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, 14 February 2019

Minutes

Meeting of the MDCG and Stakeholders
Brussels, 14 February 2019

1) Opening, adoption of the agenda

The Chair opened the meeting and the draft agenda was adopted. These meetings take place in the context of a constant inclusive way of collaboration with stakeholders.

2) Implementation of MDR/IVDR (general overview)

COM announced a new version of implementation rolling plan published on its website at: https://ec.europa.eu/docsroom/documents/34041 and briefly updated on main recent developments:

- Expert panels: the implementing act is being drafted based on the input provided by the survey with MDCG members and stakeholders
- UDI: the call for application for UDI issuing entities was launched on 21 December and expired on 25 January, timing according to plan
- Notified Bodies: more applications were received over the last two months and new joint assessments took place. In addition, the first Notified Body has being designated under the Regulation. More details to be provided under separate agenda item
- Version 4 of high-level technical specifications for Eudamed have been finalised; more details will be given at the MDCG meeting
- Governance of MDR: significance progress made in the establishment of the MDCG subgroups that would enable MDR governance to be completed soon
- Annex XVI provisions: a first draft of the common specifications on Annex XVI products will be provided for consultation to stakeholders soon. Timing in line with the implementation rolling plan: Q1 2019
- Expert groups have continued to work and deliver a very high number of issues and guidelines, in accordance with the CAMD roadmap

Responding to questions, COM clarified that there is the need to manage the work load based on priorities defined by legislator.. The MDCG sub groups may decide to define their priorities or roadmaps upon their establishment. As regards the implant card, it is not included in the work plan for 2019. Some other questions transmitted in writing t are being handled and replies will be prepared.

3) MDCG sub groups – applications from stakeholders to participate as observers

COM informed that in total 53 applications have been received as a response to the call which was published on 16 October 2018. The call was inviting expression of interest from stakeholders' associations to become observers in MDCG sub groups. Part of applications excluded were on behalf of individuals instead of associations; other applicants did not have an EU Transparency Registry number; some of the applications excluded were on behalf of purely national associations or on behalf of other national organisations or committees; some other applications did not represent EU interests or did not explain their relevant competence with the mandate of the specific sub group.

COM is finalising the evaluation of the remaining valid applications and the replies are being prepared. The objective is to establish as soon as possible the sub groups and achieve a balanced representation of various stakeholders' organisations with some expertise in the specific policy area that would allow meaningful interactions amongst relevant interested parties.

4) Annex XVI products

A first draft text for the Implementing Regulation (IR) on Annex XVI devices has been finalised by COM in collaboration with MS. The text was shared for informal consultation with stakeholders to send comments. All comments received will be jointly reviewed by COM and MS. A Q&A document explaining the structure and content of the draft IR, aims at supporting stakeholders in providing their feedback.

Taking into account the timelines for the application of the MDR and the time needed by notified bodies to carry out certification of Annex XVI products, the procedure for the official adoption of the IR has to start soon and will also include the public formal consultation stage.

5) Notified Bodies designation process under MDR/IVDR

(a) Commission update (SANTE)

COM provided information on the state of play of the joint assessment process, including the following updates:

- 42 applications received in total, 33 for MDR and 9 for IVDR
- Time devoted by national authorities for checking the applications varies – average time: 60 days
- 30 preliminary assessment reports received
- Average time from the appointment of the joint assessment team to on-site assessment: 111 days
- 7 JAT CAPA plans reviews issued (6 for MDR and 1 for IVDR)

(b) Industry feedback (MedTech Europe)

MedTech Europe presented concerns of manufacturers about the designation process and the outlook for future Notified Body (NB) capacity. They asked all concerned parties to do their best in order to ensure continuity of supply for patients and hospitals as well as support of innovation and SMEs. They underlined the challenges of re-certification and

surveillance where the timelines are extended until the EU reference labs and expert panels are set up.

They also expressed concerns for the possibility of a no deal Brexit scenario and potential concerns on products' shortages and particularly asked competent authorities of MS to set up contingency plans if necessary.

(c) Notified bodies feedback (NB-Med)

NB-Med presented the results of a survey carried-out based on 41 responses received. There has been one designation under MDR and ten more applications are expected this year. According to their estimations there are around 30 applications in the middle of designation process. Based on feedback received by their members there are a lot of questions on implementation, some questions related to employment; most NBs are multinational companies and they have no clear understanding how to deal with diverging opinions.

6) New Scientific Bodies (JRC)

JRC presented the general approach for the establishment of the scientific panels (broad landscape, high workload and high number of experts required) as they are speeding up the planning for the implementation of expert panels. There are some remaining questions in relation to the EU Budget 2021-2027 which has not been adopted yet. Due to the high expected workload very efficient structures are needed and careful planning is required in order to facilitate the work of experts in the panels. The next work stream that is being foreseen is the publication of a call for expression of interest for experts who would be interested to become member of the panels. In order to attract as many experts as possible, JRC is looking at options to maximise publicity with the help of professional organisations of clinicians.

7) Eudamed

COM presented the state of play indicating that the requirements on Actor and UDI modules and related data dictionaries are under finalisation. The analysis on NB & certificate module is under finalisation and the implementation is to start soon. Significant progress on defining requirements for clinical investigation application was done. For vigilance, analysis on serious incident reports and field safety notice is under finalisation and it is well advanced for periodic summary report and periodic safety update report. .

