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, 16 April 2019

Minutes

Brussels, 09 – 10 April 2019

1) Opening, adoption of the agenda

Agenda was adopted. It was announced that the meeting on 9/4 would be followed by a Brexit Technical seminar with EU-27. Agenda item 14 was not presented for endorsement as initially announced, more information under that point.

2) Adoption of the minutes of the meeting held on 14-15 February 2019

Minutes of the MDCG meeting of 14-15 February 2019 were adopted.

3) Implementation of MDR/IVDR including Corrigendum to MDR/IVDR

The Corrigendum was adopted a few days ago and is expected to be published in the following days. It is considered to offer useful clarifications for the sector. The second Corrigendum is planned for autumn 2019; work is expected to start soon.

Other recent developments: publication of version 4.1 of technical specifications of Eudamed, MDCG sub groups launched, launch of the call of UDI issuing entities, publication on decision on nomenclature and feedback received by stakeholders on the draft standardisation mandate.

A new updated version of the rolling plan was published on the Commission's website after this meeting.

4) Annex XVI products (update)

The draft text was sent to stakeholders in February 2019 and numerous contributions with big number of comments have been received. All this information is being processed and will be discussed with Member States at a meeting that will take place on 8 May. COM announced that they will prepare a new draft text in a few weeks. The plan is to have a final text for formal adoption in the near future.

5) MDCG subgroups (update)

COM informed that the MDCG subgroups have been launched and are operational since 1st March, 2019. They operate under COM rules on expert groups therefore they would need to follow same rules as MDCG. Membership for subgroups will be made public as well as summaries of the meetings of each subgroup. Member States have nominated

their representatives for subgroups. Participation for stakeholders' associations is based on the call for expression of interest published in autumn 2018. Some of the sub groups already had their first meetings and others will meet soon. Most MDCG sub groups will prepare guidance documents in their areas of expertise that will eventually be presented to MDCG for endorsement. COM gave a short update on the progress of subgroups meetings until now:

- PMSV (Post Market Surveillance and Vigilance). Met on 4-5/3/2018, main issues discussed: revision of various forms (MPSR, PSUR, FSCA), implementation of MIR form and updating of vigilance MEDDEV guidelines.
- Market Surveillance: first meeting scheduled for 30/4. There was already a meeting of the Task Force on Eudamed on 25/3 where it was decided to create two work packages, one on final inspection report and summaries of surveillance activities and one on non-compliant devices.
- NBO (Notified Body Oversight): first meeting took place on 29/3 with wide attendance and active participation. Main issues discussed include the status of NBs designated under the Directives after the repeal date, NB designation status under MDR/IVDR and an extensive examination of the Q&A document on requirements to be met by NBs and the designation process.
- New Technologies: first meeting took place on 8/4 with focus on software issues like progress report on the EU medical devices cybersecurity Task Force, progress report on the clinical evaluation for medical software, state of play for Com Reg. 207/2012 on electronic instructions for use of medical devices and legal status of app platforms.
- The subgroup CIE (Clinical Investigation and Evaluation) will have its first meeting in the new formation on 16-17/4/2019. Parallel work packages are ongoing: clinical evaluation, template development and Eudamed; summary of safety and clinical performance for which guidance is developed and will be presented to the next MDCG meeting for endorsement.
- The subgroup B&C (Borderline & Classification) was also transferred to the MDCG and had a coordination teleconference in March. Two guidelines are currently in preparation: one on classification of medical devices and one on borderline products with pharma. A meeting of the subgroup is scheduled for 4 December 2019.

It was reminded that dates of meetings are published on GROW's website: https://ec.europa.eu/docsroom/documents/34643.

6) Notified bodies under MDR/IVDR

a) Joint Assessments - Progress Report

COM provided delegations with updated information concerning the joint assessment process. The most salient points presented were as follows:

- 47 applications received (by SANTE) in total, 38 for MDR and 9 for IVDR
- For MDR in particular, 35 of the existing 53 notified bodies (under the medical device Directives) have applied. For IVDR 8 out of 21 current notified bodies have applied

- 33 preliminary assessment reports (PAR) have been received (hence, 33 on-site assessments either have been carried out or will be scheduled)
- The number of diverging opinions remains very low, with 50% of assessments resulting in none. There is also a very discrete range of topics for which diverging opinions have been raised, touching upon only 9 themes.
- 11 corrective and prevention action (CAPA) plans have been received, for which opinions the joint assessment teams have been issued or are under preparation.

b) Legal Requirements for Notified Bodies

i. Unresolved diverging opinions

MDCG discussed some issues identified during joint assessments of the applicant notified bodies as diverging opinions between the joint assessment team and the national designating authority. There were efforts in finding common positions at MDCG in order to facilitate more coherent approach in future joint assessments. Some members requested more background information from the NBO (Notified Bodies Oversight) working group in order to be able to assess an impact of each position taken by the MDCG. MDCG discussed the following diverging opinions.

