

Minutes of the expert groups

Brussels, 26 November 2019

Minutes

Meeting of the Medical Devices Coordination Group¹ (MDCG) and Stakeholders
30/09/2019, Brussels

1. Opening, approval of the agenda

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

2. Nature of the meeting

MDCG & Stakeholders meetings are not public; they are intended only for MDCG members and participating stakeholders.

3. List of points discussed

a) Agenda item 2 – Implementation of MDR/IVDR

General overview: Commission recognised the effort required for the implementation of the two new Regulations within the foreseen timelines. It was noted that implementation of the new legislation is a shared responsibility which relies on the active engagement and cooperative spirit of each single party. Although a lot of progress has been achieved so far there are still many challenges ahead. COM presented in brief the main achievements so far as well as the main next steps. It was noted that a lot of information can be found at the dedicated Commission website which is regularly updated: https://ec.europa.eu/growth/sectors/medical-devices_en. As usual the Rolling plan implementation can be found at https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en. Furthermore, it was announced that new documents with information on guidance under development in various subgroups will be soon made publicly available at the same website. The main objective is to enhance transparency regarding relevant Commission activities. As regards specific implementing measures, the Commission informed that work is ongoing and in particular they thanked stakeholders who had sent comments on IA on reprocessing of single-use medical devices; on IA for Annex XVI products consultation of stakeholders has not started yet as the internal consultation in the Commission is still ongoing.

MDCG subgroups activities: the Commission reminded that a list of all meetings is published (https://ec.europa.eu/growth/content/medical-devices-list-events-2019_en) and stakeholders will be better informed after the publication of the guidance documents mentioned above; for the moment they briefly updated on the main current activities of each MDCG subgroup, keeping in mind that the following is not an exhaustive list of their activities:

Notified Bodies Oversight (NBO): sampling of devices, explanatory note for MDR codes, batch verification for class D for in vitro diagnostics, application of article 54.1-b), update of the document Q&A for Notified Bodies (NBs), outstanding issues on diverging opinions and

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transitional provisions for NBs as well as harmonisation of procedures between designating authorities in the context of Joint Assessments.

Market Surveillance: guidance on Class I manufacturers, development of Eudamed requirements for the market surveillance module, guidance for authorised representatives and guidance on custom made devices. Work to start soon also for in house manufacturers and revision of the requirements for the responsible person for regulatory compliance.

Annex XVI: the main objective of the subgroup is to develop common specifications for products listed under Annex XVI of Regulation (EU) 2017/745; as soon as these are developed there will be more specialised guidance and work is expected to start with development of guidance on qualification of devices. Commission was asked by one association to consider a grace period for these products as they have not been regulated before and manufacturers have to implement a lot of changes. European Commission took note of this comment but reminded that the application date according to the Regulation is six months after entry into force.

Clinical Investigation and Evaluation (CIE): guidance on equivalence, on sufficient clinical data, templates for input to Eudamed, coordinated procedures for clinical investigation and cooperation with IVD subgroup, transparency rules, common specifications on coronary stents, clinical investigation for products bearing the CE marking and other clinical investigation based on national rules and development and update of the work programme of the subgroup.

Borderline and Classification: update of guidance on borderlines with pharmaceuticals including main text, herbal products and definitions (pharmacological, metabolic and immunological means of action and diagnosis), classification of medical devices, Helsinki procedure (specific cases brought for discussion by competent authorities), possible future guidance on selected topics on borderlines with tissues and cells and biocides.

Post-Market Surveillance and Vigilance (PMSV): development of an updated version of MIR (Manufacturer's Incident Report) form to be published soon together with the XML file, a help text and a Q&A document; discussions on PSUR (Periodic Safety Update Reports), work on field safety corrective action and periodic summary report almost completed, new vigilance guidance on MDR and a dedicated transparency task force examines access to public for parts of MIR forms.

