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, 20.11.2018

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 17 July 2018

1) Opening, adoption of the agenda

This was the 4th meeting of the MDCG. The 5th meeting is planned for September 2018.

The agenda was adopted without modifications, but one additional topic was included by IE, who asked to add the issue of the clinical evaluation work group.

2) Adoption of the minutes of the MDCG meeting of the 02/05/2018

The minutes of the open session of the MDCG on 2/5/2018 were adopted without modifications.

BE volunteered to contribute to the proposed MDCG Task-Force on scientific bodies and consequently requested that to be mentioned in the minutes.

3) Eudamed

a) State of play

COM gave an update regarding the state of play for the setting up of the functional specifications and related implementation plan (prioritisation, content of actors, content of UDI/device, content of NB/certificate, content CI/PS, content vigilance, content market surveillance, organisation/means, deadlines, objectives, working documents, milestones, planned milestones in 2018 and 2019). For details refer to the presentation "MDR Eudamed – State of play".

IE raised the question about the role of the Steering Committee for ensuring consistency between the modules (the working groups have not the global view). IE found very important to have more detailed specifications, which are not in the functional specifications document, in order to pass the requirements back to their members.

COM indicated that many issues arise from the fact that WGs may decide on requirements without understanding the impact it could have on another module and on Eudamed as a whole. At the moment, it is mainly the COM, with the collaboration of the MDCG, that plays this role. The next Steering Committee will be only in December 2018, and there are many WG meetings to be handled before then. About the functional specifications, more details will be provided through data model and business rules documents that will be associated to the functional specifications/features.

BE asked to receive the presentation and raised the question whether the progress of the second set of modules is an alarming sign that the deadline of October could not be met.

COM informed that the presentations will be provided within 48 h after the meeting.

COM agreed that all the detailed requirements of the second set of modules may not be ready by October but that at least all the functional specifications/features (without the details) will be defined and asked Member States to communicate the real needs/priorities associated to them. COM wants to have the functional specifications document finalised by that time.

DE mentioned that the functional specifications need to be implemented in collaboration with the MDCG. DE does not see enough collaboration for this project and considers that the meta-data are actually of great importance for searching possibilities.

COM explained that there are many TFs and WG meetings. Moreover, this MDCG meeting that has been set up specifically to discuss about Eudamed shows how much the COM is keen to work in collaboration with the Member States and the MDCG. COM always asks for needs and for comments/feedback to make sure the MS are consulted and properly informed and involved. All is done to interact with the MS.

COM explained that meta-data are indeed of first importance for the search that can then be effected thanks to these data. Search in a document is difficult; it is why you need always meta-data associated to it. It is why also the templates for documents are not a first priority for Eudamed. On the contrary, knowing which meta-data are associated to them is of high priority. Advanced search functions are planned in the second step.

UK, speaking as chair of the CAMD, thanked the COM for organising this meeting and indicated that they are willing to tackle the efforts together. They understand the reason for prioritising, but are afraid that this might end up in a massive "black hole" data. MS need the search capability and upload functions. They would like to have most of the necessary features for market surveillance from the beginning. They ask to keep this dialogue open.

COM is thankful and glad to receive the information from the CAMD but cannot include all functions from the beginning. The COM would like to know what should be the most important search functions (obtaining search criteria forms will be very useful).

b) Discussion based on questions addressed to the MDCG Members (on 22/6/2018 via CIRCABC and at the MDCG Meeting on 6/3/2018)

i. Level of access to data for Vigilance, Clinical Investigation/Performance Study and Market Surveillance (comments/feedback)

COM presented a summary of the received answers to questions addressed to the MDCG members (17 MS and CAMD replied, Actor type responsible for system/procedure packs, harmonization of actor registration validation process, communication SRN (Single Registration Number) to economic operator, registration of manufacturer of custom-made devices, special certificate types, vigilance data, CI/PS data accessibility, market surveillance data). For details refer to the presentation "MDR Eudamed – Discussion (Q/A)".