Regarding applicable requirements for re-certification of quality systems, MDCG members could not reach a clear agreement therefore the topic will be re-examined first at the level of the NBO subgroup and then a new proposal will be presented at a future MDCG meeting.

On the question of the role of the personnel with relevant clinical expertise ("internal or integrated clinician") in the NB's assessment and decision-making process the MDCG exchanged views mainly on interpretation of this aspect in relation to the requirement of the products to be subject of a conformity assessment. The MDCG endorsed, with the exception of Germany, the position that the abovementioned personnel with relevant clinical expertise is responsible for identifying when specialist input is required for the assessment of the clinical evaluation in all cases where the conformity of the device is achieved also by clinical data. DE supported that the personnel with relevant clinical expertise does not need to be involved in each conformity assessment procedure, but the need for such involvement could be reflected in NB's procedures, as prior approved by the personnel with relevant clinical expertise .

Next, the MDCG discussed the meaning of "publicly available" as regards the list of NB's standard fees. MDCG supported that NBs need to meet the transparency objectives and to make the list of standard fees publicly available, without the need for any additional steps. It was agreed that the structure of typical types of (standard) fees would be published after alignment between NBs; the Commission will contact the coordination group of notified bodies (Article 49 MDR) accordingly.

ii. Q&A document on issues emerging from joint assessments

A Q&A document that was prepared and reviewed by NBO in the 29 March meeting was presented to MDCG and it was concluded that additional time should be allowed for the MDCG members to review it. MDCG members were asked to provide further possible

comments in writing within 2 weeks' time after the meeting. Eventually this Q&A will be made publicly available on COM website dedicated to medical devices.

c) MDCG recommendation on the draft designation of a Notified Body under Regulation (EU) 2017/745:

i. Final assessment report of the designating authority and final opinion of the joint assessment team

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

ii. MDCG recommendation under Article 39(9) MDR

MDCG issued a positive recommendation under Article 39(9) of Regulation (EU) 2017/745, according to which the applicant notified body should be designated in the scope proposed by the designating authority.

7) Eudamed (update)

COM provided an update on the implementation plan of Eudamed and reminded of the numerous working groups involved and meetings organised since more than two years. Version 4.1 of the Functional Specifications document was published on Europa (Medical device sector) in March 2019 considering comments received from MDCG members. The second version of the implementation plan with scope for 1st and next releases should follow (normally in June 2019). MDCG members were reminded that they can have access in CIRCABC to minutes of all Eudamed working groups meetings where they can find much information on requirements and related issues. Progress on the various modules are ongoing with still important issues, first release is still foreseen for March 2020. The audit (art. 34 MDR) should start around September 2019 and the final audit report on the first priority functional specifications should be available end of February 2020. Another audit should follow later in Q4 2020 for the remaining scope. The first draft of the required Eudamed Implementing Act (Art. 33.8 MDR) is under finalisation internally and should be sent in May to the Eudamed Steering Committee competent authorities members for comments before being presented at the next MDCG meeting.

The Eudamed public website URL will be: http://ec.europa.eu/tools/eudamed.

Member States expressed concerns that the System/procedure pack producers (SPPP) should not be able to submit vigilance cases to Eudamed. COM explained that there is no legal basis to oblige them to do so. On the request of several Member States, COM undertook to analyse what could be done to have a legal basis for having vigilance reports from SPPP in Eudamed and to possibly present a document to be endorsed by the MDCG as a legal basis.

8) Timelines for registration of device data elements in Eudamed – document for endorsement

The issue of timelines was extensively discussed especially in the context of corrigendum procedure. The document presented to MDCG concerns the possible alignment of timelines for registration in Eudamed of device data elements contained in Part B of Annex VI with timelines for registration of device data elements contained in Part A, Section 2, of Annex VI.

COM clarified that custom made devices are exempted from registration and that, even in the context of the 18-month voluntary period for registration, the registration of a device remains a pre-condition for submission of any serious incident.

MDCG endorsed the document, based on the need to register a device upon submission of serious incidents.

