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, 27 March 2019

Minutes

Meeting of the Medical Device Coordination Group (MDCG)
Brussels, 14 – 15 February 2019

1) Opening, adoption of the agenda

Agenda was adopted. It was announced that the meeting will be followed mid-morning next day by a Brexit Technical seminar with EU-27.

2) Adoption of the minutes of the meeting held on 30 November 2018

Minutes of the MDCG meeting of 30 November 2018 were adopted with few adaptations.

3) Implementation of MDR/IVDR follow up and state of play on Corrigendum to MDR/IVDR

COM informed that progress is according to plan with two exceptions: the implementing act related to Annex XVI has moved to 2020, some delegations asked for a more stabilised version before the consultation with stakeholders; for Eudamed, there might be a delay for two modules CI/PS (Clinical Investigation / Performance Study) and Market Surveillance which may not be available at the time of implementation and will be finalised at a later stage. Both points will be discussed more on dedicated agenda items.

Corrigendum: Council decided for a two-step corrigendum; with regard to first and more urgent corrigendum a silence procedure will be launched soon, this will be a take it or leave it procedure.

4) Notified bodies under MDR/IVDR

a) Joint Assessments - Progress Report

COM informed delegations on the latest news as regards Joint Assessments. Main information provided:

- 42 applications received in total, 33 for MDR and 9 for IVDR
- For MDR in particular, roughly 60% of the existing NBs (under the MDDs) have applied
- Turkey: all NBs are scheduled for Joint assessment under Regulation 920/2013 during Q1-Q2
- 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
- National experts from the UK will have to be replaced
- Diverging opinions presented per topic
- In 72% of the Joint Assessments there have been no or up to 2 diverging opinions
- Most frequent scenario, by far, is the absence of any diverging opinion
- 7 JAT CAPA plans reviews issued (6 for MDR and 1 for IVDR)
- We have to aim at proceeding faster with the CAPA (Corrective and Preventive Action) review:
    - Main issue is the need to carry out a translation
    - Following the on-site assessment, non-conformities could be translated by the JAT and be made available to the designating authority
    - The translated non-conformities could be passed on to the applicant
    - The designating authorities could consider submitting, earlier, a version of the CAPA plan, so that translation can start as soon as possible.

Responding to questions the COM clarified that they will undertake one assessment before March 2019. As regards the possible streamlining of criteria / procedures, COM noted that CAPA plans contain different details when submitted. The assessment team consists always of two COM representatives and two national experts. One main issue they face is that the quality of CAPA plans differs significantly.

b) Legal Requirements for Notified Bodies – Article 36(1) third subparagraph MDR / Article 32(1) third subparagraph MDR (employment of the key personnel) – state of play on the horizontal guidance by the Commission

The group was informed about a technical seminar on New Approach that tackled horizontal issues. It was emphasised that any plans for relocation would have to mean a real relocation including resources, capacity and of course including employment of personnel and their social security allocations. COM stated that employment should be covering essential elements such as payment.

One delegation expressed some doubts on whether these aspects can be covered by horizontal regulations and asked MDCG to reflect on it.

5) UDI – Unique Device Identifier

a) General state of play

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.

b) Publication of the call for issuing entities and first steps of evaluation

COM published a call on 21/12 until 25/1/2019 and four applications were received.

The four application files have been shared on CIRCA. Their evaluation will be concluded by end of February.

A preliminary view of the Commission is that, based on the legal criteria laid down in the Regulations and the provisions of the relevant call, there are no impeding reasons to exclude any of the applicant organisations from designation. The Commission asked Member States to raise any issue that they might have detected with any of the applications. There was no comment from Member States. Delegations were invited to submit their comments by end of February.

The Commission also clarified that all applications will be published on its external website upon consent of the applicants.

c) Endorsement of two guidelines:

i. Clarification of certain issues related to the basic guidance on Basic UDI-DI and changes to UDI-DI

The guidance was endorsed by the MDCG, with no modification.

ii. Guidance on products referred to in Article 1(8), 1(9), 1(10) of Regulation (EU) 2017/745

The guidance was endorsed by the MDCG, with no modification.

d) Nomenclature (state of play)

The Commission announced that in accordance with Articles 23 IVDR and 26 MDR, having due regard to the views provided by the MDCG, the CND nomenclature, to be mapped to the GMDN nomenclature, will be made available in the future Eudamed.

