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, 19 July 2019

Minutes

Brussels, 20 June 2019

1. Opening, adoption of the agenda

Agenda was adopted.

2. Adoption of the minutes of the meeting held on 9-10 April 2019

Minutes of the MDCG meeting of 9-10 April 2019 were adopted. Provisional date of next meeting: 30/9 – 1/10/2019, including half day meeting with stakeholders.

3. Implementation of MDR/IVDR

3.1. Overview

A new version of the implementation rolling plan was shared with MDCG members and as usual it will be published on the Commission website after the meeting. Main developments (some of which will be examined closely under other agenda items): number of Notified Bodies applications has increased to 51 and a second Notified Body has been designated; the implementing act designating the UDI (Unique Device Identification) issuing entities has been adopted on 6 June 2019 and published as Commission Decision 2019/939; the draft Implementing Act on expert panels has reached the stage of consultation with other Commission services; the draft standardisation mandate is complete and ready for the internal procedure; a request for the establishment of a new MDCG sub group on "Nomenclature" is completing internal validation and the relevant call will be officially launched in the coming days.

3.2. MDCG Sub groups

All thirteen MDCG sub groups operate under the same rules as MDCG and the Commission framework for Expert Groups and they have been formed to provide guidance to MDCG based on their expertise. The composition of each MDCG subgroup is published on the "Register of the Commission and other similar entities". The meetings' planning until the end of the year is published at: https://ec.europa.eu/docsroom/documents/35501. COM updated orally on the latest activities/future plans of each MDCG sub group and reiterated the importance of having more competent authorities participating actively in the work of these subgroups so as to ensure widest use of expertise but also that a variety of opinions is taken into consideration at early stages of guidance development. MDCG requested that in the

future similar updates are provided in writing in a standardised format and that any necessary precautions are taken to avoid overlaps in the guidance developed in the various sub groups. COM recognised that these proposals would facilitate the work of MDCG and will follow up as requested by MDCG.

3.3. Annex XVI – progress on implementing act

The large amount of feedback received by stakeholders has been discussed by COM and Member States and a final orientation has been taken jointly. The updated version of the text was sent to the MDCG sub group and MDCG. Following the internal procedures of the Commission and public consultation the text is expected to be adopted as early as beginning of 2020. As soon as the text is finalised there could be further discussion in an effort to develop guidance on common specifications.

3.4. Reprocessing of single use devices – progress on implementing act

Work is ongoing on the update of the Implementing act on Common Specifications for the reprocessing of single-use medical devices based on comments received by other Commission services. At the end of the inter-service consultation the updated version of the act will be shared with the MDCG and the four weeks stakeholder feedback will be launched on the Better Regulation portal.

3.5. Follow up to EPSCO (Employment, Social Policy, Health and Consumers' Affairs Council)

At the recent meeting of 14/6/2019 a discussion was triggered based on a paper prepared by Germany and Ireland; concerns were raised that were shared by the other Ministers who intervened in relation to the implementation period for the new legislation, a possible extent of the scope of the grace period, a potential longer period of transition and the need for all Member States and COM to closely monitor the situation. COM from their side reassured that they will make every effort to intensify their efforts which are already at a very high level. In an effort to speed up procedures some of the decisions may be sent to MDCG for written consultation/ endorsement instead of waiting for the following physical meetings and they also asked competent authorities of MS to accelerate their internal procedures and be more involved in management and organisation in the work of MDCG subgroups. In addition COM informed that they are about to launch the second Corrigendum so they asked MDCG members to reflect in case they have concrete proposals to improve the text, so as to take full advantage of the exercise.

4. Vigilance: Manufacturer Periodic Summary Report (MPSR) form

MDCG endorsed an updated version of the MPSR form. The form has been presented at the MDCG meeting of February earlier this year as well but since then and following some comments it was updated to reflect the following: clarify that it will be applicable under the MDR/IVDR, allow the identification of legacy devices, include the CND nomenclature and possibility for revision after two years.

5. Implant card guidance

The draft guidance submitted to the MDCG on the implant card has undergone several consultations with contributions from representatives from all Member States. The objective of this work is to achieve a practical and implementable tool for the healthcare professionals and manufacturers.

The guidance was endorsed by MDCG subject to a few modifications, notably in relation to clarification on the expectation nature of the use of stickers and some editorial revisions.

