Minutes of the expert groups

Brussels, 03 December 2019

Minutes
Extraordinary Meeting of the Medical Devices Coordination Group[1] (MDCG)
on EUDAMED
Brussels – 21 November 2019

1. EUDAMED – state of play

The Commission welcomed the participants to this extraordinary MDCG meeting dedicated to EUDAMED, the European database on medical devices established by Regulation (EU) 2017/745 (MDR). The meeting was organised further to relevant requests by some MDCG members notably to discuss more in details the issues arose at CAMD (Competent Authorities for Medical Devices) Transition Sub Group meeting held on 7 November 2019.

COM recalled that it had communicated to MDCG and the CAMD Transition Sub-Group two messages in relation to the delayed entry into operation of the database.

- On 29 October COM shared a note clarifying that, further to legal analysis, it was concluded that, in order to ensure full legal compliance with the MDR, only when COM has verified that the entire EUDAMED electronic systems have achieved full functionality on the basis of an independent audit, COM will be entitled to publish a notice to that effect in the Official Journal. This means that the progressive entry into operation of EUDAMED (e.g. module by module) would not be possible. The notice to be published in the Official Journal will only be issued after 26 May 2020;

- Another message with further analysis of the legal implications of the delay of the entry into operation of EUDAMED was communicated to MDCG on 20 November 2019.

DE, IE and DK expressed their concerns for the delay and have asked to focus on concrete actions that would ensure coordination at EU level and coordination with CAMD.

COM reassured that they also support as much convergence as possible by exploring concrete actions that will lead to operational outcomes.

2. Analysis of implications of postponement of entry into operation of EUDAMED

COM elaborated on the scope of postponement of EUDAMED and the obligations in relation to article 123(3) (d) MDR. The relevant regulatory framework can be summarised as follows:

- The obligations and requirements that relate to EUDAMED will become legally binding only after 6 or 24 months (depending on the obligation) from the date of publication of the notice in the OJ. Before that moment, it will not be possible to impose obligations related to part(s) of the EUDAMED system.

[1] Published in the Register of Commission Expert Groups and Other Similar Entities, code number X03565

- Until EUDAMED is fully functional the corresponding provisions of the Directives 90/385/EEC and 93/42/EEC (MDD) shall continue to apply for the purpose of meeting the obligations that relate to the exchange of information. Conversely, the application of requirements that are strictly related to the practical operation of EUDAMED (as the use of the Single Registration Number – SRN) would be postponed.

- However, until EUDAMED achieves full functionality, the authorities of the Member States could consider, in the framework of the cooperation within the MDCG, to establish common harmonised administrative practices for the application of Article 123(3) (d) MDR. The establishment of common harmonised administrative practice could concern the alternative systems by which the exchange of information would be performed in absence of EUDAMED as well as the possible voluntary use of EUDAMED-related tools (as the Actor registration module in order to make possible obtaining the SRN).

- EUDAMED 2 will be in force until the new fully functional EUDAMED is available and all Directives are repealed (IVD included).

Responding to questions COM clarified that existing EUDAMED 2 will continue with the same set of data (no expansion) and with the same purpose of exchanging data between Member States, therefore, only the National Competent Authorities have the responsibility of entering data in EUDAMED 2; economic operators are not concerned.

Also during the discussion, COM shared the view of some MDCG members that the previously mentioned article 123(3) (d) MDR does not provide enough details; therefore, they proposed to explore the possibility of guidance development through MDCG in order to establish the necessary administrative practice for exchange of information.

Further to the above, COM presented their view on the comprehensive document prepared by the CAMD Transition group on the interpretation of article 123(3) (d) MDR and the possible procedures for the exchange of information to be implemented in absence of EUDAMED.

Overall COM agreed with the analysis made by CAMD and highlighted the following:

- Registration of devices will be postponed.

- UDI registration will be postponed but no need to postpone Basic UDI-DI and UDI-DI assignment and UDI labelling.

- A MDR SRN must be obtained through EUDAMED and economic operators will have to register themselves at a certain moment in time through EUDAMED in order to get a SRN and have access to the system.

- As regards several aspects, COM proposed to facilitate exchange of information between COM and MDCG members through CIRCABC platform.