For the actor type responsible for system/procedure pack, everyone agrees on the need to identify a "system/procedure pack producer" as an actor type. However, the COM considers that this actor type can be associated to the manufacturer actor type and have only one SRN for both types. The rationale behind this choice is that it will require less validation of actor registration, but above all that a manufacturer can be also a system/procedure pack producer for which only one certificate could cover both devices and sterilised systems/procedure packs. Moreover, Eudamed will have no problem to identify clearly if an actor is only a manufacturer, only a system/procedure pack producer or both even if they are have the same SRN. However, to have two separate registrations and SRNs for the two types would be more consistent and easier to implement in Eudamed.

The SRN should be communicated to the economic operator through Eudamed but not by ordinary email.

Only manufacturers of custom-made devices that are also manufacturers of other devices and/or that are manufacturers of custom-made class III implantable devices should get a SRN and be registered in Eudamed.

The only special certificate types to be registered in Eudamed are "Sterilised system/procedure packs" and "Custom-made class III implantable".

For the time being, only the FSN (Field Safety Notices) and associated meta-data among vigilance data should be for the public. More could be disclosed later (in a next release of Eudamed) when a common agreement is reached among the Member States.

Authorised Representatives (AR) may have access to all vigilance data in Eudamed to which they are associated. Moreover, if clearly stated in the mandate and flagged as such in Eudamed, the AR may enter vigilance data in Eudamed instead of the manufacturer. It will be either the manufacturer or the AR that will enter vigilance data to which it is associated but never both (Eudamed will prevent that).

For accessibility to CI/PS data in Eudamed, it is agreed that not only the final report made by the sponsor should be public. Further guidance should be provided by the CIE WG to determine the details on what else should be accessible to the public.

For the market surveillance module in Eudamed, a task force of the COEN WG should define templates as soon as possible. English should be the common language for this module. Only summaries of the results of the review and assessment of market surveillance activities are for the public, some more information could be disclosed to the public but on a case by case basis (to determine by COEN).

ii. Functional specification document (comments/feedback)

COM presented a summary on the questions and issues raised by the MDCG members related to the functional specifications, implementation plan and other issues/comments/feedback. 11 MS and CAMD gave feedback (see presentation "MDR Eudamed – questions/issues").

General:

The main concerns are clearly about the interoperability of Eudamed with national systems, the possibilities to get data from Eudamed and the search capabilities that will

be available in Eudamed. The COM has well understood that and it is considering those aspects as much as possible.

Training to CAs on Eudamed will be organised by the COM, and of course user guide and helpdesk will be available.

Member States (MS) consider that the functional specifications (FS) document as such is not really suitable for a thorough and efficient audit of the full functionality of Eudamed. COM explained that more details will be added as an annex to the FS document in the same way as the business rules associated to them. Moreover, COM will see how the order could be improved in order to have it more consistent and efficient for the review.

COM explained that the functional specifications document is still a living document for which new releases will come. In this context possible comments received and new information available will be considered.

The architecture of Eudamed with one restricted site for authenticated users (webgate domain) and another web site for the public (anonymous users, Europa domain) is a standard followed by the COM allowing better security and transparency. Behind there will be only one database that will be used for both web sites.

At the request of MS, designating authorities should be allowed to view and search for all data in Eudamed as any other CA.

The review of the FS document can be done by the MS directly in the document with track changes and sent back to GROW D4.

The MDCG members will have access to all information/deliverables communicated to the Eudamed WGs in CIRCABC.

A testing environment will be available also for data exchange but it will be possible only if the MS has the necessary IT infrastructure properly configured. There will be different kinds of download that the COM has/will distinguish(ed) in the FS.

All notifications will be at least by email, but the email will not contain any information that should require a specific access to Eudamed (a link will be in the email to access the related record in Eudamed). Notifications on tasks to do will be also available in Eudamed from its user interface. Subscription to notifications will be manageable through Eudamed but only to a certain extent (scope definition will be possible but not as granular as to ask for a specific nomenclature code).

The COM will be the owner of the data in Eudamed. Yet, MS will have full access to the data. Nevertheless, GDPR rules and confidentiality rules of data copied from Eudamed into a MS database will have to be followed by the MS.

The COM understands the need for having warnings notified by Eudamed on any forthcoming deadline. However, at the beginning, this function should be considered important only in some cases, like for CI/PS validation and authorisation workflow.