The correspondence between the nomenclatures will be visible to operators and incorporated in the future database. This will allow all operators registering their device to find CND nomenclature equivalent to a GMDN code. To the purpose of providing better regulatory oversight over the EU nomenclature system, a sub-group of the Medical Device Coordination Group (MDCG) will be soon established.

Ways will also be explored to support the work that the World Health Organisation (WHO) is carrying out in the field.

Any additional informational on the details related to the governance and operational functioning of the system will be provided in the course of the next few months.

IT provided a presentation explaining the commitments taken by the Italian Ministry in the context of the implementation of the new system.

While supporting the choice made some delegations pointed to the need to leverage on high-quality nomenclature to improve market surveillance and analysis activities.

An MDCG sub group on nomenclature will be launched and will be co-chaired by COM and IT, as they have significant experience in the field.

COM clarified that more details on next step will be explored at the dedicated sub group to be launched.

6) Document on principles to be applied for registration of MDD devices after May 2020 for endorsement

A document on principles to be applied for registration of MDD devices after May 2020 was discussed in relation to the registration of legacy products in the future Eudamed.

As UDI obligations do not apply to those products the situation is not clear. A scenario was discussed whereby legacy products placed on the market as from date of application of the MDR would not be registered at all in Eudamed. Relevant registration requirements under the MDD/AIMDD after date of application of the MDR would in this situation remain applicable to those products.

An exchange of views with MDCG followed with several MS highlighting their concern vis-à-vis the scenario discussed, which in their view could compromise vigilance and market surveillance. COM asked for written comments to be provided by delegations. Based on that, a new document will be presented at the next MDCG meeting for endorsement.

7) Eudamed (state of play on the implementation plan and the Functional Specifications document)

COM highlighted the high number of WGs with which the Eudamed team is working in collaboration beside the MDCG and as a consequence, the high numbers of feedback and opinions making the gathering of requirements challenging.

COM introduced a new version of the functional specifications (version 4) pointing out the changes in the timing priorities. Only the functional specifications with the timing priority “High (1)” will be for first release to go-live in March 2020. The ones with timing priority “Medium (2)” will be in a next release before end of 2020. The “Low (3)” functionalities will follow later.

COM explained that we are at least 6 months behind schedule for having the requirements defined, which means that only the actor, UDI/Device, NB & certificate modules and part of the Vigilance module (serious incident report, field safety corrective action and field safety notice) should be ready with the essential requirements in first release. The other part of Vigilance module and the clinical investigation and market surveillance modules will be available later in further release(s) in 2020.

COM explained that the upcoming audit will consider only functionalities related to a specific release identified from the timing priority. Further audit(s) will be performed for next release(s) until the full scope of the functional specifications is covered, therefore, until Eudamed is considered fully functional. COM would welcome any comment from the Member States before end of February and it will publish the Eudamed functional specifications reviewed version on Europa as soon as possible after that.

IE was asking for more details on schedule for next releases following the first one. COM explained that it is too early yet to provide such details. COM will do its best to come with a fully functional Eudamed as soon as possible.

8) Interpretation of Article 54.2 (b) MDR guidance document for endorsement

A document on interpretation of Article 54.2 (b) MDR was examined and finally endorsed by MDCG, with one modification. The main conclusion is that the expression "device already marketed" cannot be intended to refer to a device already marketed uniquely under the new Regulation. However, modifications for devices that have already been marketed under the Directives other than those needed to comply with the MDR do not fall under the exemption of Article 54.2 b.

It was also agreed that further clarifications on this aspect will be provided in the near future.

9) The standardisation request to CEN/CENELEC (state of play)

An updated draft of the COM standardisation request was outlined. Among others, some standards were added or removed from the list, and the deadlines for the key standards were extended until May 2020 to avoid the need for a modification of the request in case of delays in standards development. The draft may be further modified according to the developments regarding the parallel standardisation request in the field of personal protective equipment (PPE). MDCG members were invited to send their comments by 10/3/2020. A new consultation of the stakeholders in the standardisation field will be launched in the coming days.

10) Annex XVI products (state of play)

COM informed on the processing of feedback received and informed that the next step would be a public consultation of the stakeholders. According to a preliminary estimation of the comments received until now, there is still a number of diverging views.