Unique Device Identification (UDI): the subgroup examines issues of UDI including interpretation of article 18 MDR, implant card; it also collaborates with Eudamed as UDI is one of the main modules of the database. Implementing act designating the issuing entities has been adopted; currently working on guidance on integration of quality management system of manufacturers and assignment of UDI in a specific device types such as contact lenses and spectacles; in parallel aiming at collaboration with USA in order to align relevant requirements, stakeholders will be consulted as well; working to establish a UDI helpdesk so that operators applying UDI can be supported.

New Technologies: this subgroup combines work previously done under two groups, one on software and one on new and emerging technologies. Main current work includes the development of guidance on cybersecurity, working on a draft act for electronic instructions for use, regulatory considerations for app stores, internal consultation in the field of artificial intelligence and medical devices in the existing regulatory framework. The next work output

from the subgroup for MDCG endorsement is expected in December, this guidance addresses clinical evidence for medical device software. Guidance on Qualification and Classification of software has been developed and will be presented to MDCG for endorsement at the meeting on the following day, 1/10.

Nomenclature: first meeting to be held early October and will focus on the extraordinary revision of the Classificazione Nazionale dei Dispositivi medici (CND). The aim is to develop the future European Medical Devices Nomenclature (EMDN). The work will also include a governance guideline, a GMDN-EMDN mapping exercise, cooperation with the WHO, establishing guidance on the EMDN for the future nomenclature and guidance on the use of EMDN. The Commission informed the group that EMDN will be translated into all EU languages and that validation by Member States on those translations will be necessary.

Responding to questions, the Commission reassured that stakeholders are systematically consulted on the development of guidance and the same practice will continue for the future.

b) **Agenda item 3 – Notified Bodies designation process under MDR/IVDR**

3.1. Commission update progress report on joint assessments: Five NBs have been designated under the new framework and more joint assessments are organised and will take place before the end of the year. At the time of the meeting there were 51 applications, 40 for MDR and 11 for IVDR. The system is moving towards full capacity, with 80% of the current NBs having applied for designation under the MDR and about half of existing NBs having applied for designation under the IVDR. In addition it was reminded that Joint Assessments rely on the collaboration between competent authorities of MS and the Commission and noted that the number of diverging opinions in 2019 was only 4; this reflects also the work done at the level of NBO/MDCG in order to reach consensus on various issues. The average time of the joint assessment process is being 13 months, and based on this average (and others concerning the last part of the joint assessment process) the forecast is that there could be 20 designations by the end of 2019.

3.2. Industry feedback:

- MedTech Europe shared some feedback from their members based on their experiences from contacts with NBs and areas in which they would like MDCG to work on. Their main concerns regard NBs capacity to deal with the Regulations and there are strong doubts on whether the existing 58 NBs have the capacity to renew all existing certificates; other concerns: on the sampling guidance; increased fees of NBs without adequate transparency e.g. publication of fees on their website; possible effects on entry delays for innovative products in the European market and readiness of the overall regulatory system for the transition.
- COCIR presented from their side the essential elements for MDR implementation that in their view are still missing: NBs, harmonised standards, Eudamed, guidance e.g. on clinical evaluation, post-market surveillance and vigilance and reporting templates. It was highlighted that it is crucial for manufacturers to make full use of the grace period and asked for the extension of grace period to Class I devices; challenges in particular in grace period for medical software; proposed creation of a common industry

position on significant changes according to MDR; support for the work done at international level under MDSAP which facilitates industry when placing their products beyond EU markets; with regards to obligations for economic operators under MDR: special attention should be paid in order to avoid duplications especially for verification activities and incident reporting.

3.3. Notified Bodies feedback: Team NB, NB-Med (representing Notified Bodies). Based on replies received on a survey of 40 NBs they provided comments on designation process, capacities of NBs and measures to improve the implementation of new Regulations. Based on the number of applications for designations of NBs under MDR/IVDR as announced by the Commission, they confirmed that the grace period for 4 more years is essential as it is not possible to certify all products for all manufacturers under the new Regulations on time. They mentioned better communication is needed between interested parties as regards diverging opinions; reclassification guideline (it will have an impact on the planning for resources for NBs); Corrigendum; European harmonised approach on definition of employment and in general they stated that they need more guidance in order to support implementation process; for combination products and when there is no significant change no need for consultation.