The COM will make available a translation tool (machine translation from DG Translation) for translation of information, but it will not translate all contents available in Eudamed.

The data of Eudamed2 will not be copied to the future Eudamed. The data should be either available in Eudamed2 (Directives data) or in the future Eudamed (MDR/IVDR considering transition rules). We may have information in the future Eudamed that will be related to devices, certificate and/or CI/PS under the Directives.

Actor:

Clear rules must be defined to know when a new SRN will be required. However, the COM pointed out that such rules must consider that Eudamed will have a versioning system allowing searching on old names and that a new SRN can have a huge impact for an economic operator. A new SRN should be only required in case of a new legal entity (and not necessarily to change some data in Eudamed).

A feature will be available to facilitate exchange of data in the context of the validation of actors by the CAs (not necessarily full Machine to Machine (M2M)).

There will be different profiles and definition of scopes of responsibilities for the CAs in order to allow specific access rights among the users of a CA.

A CA will be able to grant access to any user that it considers as holding the rights to access and act on its behalf. However, a user of a CA can be only a user of that CA (the same for NB). Only users associated to an economic operator or a sponsor could be associated to different actors that are also economic operators or sponsors.

The COM took note that a qualification document should be available in Eudamed for each person responsible for the regulatory compliance. It is up to the MS based on common guidelines to determine if the checks for these qualifications are to be considered for the validation of an actor.

Each actor will have a SRN per type (manufacturer, AR …) with the possible exception mentioned previously in relation to the system/procedure pack producer that is also a manufacturer. For example, an organisation that is a manufacturer and also an AR will have to register twice and it will get two SRNs, one for each actor type.

The role of sponsor for actor registration is not in the Legal Requirements (LR) because there is none, but it is well recognised as a necessary FS.

The COM tends to consider that the confirmation that the Ethics committee and the Legal representative for a sponsor should not be considered as actor types in Eudamed and should not be registered as such. The list of Ethics Committees for a MS can be managed by the MS through one of its CA (it will be just a list of reference of organisations). The Legal representative will be just an organisation associated to the sponsor actor data (like for a sub-contractor).

UDI/Device:

Information on status on nomenclature, and how the UDI-DI works, will be given in the next point of the agenda (4 – UDI State of play). The COM pointed out the importance to have a good understanding of the UDI because in the future UDI will be the access key to all data. Information regarding substances will be part of the UDI-DI.

The COM understands the important need of the MS for having in Eudamed advanced and complete search possibilities on UDI and device data. It is indeed a core module of

Eudamed for which search possibilities must be good enough. However, very advanced search features (like SQL (Structured Query language) queries) are reporting features that must be developed at a later stage (not in 1st release).

A notification system will exist in Eudamed, also for UDI data. The COM took note of the need for having the CAs notified for UDI-DI/Device status changes.

The COM explained that the possibility to link Basic UDI-DIs is a low priority and that it is there for having a data model able to handle that. As the CAMD mentioned, it is a feature that could be a source of issues and for which the rules/requirements associated to it should be precisely defined.

NB & certificates:

The CAs will have the possibility to download (M2M) certificates. That is reflected in the FS.

The testing of medical devices by CAs in laboratories is not related to Eudamed. The registration of exemptions (under Art 59(1)) and the creation of free sale certificates are not within the scope of Eudamed.

There is no agreed definition of "certificate device group" for the time being.

The COM understands the need to do combined search, but in a first step (for 1st release), it will be done only to a certain extent (not every combination could be possible).

Vigilance:

The CAs will be able to comment the FSN in Eudamed.

A M2M data exchange system will exist to transmit the vigilance data to MS national databases.

All data associated with monitoring of vigilance data for data analytics and signal detection should be in Eudamed, but the COM will consider it as a first/high priority only after go-live (after 1st release). The same rule should apply for incorporating a complete coordination platform and for having complete and full search functionality on vigilance data in Eudamed. The first priority is to get all the necessary data with enough search capabilities to find and access it but not to have from day one the most complete and advanced search functionality.