6. Guidance on Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) is a legal requirement for implantable and Class III devices as per article 32 of MDR and it has been developed by the Clinical Investigation and Evaluation MDCG subgroup. The work in CIE was led by two competent authorities and great effort was made to meet as many of the concerns raised as possible. MDCG recognised that the guidance on SSCP can be a useful tool for patients and healthcare professionals but still need to consult members of Post Market Surveillance and Vigilance (PMSV) subgroup in particular as regards vigilance and surveillance aspects. The guidance will be updated if needed after the later consultation and will be resent to MDCG for their final endorsement if there will be substantial modifications by PMSV.

7. Person responsible for regulatory compliance, guidance on article 15 MDR/ IVDR

This guidance was developed in relation to the obligation for the manufacturers and authorised representatives to have respectively available within their organisations or permanently and continuously at their disposal at least one person responsible for regulatory compliance. Market Surveillance subgroup was consulted while preparing the draft. MDCG recognising that this is a new obligation for the medical devices sector endorsed the guidance subject to some wording adjustments, notably in relation to the qualifications of the person. Moreover it was decided to postpone any consideration on liability.

8. Medical Software/Apps

MDCG was updated on various ongoing work streams and was informed that during the summer they could be receiving some guidance documents for their possible endorsement, notably in the field of classification.

9. Guidance on Class I manufacturers

- A guidance for manufacturers of Class I medical devices has been prepared by the Market Surveillance subgroup describing all the necessary steps that have to be performed by manufacturers before placement of devices on the market. Stakeholders were consulted and their comments are being currently processed. COM received requests for developing a similar guidance under IVD Regulation and will consider that for the future but this will not be possible without the support of IVD experts from Member States, especially since it was highlighted that the huge job achieved for this guidance under MDR, would not have been possible without the active input by experts from Member States. DE proposed to focus the guidance in particular on practical approaches to implement the required new lifecycle processes like risk management, clinical evaluation and PMS instead of elaborating the old and no more valid step-by-step approach and instead of focussing on how class I manufacturers should be controlled by CA . PT as coordinator of the TF of guidance for manufacturers of Class I medical devices, clarified that the focus of the group was the update of current guidance considering MDR. Thus, was decided to keep the same structure based on a step-by-step approach which seemed to be very useful for manufacturers, in particular for those that didn't have a robust knowledge of medical device legislation. The proposed text was already agreed by the TF and MS WG.

10. Notified bodies under MDR/IVDR

10.1. Update and progress report

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

- 51 applications received by COM in total, 41 for MDR and 10 for IVDR
- 39 preliminary assessment reports (PAR) have been received, 32 under MDR and 7 under IVDR
- The number of diverging opinions remains very low and is expected to stay at the same low levels
- 17 corrective and prevention action (CAPA) plans have been received, for which opinions the joint assessment teams have been issued or are under preparation.

10.2. MDCG recommendations on two draft designations of notified bodies:

10.2.1. final assessment reports of the two designating authorities and draft designations – summary presentation by each designating authority

The two designating authorities presented their final assessment reports on the applicant notified bodies. The Commission presented also the final opinions of each of the joint assessment teams. A brief discussion followed and it was signalled that there were no remaining diverging opinions in either case.

10.2.2. final opinion of the joint assessment teams, one for each notified body – summary presentation by SANTE

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

11. Eudamed

11.1. Update and system development

MDCG was updated on the progress of the system development by the Commission's team responsible for the technical development and was informed that full functionality will not be achieved at one stage but on a gradual or progressive approach. Furthermore, the scope of the first release will be decreased in compared to what was initially planned with the first go live day remaining for March 2020. The delays will concern vigilance and part of the certificate, clinical investigation and market surveillance. At the same time Commission are intensifying their efforts while the budget is secured. There is ongoing work on multiple topics with eight different working group meetings which took place in 2019 until now. A document with functional specifications with legal requirements was published in March and an updated version will be published this summer including updates for planning.

11.2. Implementing Act (Article 33.8) update

The draft Implementing Act lays down the criteria and detailed arrangements which are necessary for setting up and maintaining Eudamed and it was shared with the Eudamed Steering Committee and MDCG before this meeting. No comments were received by the Steering Committee and MDCG members were invited to do so by 6/7. Keeping in mind the progressive entry into force of Eudamed, the draft makes an effort to offer as much legal clarity as possible. COM committed to act as quickly as possible and continue sharing information with MDCG in the same transparent way.