Some delegations acknowledged the huge work already done and COM reassured that all diverging opinions will be tackled.

11) Requests under Article 13 of MDD – for information

This was a general point brought up by COM in relation to some recent requests sent by Member States competent authorities inquiring guidance on qualification of products. It was noted that qualification and classification are of national competency and that it is extremely time consuming if COM receives requests subject to comitology, whenever there is a disagreement between MS or within the same MS. COM asked MDCG members to consider this route only in exceptional cases such as those of high public health concern.

12) New Scientific Bodies – state of play

JRC informed on the progress on the work concerning the implementation act for the expert panels. They emphasised that the expert panels must be organised in a way to accommodate all types of requests in the framework of the clinical evaluation consultation procedure and that a high workload is expected which will challenge the organisational framework and the experts. It was clarified that the dossier documents should be submitted to the panel in English language as the Commission will not be able to provide translations. The draft Implementing Act will be sent to the MDCG Task

Force on Scientific Bodies for comments as soon as a stable draft is available. Some MDCG members proposed that stakeholders could be also consulted at some earlier point of the process. JRC plans to call for a meeting of the MDCG Task Force on Scientific Bodies in the second half of March.

13) Vigilance

COM presented three separate documents. It was decided that revised versions will be presented in a future MDCG meeting following adjustments, pursuant to the comments received during the meeting. The Post–Market Surveillance and Vigilance working group at its next meeting on 4-5/3/2019 will examine these documents further.

(a) MPSRF – Manufacturer Periodic Summary Report form for endorsement

The main issue which needs to be addressed in the document is whether the document would be applicable only under the new Regulation or also under the current Directive as the scope of incidents to be reported changes. One Member State also asked for a review of the MPSR form after a period of two years from its entry into application.

(b) Device Specific Vigilance Guidance on Cardiac Implantable Electronic Devices for endorsement

This is a guidance document template for manufacturers for the harmonised reporting of incidents for this type of devices. It was noted that there was a need for wording alignment with the applicable legislation especially as regards the use of the term ‘adverse” incidents.

(c) Device Specific Vigilance Guidance on breast implants for endorsement

This is a guidance for manufacturers of breast implants for the harmonised reporting of incidents for this type of devices and adaptation to regulatory framework; in practical terms same wording alignments needed as in point (b).

14) Common specifications under IVDR and CTS under IVDD (state of play)

Discussions are currently ongoing in the IVD group regarding priorities for future common specifications under the IVDR. Competent Authorities were encouraged to provide their views on this within the IVD group.

15) CAMD – Competent Authorities for Medical Devices (state of play)

The Chair of CAMD updated on the work and the efforts of the network to be more transparent and engaging. During the last meeting in Brussels early February, the network examined their rules of procedure for the election of chair. It was concluded that if the chair decides to step down there is no need for a vote but the vice chair takes over. The current Presidency of the Council will not organise a CAMD meeting. A document on the future of CAMD will be sent to MDCG.

16) AOB

- France raised the issue of ethics committees that will have an even more important role under the MDR; following the example of authorities for medicinal products they proposed to introduce some exchanges with ethics committees in order to facilitate the transfer of information between them. COM noted that they would wish to be informed if this initiative materialises between competent authorities.

- UK delegation briefly updated on their national situation as regards Brexit preparedness. As reflected in NANDO, BSI NL (related to BSI UK) has been designated under the Medical Devices Directive.

- Next MDCG meeting: 09-10/4/2018.

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 - EXCUSED
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.	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), General Directorate for Health, Ministry of Health and Solidarities
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	LI	Office of Public Health, Lichtenstein
17	LU	Ministry of Health Luxembourg
18	MT	Ministry of Health – EXCUSED
19	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
20	NO	Norwegian Medicines Agency
21	PL	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
22	PT	National Authority of Medicines and Health Products, I.P. (INFARMED)
23	RO	National Agency for Medicines and Medical Devices
24	SI	Agency for Medicinal Products and Medical Devices
25	SK	State Institute for Drug Control
26	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
27	SE	Medical Products Agency (MPA)
28	TR	TMMDA – Turkish Medicines and Medical Devices Agency – EXCUSED
29	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- JRC F2
- DG SANTE F5
- DG GROW D4