CI/PS:

The plans attached to post-market CI/PS should be in Eudamed. The kind of files that can be exchanged for CI/PS will be normally "pdf" or possibly, if track change is necessary in the document, "doc(x)".

The CI/PS not performed for the purpose of conformity assessment (Art 82) are not included in the FS, because in this phase, it is only possible to develop FS covering CIs based on art 62 and 74. Consideration of development of FS covering art 82 must be postponed to a later phase.

The registration of requests by manufacturers for compassionate use of medical devices is not within the scope of Eudamed.

The COM took note of the need of having for CI/PS performed outside the EU an identification number in combination with countries. This requirement is already considered.

MS wondered why some comments on FS on CI/PS were not considered. The COM explained that first, most of them were actually business rules (too detailed specifications for being in FS document) and second, that the CI/PS module is by far the one for which the requirements are already going far beyond what is strictly required by the MDR/IVDR. Lower priorities will have to be attached to some of them. However, the Commission will consider them, knowing that the FS document is still a living document that can be complemented. Therefore they will be either in the annex for business rules or directly in the FS document with possible lower priority.

Market surveillance:

Requirements related to Art 95(7) about no objection on measures taken by a MS could be in Eudamed (not determined yet).

The COM understands that the market surveillance module is first about communication between MSs using an existing framework (fixed format forms). However, it is important to reconsider that based on what is in the MDR/IVDR and the obligations related to Eudamed coming from Art 100 of the MDR and Art 95 of the IVDR. This is the first priority.

COEN must play a central role to prepare harmonised templates and to define meta-data for each template. For the Eudamed team, the priority is clearly for having first the meta-data and forms.

The COM took note of the need for a communication tool/coordination platform with a powerful search tool but it is clear that these features will have to be implemented step by step (from different releases). This is clearly not something that can be reached from day one.

iii. Implementation plan (comments/feedback)

MS consider that the deadlines are unrealistic for Eudamed implementation and that we should think of plan B. COM explained that indeed the deadlines will be difficult to respect possibly for some requirements for the 2nd set of modules. However, there is no discussion on any plan B yet, as the whole 1st set of modules will be ready on time together with the main features of the 2nd set of module. There is a need to agree on priorities.

The timetable of the project is actually the implementation plan that, like the FS document, is a living document that can show progress made and things still to be done.

The COM agrees that any delay could impact the CAs' ability to integrate in their national systems the necessary requirements for data exchange with Eudamed and that they need data model, XSDs (XML Schema) and M2M use cases in time. The COM will try to provide all the necessary deliverables as soon as possible.

In relation to the request of the MS for having the information relevant for the different WGs shared enough time prior to the relevant deadlines, the COM agrees and it will try to do its best to follow this rule.

iv. Any remaining issues/comments/feedback raised by the MDCG Members

This topic is included in the presentation mentioned in points (i) and (ii).

NL asked when it will be possible to test Eudamed with the interface of the national systems (data exchange).

COM mentioned that this is foreseen from the beginning of 2019 (first quarter). It will need preparation of the systems (infrastructure and configuration) on both sides (Eudamed and national systems).

IE asked questions about the business rules associated to the functional specifications. This is needed to confirm that Eudamed is fit for purpose, to understand the system and prepare their national system. They asked on how IE and other MS can collaborate to this effort.

COM agrees on this, but does not have all details yet. The COM will share them with the MS as soon as the details on the data model and business rules are available. It is not an easy task because most of the information is connected to different parts of the system since Eudamed is an integrated system. The best way for the MS to help the COM on this would be to agree between them on what should be the requirements and the sensible priorities associated to them - taking the relevant deadlines into account.

NL mentioned that there is a lot of work to be done and raised the question about transparency on the data. A document with guidelines on disclosure should be made.

PT thanked for the information provided by the COM on this complex system. PT would support the points made by IE and NL. As Eudamed has to replace the national systems it needs to cover all the functions of the national systems. Therefore more details are needed from all MS. It is important for PT to guarantee the search and the communication between the modules, as well as download functions and implementation of data exchange (interface with national systems). PT indicated that certain aspects are missing in the received documents (expert panels entity, information related to point 15 of article 10 of the MDR, so as to ensure the possibility of carrying out inspections of subcontracted entities of the legal manufacturers, etc.). This was also sent to COM in writing prior to the meeting.