- With respect to clinical investigation and vigilance there are already some templates developed by the relevant MDCG sub groups and it can be reflected how to make best use of them. Notably, the work of the MDCG sub group on clinical investigation should continue to address the issues specifically related to the use of EUDAMED in this sector.

MDCG members expressed various concerns, mainly LT on the use of UDI and whether it can be used on a voluntary basis, DE on whether SRN can be used on a voluntary basis and on the fact that it is a rather national obligation which entails the obligation to identify the right tools to do that. BE and NL supported the voluntary approach for the use of SRN issued by EUDAMED.

It was noted that for MS that already have national registration schemes like DE there may be a need to reflect on possible changes of their national provisions in order to transmit a clear message to all concerned stakeholders.

COM underlined the possibility to rely - on voluntary basis – on the EUDAMED actor registration module, that will be ready on May 2020. In particular, it would be possible to rely on such module for the purpose of generating and issuing – always on voluntary-basis – a pre-SRN (that at a later stage when the notice for a fully functional EUDAMED is published will be the official SRN), thus facilitating economic operators wishing to rely on this tool and avoiding disruption of procedures. This arrangement could be reflected in a dedicated MDCG guidance as soon as possible.

DE asked for guarantees from the Commission that this first module will be operational in May 2020.

3. Operational conclusions and possible actions

COM will consider offering a statement that EUDAMED actor registration module will be ready May 2020 at the forthcoming EPSCO – public deliberation.

Guidance development: COM proposed the urgent development of the following guidance documents with the objective to try to achieve endorsement of these guidance documents at the MDCG meeting scheduled for 13 December, 2019:

- Procedures for exchange of information in the absence of EUDAMED.
- Use of EUDAMED 2 (to be addressed to competent authorities only).
- Guidance on the voluntary use of the EUDAMED Actors registration module and use of the SRN (to be addressed also to economic operators).
- Guidance on clinical investigation (at later stage).

MDCG members noted that the endorsement of guidance on 13 December 2019 could be too ambitious and expressed concerns on voluntary collaboration on the actors' module.

SE and IE asked for the involvement of their Heads of Agencies (depending on the administrative organisation in each MS) before committing to adopt specific alternative procedures for the exchange of information in the absence of EUDAMED. In addition, IE and DE expressed scepticism on whether MDCG was the right forum for discussion and the need to understand their legal obligations arising from the delay and identify commonalities amongst them. They also mentioned the need to define a long term strategy to mitigate the consequences of the delay.

COM recalled the forthcoming discussion at high political level at next EPSCO on 9 December and the fact that the MDCG is the highest level group in accordance with the legislative framework, where MS can nominate their representatives at the level they wish. COM also expressed the willingness to combine both the definition of a long term strategy but also the urgency to adopt concrete operational measures very soon.

4. AOB

- The next Health Ministerial Council (EPSCO) is scheduled for 9 December and implementation of medical devices legislation will be included (again) in the agenda for discussion by the Ministers.

- Corrigendum: at the last meeting of the Council working group (13-14 November 2019) no delegation expressed any objections so it is expected that Council should approve by late November, early December the text which will then be forwarded for approval to the European Parliament.

- Ongoing written consultations of MDCG: draft Implementing Act on Reprocessing; guidance on sampling of devices for the assessment of technical documentation; explanatory note on MDR codes: deadline for all is 2 December. As regards the Implementing Act on Reprocessing, MS were exhorted to share their comments and to clarify their interest, if any, to have a conference call to discuss in details the last draft before the next MDCG.

5. Next meeting

Next MDCG meeting: scheduled for 13 December 2019.

6. 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 - Excused
7	CZ	State Institute for Drug Control
8	DK	Danish Medicines Agency
9	EE	Estonian Health Board
10	FI	National Supervisory Authority for Welfare and Health (VALVIRA)
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) – excused
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) – excused
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	Turkish Medicines and Medical Devices Agency – excused
32	UK	Medicines and Healthcare products Regulatory Agency (MHRA)

Commission:

- DG JRC F2
- DG SANTE F5
- DG GROW D4
- DG SANTE A4
- DG GROW R3