A new reviewed version of the functional specifications will be issued soon. The first release of Eudamed will not be for a fully functional Eudamed covering all its modules yet, its scope will be defined from timing priority of the functional specifications after consultation with the MDCG. Nevertheless, date for go live for Eudamed first release is still scheduled by 26 March 2020, in compliance with article 34 MDR.

Questions were raised by participants about legacy devices registration and access to vigilance data to expert panels, health care professionals and patients. COM explained that these questions are not answered yet and they are still under discussions among the Member States and the Commission.

8) Unique Device Identifier (UDI)

COM informed on progress in governance with the establishment of the new sub group under MDCG which will provide a platform for exchange of information. The two task forces on implant card and UDI guidance will continue to work under the new framework, with a renewed composition. A new MDCG subgroup on nomenclature will be established at a later stage.

On nomenclature COM informed about progress. Three providers have expressed their interest; COM has taken a decision based on the MDCG views expressed in November and the report produced by a regulators' task force. This decision will be shared with MDCG later.

9) The standardisation request to CEN/CENELEC

COM provided an update regarding the stage of preparation of the standardisation request. Among others, the meeting of the Committee on Standards is scheduled for 5/3/2019. If the standardisation request in the field of personal protective equipment is voted, it will open the road for mandates in other sectors, including medical devices. The relevant stakeholders in the field of standardisation will be soon consulted on the draft mandate.

First meeting of the working group on standards is envisaged for the first half of 2019.

10) Common specifications under IVDR and CTS under IVDD

There are two remaining sets of Common Technical Specifications to be sequentially adopted under the IVDD. The first one (combined tests) will shortly be submitted for written adoption; the second one (HIV self-tests) is about to enter Commission interservice consultation on the pathway to adoption.

The drafting of Common Specifications under new Regulation will begin once the CTS under the IVDD are finalised.

11) Vigilance (state of play)

COM provided information on the work currently ongoing regarding the revision of reporting forms. These forms are the Field Safety Notice (FSN), the Field Safety Corrective Action (FSCA) and the Manufacturer Periodic Summary Report. As regards the issue of public access to vigilance data in future Eudamed, a first discussion with the competent authorities of Member States and stakeholder organisations will take place at the Post-Market Surveillance and Vigilance WG group on 4 – 5 March, 2019.

12) International issues

A meeting on international issues is scheduled for 26 February to examine international and multilateral issues.

Medical devices were on the agenda of the meeting between President Juncker and President Trump that took place last July. Following further discussions the proposal to

make the MRA – that was concluded some 20 years ago – more workable was not accepted by US.

Discussions with Taiwan: Taiwanese authorities asked for reciprocity in relation to a scheme which was approved some years ago and allowed easier access for EU certified products from some EU notified bodies in their market. We have recommended Taiwanese authorities to contact NB-Med.

13) CAMD – (Competent Authorities for Medical Devices)

The Chair of CAMD stressed that safety of patients is the priority for their work and the new legal framework that will enter into force is very important especially for strengthening the rules for placing on the market and market surveillance.

Responding to a question they clarified that they will look in to the possibility to engage more with stakeholders in some aspects of their work.

14) Communication campaign

COM outlined the progress of the communication campaign and invited the participants to consult the new website. A set of factsheets has been developed, five are already available and two under development, one for healthcare professionals.

Pop up banners are available for those interested and COM can provide them electronically. COM also informed that they will organise a webinar with patients.

15) Collaboration with EMA (European Medicines Agency) / Combination products

(a) Introduction

COM in an effort to facilitate a smooth transition from the current to the new legal framework (MDR / IVDR) tried to address important legal and practical clarifications related to application of Article 117. This was a common effort between GROW / SANTE and EMA and aimed at achieving adequate clarity for stakeholders. It is important to note that, while contributing to this effort, involvement of medical device competent authorities via the CAMD was also ensured.

(b) Presentation by European Medicines Agency (EMA)

EMA provided an overview on the way they operate by utilising scientific expertise by the Member States. EMA in collaboration with its network facilitate the implementation of new devices framework by drafting scientific and regulatory guidance. With respect to Article 117 of MDR which concerns a medicinal product with an integral device component a Q & A document will be published soon with the objective to give clarity to applicants for such products. It is to be noted that the document has been prepared after consultation with CMD and CAMD (informal networks of competent authorities of medicinal products and medical devices respectively).

16) AOB

The next MDCG session with stakeholders is expected to take place late in 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.	HR	Agency for Medicinal Products and Medical Devices (HALMED)
4.	CH	Swiss Agency for Medicines and Health Products
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.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Stakeholders:

- AESGP
- APPLIA EUROPE
- BEUC
- CED
- CEN-CENELEC
- COCIR
- CPME
- EAAR
- EBE
- EHIMA
- EPF
- ESC
- EUCOPE
- EUROMCONTACT
- EUROM VI
- FIDE
- GMDN Agency
- HOPE
- Medicines for Europe
- MedPharmPlast Europe
- MedTech Europe
- NB-MED
- TEAM-NB

Commission:

- JRC
- DG SANTE F5
- DG GROW D4

Other:

- EMA (European Medicines Agency)