FI raised a question similar to NL on transparency, namely related to data ownership and responsibilities.

BE thanked the COM about the work and raised the question on how to proceed further until October, because time is very short. BE mentioned that Eudamed is not solely about MDR as it also needs to comply partially with the MDD. Eudamed needs to have a basic model on MDD devices.

DE is confused about the clarifications mentioned for vigilance data disclosure. DE does not agree that it is up to the COM to come up with clarifications and raised the need for MS to be more involved in the decisions. DE hopes that COM will apply recognised development standards to the Eudamed system.

COM mentioned that the details on data model and business rules associated to the functional specifications for the 1st set of modules should be provided soon and it will review the FS document considering the comments received (before end-August).

Transparency considerations on the disclosure are attached to the business rules. For the 1st set of modules most data are for the public. For the 2nd set of modules COM has now a better view on what should be for the public or not in the first step.

COM understands that the search functions are very important as well as the download functions. There will be possibilities, but not all search functions will be available in the first release.

The original manufacturer is among the data that have to be provided to Eudamed for a device and the list of expert panels should be available in Eudamed (however still under analysis). However, the sites of manufacturing are not for the time being foreseen to be in Eudamed.

The COM is the owner of the data but MS will have full access to all data in Eudamed and they will have to follow GDPR and confidentiality rules also in their national systems for data coming from Eudamed.

The next step is to provide as much data on the business rules as possible and a new version of the FS document.

The devices covered by the MDD need to be registered in the national database (and Eudamed2). Some special cases will be considered in the context of the transition period like the incidents on MDD devices which will be entered in the future Eudamed.

If there is a general agreement among MS on vigilance data to be disclosed to the public beyond the FSN, COM will try to implement it (content for disclosure is otherwise still under discussion).

COM can provide the MS with information on the standards followed by the COM for the development and project management methodology for Eudamed.

UK, on behalf of CAMD, asked how the CAMD could help for defining some common export and search functions that should be available in the first release of Eudamed. Besides, there is a big variety of opinions/needs about the transparency. There need to be more discussion about this subject. The "black hole" of incident information demotivates the users to report incidents. Therefore some information need to be disclosed to show the users' impact.

COM agrees on the need for transparency and is willing to discuss further and to go beyond what is proposed now. Nevertheless, as long as requirements are not agreed among all or at least a sufficient number of MSs, knowing also the deadline for Eudamed implementation, the disclosure of data related to the 2nd set of modules will be limited to what is agreed by most of MS. In order to help the COM to define what search criteria should be possible from first release, the COM welcomes this proposal and would be glad to get search forms and export features to be considered for first release.

NL raised the need for a document containing rules on transparency (not a yes or no question at field level). A document with clear rules/guidelines needs to be written together by COM and MS.

PT raised the question if it is possible under the MDR for the MS to ask the stakeholders to provide data to their database, like for example the manufacturing sites that would not be in Eudamed.

IE thanked again the COM for the big amount of work, which has been done. They also believe that transparency was not discussed enough. It was discussed by the vigilance WG. Ways to progress on that discussion must be sought.

COM mentioned that one objective of today's meeting is also to raise questions and start discussions on the most important topics. COM is impressed by the amount of wishes, needs and questions related to Eudamed. Answers to all questions cannot be provided today. Prioritisation is very important. COM will provide minutes of all questions, answers and comments received. The MDCG meeting in September will provide a possibility to discuss further. The functional specifications will be reviewed reflecting to a certain extent the comments received. The work cannot be done only by the COM, but there is the need for a pragmatic spirit from all sides. COM thanked the participants for the fruitful discussions.

4) UDI – state of play

COM informed about the main topics that will be looked at by the UDI Work group over the next few months: contact lenses, examples for UDI assignments, manufacturers' quality management system, clarification of certain provisions of the basic guidance on Basic UDI-DI, follow-up on language issues.

COM provided a state-of-play of the ongoing IMDRF work on UDI, which is chaired by the EU.

