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, 08.05.2018

Minutes

Meeting of the MDCG and stakeholders
Brussels, 05 March 2018

1) Opening, adoption of the agenda

2) Objectives of the meeting

MDCG met with the representatives of the competent authorities and the stakeholders which had attended the already existing MDEG stakeholder group under the Medical Device Directives. The purpose of the meeting was to update the stakeholders on the ongoing implementation work with regard to Regulations (EU) 2017/745 (MDR) and 2017/746 (IVDR).

3) Follow up with regard to decisions taken in the MDCG meeting of 28/11/2017

The update on the documents endorsed in the first MDCG meeting of 28/11/2018 was provided, notably:

- MDCG governance documents;
- guidance for notified bodies on application and designation procedures;
- revised MIR form.

The milestones of the last months were summarised:

- Implementing Regulation 2017/2185 on designation codes for notified bodies;
- mandate to SCHEER to produce guidelines on phthalates;
- COM/CAMD roadmap on priority work items (incl. guidance) to be finalised during the transitional period; the process included joint COM/CAMD workshops with stakeholders on 9/3/2017 and 18/10/2017;
- EUDAMED: 5 meetings of the Steering Committee and 15 meetings of the *ad hoc* Working Groups related to the different modules took place;
- transitional provision: 1st Q/A paper finalised by the CAMD task force and published on the CAMD website.

Stakeholders stressed that sufficient time should be given to respond to consultations and that the relevant documents need to be available on the COM website. They emphasised the need to have sessions for stakeholders more frequently.

4) MDCG governance

PPT presentation was given. The need to use synergies between the clusters was emphasised.

Stakeholders indicated the general need for clarifications on the structure of some of the proposed working groups.

5) Implementation of MDR/IVDR

(a) Implementing Acts (state of play)

COM presented the state of play. The Implementing Regulation on the codes to be used by notified bodies when applying for designation has been smoothly adopted in time by the end of November 2017. Another implementing act on the application for designation as a notified body has been dropped due to technical difficulties. The implementing act on reprocessing of single-use devices makes good progress. Other implementing acts are in preparation, including the one on expert panels and reference laboratories. The implementing act on the so called Annex XVI products has made good progress regarding the general requirements which are applicable to all six product groups. The development of product-group specific requirements takes more time. Stakeholders will be consulted as soon as possible regarding both the implementing act on reprocessing and the implementing act on Annex XVI products.

Stakeholders inquired whether there is a room for giving input to COM regarding the structure of the Implementing Acts and whether stakeholders could take part in drafting. COM explained that due to the many drafting constraints, it is too time consuming and a waste of resources to involve stakeholders at the stage of drafting, but COM will duly integrate their input and proposals.

As regards the common technical specifications, e.g. for electrical products, it was indicated that they already exist and should be used.

(b) presentation from the CAMD Implementation task force

PPT presentation was given, which will be available on the CAMD website. By the end of April 2018, questions can be submitted. CAMD and COM will work jointly on the replies.

Stakeholders raised questions regarding the status of the CAMD, the schedule of its works, and the available resources.

6) Eudamed (state of play)

COM presented the state of play of the Eudamed implementation. Important progress has been made for the first set of modules (Actors, UDI/Devices and Certificates), especially for the actor registration and NB & Certificates. Due to changes in rules for Basic UDI-DI assignment beginning of last quarter of 2017 decided by the UDI Task force for guidance on UDI, there is some delay for the UDI & Devices module. The first acceptance testing session for the actor registration will take place on 12/4/2018. Only persons from or delegated by members of the Eudamed Actor registration WG may participate.

All the modules have been tackled in Eudamed *ad hoc* working group meetings (the last one for market surveillance at the beginning of March 2018).

For the time being, the focus is on the definition of the functional specifications in order to provide their implementation plan before 26/5/2018.

The main project milestones are: the implementation plan, finalisation of the definitions of all the functional specifications, process descriptions, data models and business rules - by October 2018, in order to have Eudamed development completed by September 2019 for the audit, and finally, to have Eudamed 'go live' before 26/3/2020. More details are available in the slideshow presentation.

The stakeholders pointed out to the different transition periods for UDI (date of application) and device data (18 months from date of application). How and who will determine what is to be audited for verifying if Eudamed is fully functional or not?

COM is aware of this difficulty, which is more related to the requirement of having all UDI data available in Eudamed from the beginning. It is a challenge, but it is a key identifier of the device in the database. On the other hand, some flexibility will be offered for the device data that could be provided at the same time or later. For the audit, COM and the MDCG should agree on what should be audited in order to check that Eudamed is well considered as fully functional for the first release. The deliverables to be provided by October 2018 for the purpose of the audit need to be determined.

7) Joint assessments of Notified Bodies

COM provided information on the state of play of joint assessments (JAs), in particular the smooth rhythm with which applications are being received. These have been already followed by a number of preliminary assessment reports (PARs), which are the element that triggers the appointment of JA teams and the corresponding scheduling of JAs. The first on-site joint assessment is expected to take place in April.

COM also made reference to the intense preparatory work that has been done in relation to JAs, including progress on the following issues: i) the development of a number of best practice guides (BPGs), which are now available not only at the NBOG site, but also at europa.eu, ii) national experts, both in relation to their training and their availability, and iii) the streamlining of our own resources (i.e. that only one COM expert would participate in a substantial number of JAs). As a result, applications and PARs progressing as expected, COM is reasonably confident that JAs will not be a bottleneck in the process of designation of notified bodies (NBs).

Several stakeholders expressed concerns about the transparency of the process, the resulting planning difficulties, the capacity of the system to ensure timely assessment of all designation applications, and therefore, the overall availability of the notified bodies. There is a need for more information on the applications submitted. Small and medium manufacturers may be particularly affected.