- c) **Agenda item 4 – New scientific bodies:** Commission informed on the main characteristics of Implementing Act (EU) 2019/1396 on expert panels published early September; the act provides the general framework for the designation of the expert panels and basis for the relevant call for expression of interest which has just been published. There will be ten expert panels on medical devices and one on IVD and on top of these a “screening panel”. Panels can be structured in sub-groups. A coordination committee is tasked with the governance of the work of the panels. Appointment of advisers will be done by the Commission for a period of three years and they will be remunerated for their work. Eligible applicants that are not appointed to an expert panel may be included in a central list of experts for a period of five years for replacements and temporary assignments. The expert panels will have a broad spectrum of advisory roles to the European Commission, the Medical Device Coordination Group, Member States, Notified Bodies and manufacturers.

The Commission updated on the recently published call for expression of interest for expert panels on medical devices and *in vitro* diagnostic medical devices. Development of the scientific and technical aspects of the Implementing Act and call for experts by JRC was supported by several rounds of consultations and input from the MDGC and stakeholders. The call was published on 27 September and will remain open until 10 November. The selection procedure against the eligibility and selection criteria outlined in the call will run for approx. 2 months with support of a Selection Board composed by relevant Commission Services and EU Agencies. The final outcome of the selection procedure will be ranked shortlists for each panel with candidates that are eligible, have suitable clinical, scientific or technical expertise and no conflict of interest as outlined in MDR Article 107. Appointment to expert panels or inclusion in the central list will be done by the Commission in consultation with the MDCG.

The call is already published on the Commission website but in order to ensure reaching out to as many recipients as possible, a dissemination plan has been established; among others it includes notifications to the recipients of the Medical

Devices newsletter and advertisement through the official Commission accounts on Twitter and LinkedIn. The Commission strongly encouraged Member States and stakeholders to support the dissemination activities in order to attract a large number of candidates for this important task.

- d) **Agenda item 5 – EUDAMED**: Commission provided a short update on the development of Eudamed. Due to the complexity of the project COM is closely collaborating with many MDCG subgroups; more than ten EUDAMED working groups meetings took place in 2019 until now – and more are scheduled to follow. Two playground versions have been already opened (only accessible to persons delegated by EUDAMED WG members) since beginning 2019 on actor and UDI/Device registration to test and to provide feedback for improving the system. New releases of the playground will continue to be made available before the end of the year. Another playground on certificates should be available early next year and still a lot of work to be done on clinical investigation and vigilance. Requirements for clinical investigation application and serious adverse event are expected to be defined early next year. There are ongoing consultations with the Legal Service for the EUDAMED Implementing Act which may impact the development of Eudamed and the schedule for its go-live. The Commission aims at achieving full functionality of Eudamed by May 2022, at the same time as the application of IVDR.

Industry representatives expressed some concerns on whether manufacturers will be able to provide information in their own language and whether the step by step deployment of Eudamed could cause delays or increase costs for actors who have already put in place their own IT systems. In response to these concerns the Commission explained that the User Interface will be translated in all EU languages but that all translations will not be necessarily available at the beginning (especially user guides) whereas this may be possible for the user interface. As regards the chronology of full functionality the Commission reassured that they are currently analysing very carefully all options for identifying the best workable solutions.

- e) **Agenda item 6 – Unique Device Identifier (UDI)**: this point was covered under the update for MDCG subgroups, in particular the one on MDCG subgroup on UDI.
- f) **Agenda item 7 – The standardisation request to CEN /CENELEC**: Commission thanked stakeholders for their comments provided on the draft standardisation mandate; at the same time an interservice consultation within the Commission is ongoing. Further information will be provided when this consultation is completed.
- g) **Agenda item 8 – IVD**

8.1. General overview: the first meeting as an MDCG subgroup took place in June and the next one is scheduled for November; a work programme is being reviewed. The group was informed that the IVD subgroup is following closely all activities of other MDCG subgroups. Ongoing work includes IVD classification, performance evaluation and summary of safety and in collaboration with medicines agencies of MS performance and assays used in clinical trials for medicinal products.