On medical device nomenclature, COM indicated that the established task-force is waiting for detailed input from the providers that have spontaneously shown their interest in being possibly designated: SNOMED, GMDN and the Italian Ministry (responsible for the CND classification system). The proposals from the 3 providers are to be all available to the task-force by September 2018.

COM presented the 5 UDI guidelines which were circulated prior to the meeting for MDCG examination. Guidelines were agreed by the TF and discussed by UDI WG. Comments from the UDI WG have been taken on board. The 5 draft guidelines were circulated to the MDCG group prior to the meeting. 3 documents are intended to be published as MDCG endorsed documents, while two of them (UDI rules for software and considerations on language issues) are intended to be published as UDI WG documents, after positive feedback from the MDCG. .

DE mentioned that the contents of the guidance on systems and procedure packs seem not to fully match with the reflections made by the COM on EUDAMED in relation to the same subject.

SE and UK indicated that they would need more time to analyse the documents in depth.

NL raised a question about whether the document on UDI rules for software addresses the issue of UDI for artificial intelligence software, where changes are very frequent.

In reply to DE, COM indicated that the documents are in line with the COM's views on EUDAMED and there is no risk of discrepancy. The draft UDI guidance on systems and procedure packs does not touch upon the EUDAMED-specific issues discussed at today's meeting.

In reply to comments from UK and SE, COM agrees on the need to provide Member States with more time to review the document. Therefore written comments are welcome by 17 August 2018, so that final endorsement could possibly occur at the next MDCG meeting.

In reply to NL, COM indicated that the document on software is a basic and horizontal guideline on UDI rules for software and it is not intended to address specific kinds of software.

5) Progress reports

a) Joint assessments of notified bodies (SANTE F)

COM presented two slides prepared by DG SANTE about the applications received (number of applications received until June, number of applications received by SANTE F, number of Joint assessments performed and scheduled). This information will be regularly updated and presented.

FR thanked COM for the information and asked for the number of applications received by the Competent Authorities (CAs) but not transferred to DG SANTE yet.

DG SANTE requested this information to CAs, but did not receive enough reliable information to be presented.

DE mentioned that additional information is available from CAMD, but COM considers this information may not be reliable enough to be spread.

UK supported the request made by FR.

DE expressed the wish to know how those numbers are evaluated by the COM.

COM explained that further evaluation of those numbers could be the object of future discussions.

b) Scientific bodies (JRC)

JRC presented the update from the MDCG TF on scientific bodies. 3 surveys were launched covering scientific panels, expert laboratories and EURLs respectively, to both the MSs and to EU stakeholders. JRC invited the MS to reply to these surveys no later than 24 August 2018. JRC aims at summarising the results of the survey by 30 September 2018. For details refer to the presentation delivered "JRC-Update on scientific bodies".

FR raised the question on the need to circulate the information to the national stakeholders. For that, CAs will need also the stakeholder versions of the surveys, not only those for the MSs.

JRC mentioned that in principle there may be no need to circulate this information because MS and stakeholder groups received corresponding surveys. The JRC emphasised that returning even partially completed questionnaires would be preferred compared to not responding.

PT raised the question if they are allowed to place the stakeholders questionnaire on their website.

After discussion it was decided that the scoping study and the questionnaires for stakeholders may be distributed by the Competent Authorities to the national stakeholders. The link to the electronic format may be placed on the CA website or sent directly to the stakeholders. It is however hoped that the Competent Authorities, where appropriate and feasible, will be able to provide a consolidated version in relation to the replies of their respective national stakeholders.

c) Implementing acts

i. Annex XVI products

COM informed about the state-of-play and the planning for the future. The planning remains unchanged except that the linguistic polishing of the horizontal (Level 2) requirements will take place end of August/early September, on request of some Member States.

For the horizontal (Level 2) requirements, the COM is close to the stage in which it makes sense to send a consolidated version to the Member States. Some minor polishing is however still needed.

For the product group specific requirements, the COM has received input for 5 out of the 6 product groups. The input is often in the form of guidance, but some parts of them can be taken over and brought into the form of a legal text. Other parts can be used as a basis for future guidance documents or complementing national legislation.