COM explained that as to JAs, and in anticipation of their potential large number, the crucial point has been the preparatory work that has been done (and continues to be done) jointly by COM, NBOG, the JAs coordination group and national designating authorities at large. COM could not commit to a particular number of JAs, since their organisation is contingent upon the corresponding submission of PARs by the designating authorities, which itself is a factor on the robustness of the application submitted by the NBs.

As to having enough NBs designated, it must be noted that whereas the designation of NBs necessitates JAs, there are other essential elements in the process which are outside of COM control, notably the performance of the NB concerned and, as a result, the speed with which the national designating authorities will be able to resolve the non-compliances identified during JAs.

COM indicated that the designation process is fully transparent, since it is explicitly set out in the corresponding BPG, which is publicly available. That said, and as far as JAs are concerned, the balance between confidentiality and transparency is, due to the constraints of the legislation, clearly tilted towards confidentiality. That situation limits the amount of information that could be disclosed by COM (or by the national designating authorities). That said, such restrictions would not apply to the NBs concerned, to which questions could be addressed.

COM also confirmed that the current experience (on designations under Implementing Regulation (EU) No 920/2013) shows that the average time needed for designation has been 18 months. Nevertheless, it could not be assumed that the timeline will remain the same, considering in particular that the first round of JAs will largely focus on procedures.

The outcome of the survey undertaken by a group of notified bodies Team NB reflected some of the needs of differed industries. The surveyed notified bodies have increased the number of employees and their overall capacity.

8) UDI (state of play)

PPT presentation was given. The working group on UDI with two task forces works together with COM. *Ad hoc* task force, established in May 2017, includes stakeholders and authorities.

It was observed that the UDI creates a lot of work for the notified bodies. COM explained that the UDI is new to European devices. The Basic UDI will not change often, but is very important to identify the product and links to the relevant information.

9) Harmonised standards - alignment to MDR/IVDR – process for the standardisation request to the European Standards Organisation (the "mandate")

Regarding the mandate for future standards under the new Regulations, there is a majority preference both of stakeholders and of Member States for so-called broad mandates, meaning mandates that encompass many different standards. However, some standards are more important and more urgent than others. Accordingly, some of the approximately 230 standards that will be covered by the future mandate(s) will have a narrow and some others a more remote deadline. The issuing of the new mandates will take quite some time due to several procedural and formal constraints, though some structural obstacles seem now to be solved. The priority order of the standards to be worked on should be decided together.

Regarding the publication of standards under the current Directives, COM has no delay. The cross-sectoral average publication rhythm of 18 months has never been exceeded in the sector of medical devices. But we face a quality problem. Most standards submitted by CEN/CENELEC have not reached the quality level needed for their citation in the EU Official Journal.

Stakeholders expressed their concerns as regards the timing for the alignment of all standards to the new Regulations. The delayed mandate results in further delays for the industry. Industry needs certainty on which standards to apply. Furthermore, it was noted that the lists of standards in the Official Journal contains many superseded standards.

10) Corrigendum to MDR/IVDR (state of play)

Good feedback has been provided by stakeholders and passed on to the Council. The corrigendum should be available in 2018. Any additional correction suggestions should be provided in the following two weeks.

11) Full refurbishing of medical devices in the context of policy on circular economy

Full refurbishment is a process to get a device to work as a medical device. It changes the purpose of the product. Regulatory questions arise as regards the definition of a "full refurbishment" and the rules on placing of medical devices on the EU market.

PPT presentation was given by COCIR.

12) Choice of nomenclature under the Regulations

The need for industry to have stability of the nomenclature, detailed standards for the product groups, and different nomenclature for medical devices and IVDs were discussed.

13) IVDR update on guidance classification and common specifications under IVDR

PPT presentation was given. By the end of the year classification guidance should be available. The task forces started their work and the results should be available by the end of 2018/beginning 2019. Common specifications under the IVDR will be discussed within the working group.

14) Communication campaign (update)

A presentation was made on the planning for the communication campaign to be launched by COM in the spring of 2018.

15) AOB

(a) Vigilance Working Group

Presentation was given. The need for support in the task force was emphasised. Discussions will continue.

Industry emphasised the need to keep the templates short.

(b) Clinical Investigation and Evaluation Work Packages

The outcomes from the three Work Packages were presented.

Industry emphasised that more guidance was needed on sufficient clinical data for lower class devices. Additional time to comment on draft documents was needed due to coming Easter holidays.

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.	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 (Sanita)
14.	LV	Ministry of Health
15.	LU	Ministère de la Santé - Direction de la Santé
16.	NL	Ministry of Health, Welfare and Sport
		Dutch Health and Youth Care Inspectorate
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 (ANMDM)
21.	SK	State Institute for Drug Control

22.	SI	Agency for Medicinal Products and Medical Device (JAZMP)
23.	ES	Spanish Agency of Medicines and Medical Devices (AEMPS)
24.	SE	Medical Products Agency (MPA)
25.	CH	Swissmedic – Swiss Agency of Therapeutic Products
26.	TR	TMMDA – Turkish Medicines and Medical Devices Agency
27.	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Stakeholders:

- AESGP
- CED
- CECED
- CEN-CENELEC
- COCIR
- CPME
- EAAR
- EHIMA
- ESC
- EUCOPE
- EU-NESS
- EUROMCONTACT
- EUROM VI
- EUROTECH
- FIDE
- GIRP
- GMDN Agency
- GOPA Com
- HOPE
- MedPharmPlast Europe
- MedTech Europe
- NB-MED
- TEAM-NB

Commission:

- JRC – ISPRA / GEEL
- DG SANTE F5
- DG GROW D4