes an open consultation and an expert study in order to assess whether these legislations have met their objectives, increasing safety and quality, and are still up to date in view of dynamic sector developments. DG SANTE presented first findings, and invited participants to provide further inputs. The final Commission report is expected early 2019.

Key topic of interest that were mentioned relate to coherence with the MD sector, where blood, tissues and cells are used in medical devices. Also mentioned were the classification of borderline products and the organisation of coherence in oversight, in particular when serious adverse events or reactions take place.

12) Common specifications under IVDR and CTS under IVDD (update)

No additional comments were provided compared to the meeting with the stakeholders.

13) AOB

Next regular MDCG meeting will take place late November/early December, the exact date to be confirmed.

Additional item: several Member States and COM reported on an increasing media interest in the sector on issues relating to specific devices, the negotiations on the new Regulations etc. Also numerous requests for access to documents (including NCARs) have been received.

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.	CY	Cyprus Medical Devices Competent Authority
6.	CZ	Ministry of Health
7.	DK	Danish Medicines Agency
8.	EE	Estonian Health Board
9.	FI	VALVIRA – National Supervisory Authority for Welfare and Health
10	FR	National Agency for the Safety of Medicines and Health Products (ANSM)
11	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
12	GR	National Organisation for Medicines (EOF)
13	HU	National Institute of Pharmacy and Nutrition
14	IE	Health Products Regulatory Authority (HPRA)
15	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
16	LU	Ministère de la Santé - Direction de la Santé
17	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
18	NO	Ministry of Health and Care Services
19	PL	Office for Registration of Medicinal Products, Medical

		Devices and Biocidal Products
20	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
21	RO	National Agency for Medicines and Medical Devices (ANMDM)
22	SK	State Institute for Drug Control
23	SI	Agency for Medicinal Products and Medical Device (JAZMP)
24	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
25	SE	Medical Products Agency (MPA)
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