12. UDI (update)

The implementing act designating the UDI issuing entities was adopted on the 6/6/2019. Ongoing work concerns mostly the integration of UDI aspects in Quality Management System, drafting of a comprehensive Questions & Answers document to be published on our website and the drafting of a list of values for certain UDI fields. Another aspect being looked at is the divergences between EU/US systems. As regards Nomenclature, work is ongoing in two main priority areas: consolidation of CND and mapping CND/GMDN. As regards IMDRF work on UDI, coordinated by the EU, final deliverables were endorsed and published on the IMDRF website. COM informed that bilateral collaboration regarding UDI between EU/US is ongoing.

With regard to the COM decision to designate a fourth issuing entity, DE stated that according to Article 27 (2) MDR the COM should "endeavour to ensure that UDI carriers, as defined in Part C of Annex VI, are universally readable regardless of the system used by the issuing entity, with a view to minimising financial and administrative burdens for economic operators and health institutions."

13. It is noted that all applications and the COM's preliminary assessment thereof, were shared with MDCG members and no feedback was received. Following this a final

decision was taken keeping in mind that that there was no solid legal basis to reject any of the applications. **New Scientific Bodies**

13.1. Update activities

JRC presented the status of discussions on the competence landscape of EU reference laboratories (EURLs) and the Implementing Acts (IAs) according to 100.8(a) (tasks and compliance with criteria) and 100.8(b) (structure and level of fees which may be levied by EURLs). The latest version of the competence area landscape includes input from European Centre for Disease Prevention and Control (ECDC). It will be discussed in the upcoming meeting of the IVD subgroup of MDCG and the classification task force. Drafts of the IAs have been discussed in the MDCG Task Force on scientific bodies. Three principal points have been identified as requiring legal clarification. The issues are (a) applicability of horizontal Regulation (EC) 765/2008 regarding accreditation of EURLs, (b) possibility to define roles and criteria for National Reference Laboratories according to article 100.2(e) of the IVDR, (c) possibility to define rules in the implementing acts which are not specified in the IVDR (but technically/operationally meaningful). JRC emphasised that there was general agreement that the draft IA on fees should apply the principle of fees wholly covering the cost of the requested task on a non-profit basis.

Regarding expert panels, JRC recapitulated the reflections at the last MDCG meeting based on recommendations of the MDCG Task Force on scientific bodies. Key points were (a) set-up of a screening panel, (b) post-market data, c) sub-groups/panels to ensure smooth operations. JRC emphasised that these elements were reflected in the current draft Implementing Act. JRC also showed its new data-based analysis of dossiers qualifying per year for the CECP (clinical evaluation consultation procedure). The analysis was based on SANTE certificate data from 2014-2019 and concerned 34.354 entries. Application of the Article 54.2(b) "waiver" for legacy products (endorsed by MDCG at the meeting of April 2019) will reduce the number entering the CECP procedure; current COM estimates indicate ca 700 dossiers per year. JRC moreover summarised the preparations for the call of experts and the selection process, the importance of a robust policy for conflict of interest management by the COM (developed by JRC based on EMA's policy) as well as the dissemination campaign aimed at ensuring that a sufficient number of clinicians of high standing will know about the call and apply for membership of the expert panels.

13.2. Implementing Act -Article 106.1 (update)

COM presented the general structure and approach of the draft implementing act laying down the rules as regards the designation of expert panels in the field of medical devices. In particular, the following issues were highlighted: the inclusion of the list of panels in the Act itself; the introduction of an additional panel in charge of evaluating whether or not a dossier should be passed on to panels for an opinion (based on criteria laid down in Annex IX); the possibility for panels to establish subgroups, which is considered to facilitate the organisation and management of workload; the functioning of the Secretariat and the Coordination Committee; the rules related to transparency. DE expressed several concerns mainly on the number and relevance of the panels, whether they would be sufficiently occupied, the necessity to have a coordination panel and the decision making process in particular the possibility for experts to have diverging opinions and reflect them in the final opinion.

14. Transparency: orientation discussion

Commission Regulation (EU) 2017/745 (MDR) makes often reference to transparency aspects and in some cases the relevant provisions on transparency specify that public access for some documents is mandatory while in other cases they refer to a variety of reports without defining at which extent the information should be accessible as it refers to "appropriate level". Further discussion is needed within MDCG in order to ensure coherent approach. MDCG members were invited to reflect and revert back to COM on this cross cutting issue taking into consideration that the accuracy and level of information should be safeguarded and at the same time that there should be: no release of personal data, protection of commercially sensitive information and the right balance between accuracy and level of information released with the required time for competent authorities to respond. COM intends to further develop the approach for transparency for Eudamed at future MDCG meetings and invited Member States to send them their views.