Further coordinating meetings are not planned for the summer, because the timing is too tight. The input of Member States came very late so that the 6 remaining weeks of the summer need to be used for drafting the product group specific requirements. But all comments from MS and from stakeholders will be further discussed and considered towards the end of the year. End of August 2018 a draft document will be send to all MS including the product group specific requirements.

NL thanked for the work being done by the COM, but has a problem on finalizing its input and wishes to have a meeting to discuss further on the Level 3 requirements. IE supported the NL.

COM will consider this, but reminded about the need to take into account the timeline to be reached.

ii. Common specifications on reprocessing of single-use devices

COM informed about the informal consultation of stakeholder associations in May 2018: 19 associations were consulted; 6 replied. The replies were mainly positive and supported the draft common specifications. Only one reply was mainly negative and expressed the

will that most of the draft would be deleted in order to make it easier and cheaper for health institutions to reprocess single-use devices.

BE asked about the general timing.

COM mentioned that it was difficult to give a date for the adoption of the Common specifications, pending the initial comments from the Legal Service. The best scenario would be to adopt these common specifications at the latest 12 months before May 2020.

d) Set up of work groups

COM indicated that, due to few comments received, the deadline for comments to the draft terms of references of the expert groups is extended to 17 August 2018.

e) Standardisation mandate

The COM noted that it still has not received input regarding the question on whether the mandate under the new Regulations shall be broad or shall be limited and, if the latter, limited to which standards. Input is requested by mid-August.

6) Corrigendum

COM presented the contents of a document, circulated prior to the meeting with a list of 6 possible modifications to the text of the MDR that could be suggested by the COM to the Council services, if agreement is reached within the MDCG.

DE presented comments, which were submitted already in writing to the Commission. In relation to the provisions on the sampling of technical documentation of medium-risk class devices (Annex VII, point 4.5.2 a), 4th indent), they highlighted that the word "categories" shall be added to "device" or, in alternative, any word that would communicate the same meaning. Moreover, in relation to a modification proposed by the COM to Annex X, point 3(a), DE proposed alignment in the opposite direction, that is to say to leave Annex X, point 3 (a) as it stands and align Annex IX accordingly.

UK agrees on points made by DE, but is happy to support the COM on the other points.

PL indicated that more time is needed to assess the proposal. ES agreed with Poland and asked if additional explanation could be added by the COM in written.

BE agrees with DE on the point of "device categories".

DE also indicated that they might have issues with the modification proposed to one of the transitional provisions referring to involvement of expert laboratories.

COM offered to provide MDCG with a revised paper for comments, where the DE proposals would also be integrated. Deadline for comments was indicated to be 17 August 2018.

7) AOB

IE: CIE will request MDCG guidance on matters referring to the work streams covering "equivalence" and "sufficient clinical data". If possible a workshop will be organised

where broader participation than the members of the relevant Taskforce may be requested.

Short wrap up of the meeting:

- Eudamed was discussed extensively. The minutes will be provided with replies to questions raised and an update on functional specifications sent.

- Feedback on proposed UDI guidelines is expected by 17 August 2018.

- JRC will provide consultation paper for stakeholders which can be sent to them directly or placed on the website of the MSs.

- Setup of WG is planned to be launched soon. MS can indicate their interest in participation.

- Feedback on standardisation is expected by 17 August 2018.

- The next MDCG meeting is planned for September 2018 (first day with stakeholders and without interpreters, second day MS only and with interpreters). Further information on exact date, based on availability of meetings rooms and interpretation will be provided as soon as possible.

a) 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 / Agence fédérale des médicaments et des produits de santé (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 / Ministerio della Salute (SANITA)
14.	LV	Ministry of Health
15.	LU	Ministère de la Santé - Direction de la Santé
16.	NL	Ministry of Health, Welfare and Sport
		Central Committee on Research Involving Human Subjects
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
21.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
22.	SE	Medical Products Agency (MPA)
23.	CH	Swiss Agency of Therapeutic Products (SWISSMEDIC)
24.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)
25.	SI	Agency for medicinal products and medical devices (JAZMP)
26.	CZ	Ministry of Health
Commission:		DG JRC F2; DG SANTE F5; DG GROW D4