8.2. Common technical specifications update: as regards common technical specifications on combined tests under IVDD, the CTS was adopted and published in July. The final update of common technical specifications for in vitro diagnostics on

self-tests is currently undergoing a TBT notification and it is expected to be adopted and published in coming months. As for common specifications (CSs) under the IVDR, the IVD MDCG subgroup is running a prioritisation exercise taking the classification guidance into account to determine for which devices CSs are needed and what should be the timeline and process for drafting CSs. The group is also currently working on two draft CSs for which proposals were submitted by MedTech Europe (Chagas & Syphilis + Duffy & Kidd).

- h) **Agenda item 9 – Guidelines on the benefit risk assessment of the presence of phthalates in certain medical devices:** guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices, covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties, were provisionally endorsed by the scientific committee SCHEER in June and after a consistency check by the European Commission they were published in August.

- i) **Agenda item 10 – International issues**

10.1. Report from IMDRF-16 management committee meeting: this update concerned also the new MDCG subgroup on International issues that will cover such activities in the future. International MD Regulators forum objective is to reach convergence and seek common solutions as much as possible between the main jurisdictions around the world. EU (COM + MS) participated in the recent Management Committee meeting held in Russia (17-19/9/2019) and main issues discussed concerned standardisation, nomenclature (WHO), training proposal on UDI and implementation table. The next management committee meeting will take place in Singapore from 17-19/3/2020. There is a need for more representatives from more competent authorities of MS to participate in these working groups.

10.2. Developments with regard to MDSAP – Medical Device Single Audit Programme: EU and WHO are observers in this programme which aims at single audits of a manufacturer in order to fulfil the requirements of more than one geographical jurisdiction as regards QMS and GMP requirements. Following trade discussions with the USA a Task Force has been set up to develop guidelines on how MDSAP reports can be taken into account by MS.

- j) **Agenda item 11 – Communication campaign:** The Commission gave a presentation on the ongoing information and communication campaign on medical devices. The presentation focused on the results achieved during the first phase of the campaign and on the activities planned until May 2020.

Among the achievements of the first year of the campaign, the presentation indicated the following: a mapping of relevant stakeholders (over 2000 contacts in and outside the EU) and outreach towards them via direct emailing, newsletters, social media targeting and phone follow up; a new online information hub created on DG GROW's website (regularly updated); 6 factsheets finalised and available on the website and disseminated to stakeholders; 2 step-by-step guides – available on the website and disseminated to stakeholders; pop-up /roll up/banner designs produced in multiple languages for stakeholders to use for their events and further dissemination; mapping of specialised media (approx. 1500 contacts in and outside the EU).

The plan for the second phase of the campaign foresees: a general revamping of the online hub on medical devices to make sure the information is easily retrievable; new informative factsheets and webinars.

4. Next meeting

Next MDCG & Stakeholders meeting will take place in 2020, date not defined yet.

5. List of participants

No	MDCG Member/ Observer	Institution/Organisation
1	AT	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)
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
18	LU	Ministry of Health Luxembourg
19	LT	State Healthcare Accreditation Agency, Ministry of Health
20	LV	Ministry of Health – EXCUSED

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)

Stakeholders:

- | | |
|-------------------|------------------------|
| - AESGP | - EUCOPE |
| - AISE | - EUROMCONTACT |
| - APPLIA EUROPE | - EUROM I |
| - BEUC | - EUROM VI |
| - BIOMED ALLIANCE | - FIDE |
| - CED | - GIRP |
| - CEN-CENELEC | - GMDN |
| - COCIR | - HOPE |
| - CPME | - IAMERS |
| - EAAR | - Medicines for Europe |
| - EBE | - MedPharmPlast Europe |
| - ECOO | - MedTech Europe |
| - EFLM | - NB-MED |
| - EFPIA | - SBS |
| - EPF | - SMEUNITED |
| - ESC | - TEAM-NB |

European Commission:

- GROW D4
- SANTE F5
- JRC