15. Guidance on phthalates (update)

The guidance was provisionally endorsed by the Scientific Committee on Health Environment and Emerging Risks – SCHEER the day before MDCG meeting. After a final check it will be published. COM is exploring the possibility to invite a representative of SCHEER to the next MDCG meeting with stakeholders to present the guidance.

16. Standardisation request to CEN/CENELEC (update)

COM provided before the meeting the draft Commission decision on a standardisation request to the CEN/CENELEC for development of standards in support of the MDR and the IVDR. The inter-service consultation for this act is expected to be launched in the coming days. At the same time, the draft act will be published for four weeks feedback on the dedicated Standardisation Notification system.

17. Common technical specifications under IVDD and common specifications under IVDR for combined self-tests (update)

Common technical specifications on combined tests are in the last stages of adoption. Common technical specifications on self-tests have gone through an interservice consultation. The priorities for common specifications under IVDR are being discussed in the IVD subgroup.

18. AOB

18.1. CAMD activities (Competent Authorities for Medical Devices)

The Chair of CAMD informed on a very successful meeting in Copenhagen that adopted a document on the future of CAMD and the need to continue having this network. There are different options being examined on the continuation of CAMD website. CAMD is also considering scheduling a meeting with all MDCG subgroups chairs after the summer.

COM also explained that in a meeting organised with the executive group of CAMD it was decided to send a request for information both to Member States (by CAMD) and to relevant UK Notified Bodies (by COM) to receive an update on the state of play of transfer of certificates from UK to EU-27 Notified Bodies in the transition to Brexit.

18.2. Communication campaign

COM informed about the new factsheet for health care professionals and health institutions, which has been finalised and uploaded on the COM website and encouraged dissemination at national level.

They also presented the main results of the first year of the information campaign, namely: the creation on a new hub dedicated to the new regulations on MD and IVD on the GROW website, which has been popularised with details on changes brought by the new regulations, offering tailored information to stakeholders. Thanks to this new hub, the traffic on the MD web pages increased by 42% between February 2018 and January 2019. The new documents added on the online hub were downloaded more than 40000 times. Approximately 25% of the overall downloads went to a single publication: factsheet for manufacturers of MD. The number of subscribers to the newsletter increase of 58%, passing from 1800 to 3075 subscribers. The two social media posts generated 6300 link clicks and the short video produced got 780,000 views.

COM is now working on a strategy for the second phase of the communication campaign and they asked for input and support from Member States in order to plan and implement an effective and efficient information campaign.

18.3. Erasmus

COM invited MDCG members to consider some funding possibilities for the medical devices sector under the Programme Erasmus+ and in particular for the development of programmes concerning higher education (HE) and vocational education and training (VET), including continuing training for employees. The programme is eligible for Member States, organisations and individuals:https://ec.europa.eu/programmes/erasmus-plus/opportunities/how-to-apply_en A dedicated link with detailed description of the Programme Guide can be found here: https://ec.europa.eu/programmes/erasmus-plus/resources/documents/erasmus-programme-guide-2019_en COM will raise awareness among stakeholders as well.

18.4. Consultation on draft guideline on quality requirements for medical devices in combination products

COM informed MDCG members on the public consultation launched by the European Medicines Agency (EMA) on a draft guideline on quality requirements for medical devices in combination products. The draft guideline can be found here https://www.ema.europa.eu/en/news/consultation-draft-guideline-quality-requirements-medical-devices-combination-products and comments can be sent by 31 August, 2019.

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)
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
19.	LT	State Healthcare Accreditation Agency, Ministry of Health
20.	LV	Ministry of Health
21.	MT	Ministry of Health
22.	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
23.	NO	Norwegian Ministry of Health and Care Services
24.	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

25.	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
26.	RO	National Agency for Medicines and Medical Devices
27.	SI	Agency for Medicinal Products and Medical Devices
28.	SK	State Institute for Drug Control – EXCUSED
29.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
30.	SE	Medical Products Agency (MPA)
31.	TR	TMMDA – Turkish Medicines and Medical Devices Agency
32.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- JRC F2
- DG SANTE F5
- DG GROW D4