9) Registration of legacy devices in Eudamed – document for endorsement

MDCG endorsed, with only minor modifications to the original proposal, a document dealing with registration of devices which can continue to be placed on the market with Directive certificates by virtue of Article 120(3) of Regulation 745/2017 (MDR) and Article 110(3) of Regulation 746/2017 (IVDR) after the respective application dates of the two Regulations. These devices are referred to as legacy devices. The document provides means for those devices to be registered in Eudamed in the absence of a Basic UDI-DI and UDI-DI. DE expressed concerns with regards to Annex of the guidance on the registration of legacy products which states "NOTE: All the Directive-compliant devices which have been placed on the market ahead of the general application dates and will not continue to be placed on the market afterwards, should be registered in Eudamed (without a Basic UDI-DI and UDI-DI) only if a serious incident report and/or a field safety corrective action report (with the field safety notice) occurs after the application date. ” The view of DE is that there is no legal basis in the MDR nor a technical need to require a registration (nor an actor registration and validation by NCA) of products which have been placed on the market before the date of application of the MDR or IVDR”.

10) UDI and medical device nomenclature (update)

UDI: COM informed that the implementing act on issuing entities is in the course of being adopted and work on new UDI guidance (notably UDI integration in QMS and assignment examples) is in progress.

Nomenclature: a new subgroup will be established and a new call for expression of interest for stakeholders will be published in the following weeks. The basic practicalities of the nomenclature system’s implementation will be defined on the occasion of the first meeting of the group.

Implant card: a Task Force is finalising a draft on interpretation of article 18 that might reach the MDCG at the next meeting.

11) Common specifications for reprocessing of single use devices (update)

An interservice consultation was launched at the end of March 2019. A new draft will be prepared taking into account the comments made during the interservice consultation and will be presented at the next MDCG.

12) Standardisation request to CEN/CENELEC (update)

COM provided an update on the development of the "blueprint" standardisation request (the "mandate") for all industrial products sectors, and the process for adoption of the mandate for personal protective equipment (PPE) which is based on that "blueprint".

As regards the draft standardisation mandate under MDR/IVDR, after the MDCG of 14-15/2/2019, the draft mandate was sent to the relevant stakeholders for comments. The European Standardisation Organisations (ESOs) expressed concerns on the "closed" list of the standards subject to the mandate (as opposed to an "open" mandate). COM reiterated that the need for enumeration of the standards followed from the Standardisation Regulation 1025/2012 and the recent judicial decisions of the European Court of Justice. ESOs also expressed concerns about the focus of the mandate on the horizontal standards, excluding product - standards. COM reiterated that the selection of the standards for the first mandate followed discussions in the MDCG over the past months and indications in that sense is additional mandates covering other standards could be expected in the future.

As the next step, COM plans to carry out the public consultation on the draft mandate.

13) New Scientific Bodies (update)

JRC informed the group on the progress of work as regards the creation of the new scientific bodies outlined in the new Regulations. At present they concentrate on the design of the expert panels including efficient screening of dossiers and management of conflict of interest.

Next steps will include the finalisation of the implementing act on designation and publication of the call relating to expert panels.

14) Vigilance

a. Update

COM informed that the two draft Device Specific Vigilance Guidances, which were previously intended for MDCG endorsement, would not be presented for endorsement, as the working group (MDCG subgroup PMSV) decided that these forms are applicable only under MDD (Medical Devices Directive). Consequently, it will be endorsed by PMSV through written procedure.

b. MPSR – Manufacturer Periodic Summary Report form for endorsement

COM informed that the Manufacturer Periodic Summary Report Form (MPSR) would be presented for endorsement at a next MDCG meeting as it will become applicable only under the MDR but needs further adaptation as regards in particular the inclusion of legacy products.

On other developments a new Task Force has been established on public access to Eudamed and in particular vigilance data. It will be co-chaired by IE and COM.

15) Common technical specifications (CTS) under IVDD and common specifications (CS) under IVDR (update)

MDCG was informed that regarding the first CTS on combined test, the TBT (Technical Barrier to Trade) notification did not raise any comments. The text has been sent to the members of the Regulatory Committee under IVD Directive for adoption with the deadline for voting on 26/4/2019. Regarding the second CTS on self-test, the interservice consultation was launched on 8/4 and will be followed by the TBT notification for two months and it will be followed by the adoption by the Regulatory Committee under IVD Directive.

As soon as these two last CTS are adopted, the work will start in the IVD working group to adopt the CS under the Regulation.

16) Communication campaign

The new webpages of medical devices are now online and provide targeted information to stakeholders (factsheets, infographics, library with links to documents and websites providing additional information and a stakeholder toolkit to help promote the webpages). The first newsletter was sent in March to more than 1800 persons who have registered until now (https://campaign.gopacom.io/mdr-newsletter-subscription). The webpages have been promoted on LinkedIn and Twitter. The specialised press has also been informed about the new webpages in order to generate press releases. The April issue of the health newsletter from DG SANTE was focusing on the new webpages for medical devices with an interview of DG GROW Director General.

Roll-up banners and Pop-up stands have been ordered by interested MS.

COM invited MDCG members to add the COM link (http://ec.europa.eu/growth/sectors/medical-devices_en) on their national websites and are asked to check if their contact details need to be updated on the "contact" page of the website (http://ec.europa.eu/growth/sectors/medical-devices/contacts_en).

Two new factsheets are under preparation, one for healthcare professionals and health institutions, and one for eye care professionals. A webinar for patient organisations will be organised in 2019 to prepare the section of the campaign toward patients, which will start in May 2020.

MDCG members are invited to send any ideas for communication actions.

17) IMDRF (International Medical Device Regulators Forum) Committee meeting on 19-21 March 2019 (update)

A meeting of the management committee of IMDRF took place in Moscow from 19-21 March 2019. Europe was represented by COM and delegates from DE and FR. It is noted that any preparatory work for IMDRF meetings in the future will be part of the work of the new MDCG sub group on international matters.

An outcome statement of the Moscow meeting is published here: http://www.imdrf.org/docs/imdrf/final/meetings/imdrf-meet-190318-moscow-meeting-outcome-statement.pdf.

COM underlined that attention is growing on international relations concerning medical devices as well as health and trade aspects and asked for more representatives from EU competent authorities to participate and represent European perspectives in various work streams of IMDRF. COM asked MDCG members to identify possible candidates.

18) AOB

CAMD – Competent Authorities for Medical Devices - The Chair of CAMD updated on the work of the network and also informed that DK will host a meeting under the RO Presidency plus elections are under preparation for the appointment of a new Chair.

Commission informed on an initiative named **Identification of eligible sectors for Blueprint Wave 4 (ERASMUS+ 2020 Funding)**. The aim of this initiative coordinated by DG EMPL, and funded under ERASMUS+, is to develop actions to address shortage of skills in various sectors one of which is the regulatory affairs for medical devices. The fiche describing the project has been sent to all members of the MDCG. There was a general agreement about the shortage and the need to address such as lack of skills via this specific project.

If the medical devices sector is selected, all interested parties (stakeholders associations, MS, universities…) should work together to put in place dedicated training in order to increase the number of people with regulatory affairs skills in the sector.

Last but not least MDCG members were requested to communicate to the Commission any information necessary in order to keep updated the list of competent authorities on the website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

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.	CH	Swiss Agency for Medicines and Health Products
6.	CY	Cyprus Medical Devices Competent Authority
7.	CZ	State Institute for Drug Control
8.	DK	Danish Medicines Agency
9.	EE	Estonian Health Board
10	FI	VALVIRA – National Supervisory Authority for Welfare and Health
11	FR	National Agency for the Safety of Medicines and Health Products (ANSM), General Directorate for Health, Ministry of Health and Solidarities
12	DE	Federal Ministry of Health (BMG)
		Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)
13	GR	National Organisation for Medicines (EOF)
14	HU	National Institute of Pharmacy and Nutrition
15	IE	Health Products Regulatory Authority (HPRA) Health Board
16	IT	Ministry of Health – Directorate General of Medical Devices and Pharmaceutical Services (Sanita)
17	LI	Office of Public Health, Lichtenstein - EXCUSED
18	LU	Ministry of Health Luxembourg – EXCUSED
19	LT	State Healthcare Accreditation Agency, Ministry of Health
20	LV	Ministry of Health
21	MT	Ministry of Health – EXCUSED, Perm. Rep attended
22	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate

23	NO	Norwegian Ministry of Health and Care Services
24	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
25	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
26	RO	National Agency for Medicines and Medical Devices - EXCUSED
27	SI	Agency for Medicinal Products and Medical Devices
28	SK	State Institute for Drug Control - EXCUSED, Perm. Rep attended
29	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
30	SE	Medical Products Agency (MPA)
31	TR	TMMDA – Turkish Medicines and Medical Devices Agency
32	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- JRC F2
- DG SANTE F5
- DG GROW D4