EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

Health systems, medical products and innovation
Medical Devices

Minutes of the expert groups

Brussels, 24 March 2020

Meeting of the Medical Devices Coordination Group[1] (MDCG) – High Level Session 11/03/2020

MDCG meetings are not public and they are intended only for MDCG members. Due to the rapid developments and challenges caused by COVID-19 the meeting was transferred from a physical meeting as initially planned to a virtual meeting with video-audio connection.

This High Level meeting was an extraordinary session further to a specific call by EPSCO (Employment, Social Policy and Consumers Affairs) Council meeting of 9 December 2019 and the MDCG meeting on 13 December to come up with a Joint Implementation/preparedness Plan (JIP) in order to agree on priority actions to be undertaken in order to have an operational system in place by May 2020. It is noted that Regulation (EU) 2017/745 becomes applicable on 26 May 2020 and although a lot of work has been done, there are still challenges ahead.

Further to the above, the Commission services prepared a draft JIP based on input from competent authorities in particular the CAMD EG and other relevant stakeholders. Following receipt of comments by some countries (BE, DE, DK, IE, IT, FR, LV & SE) JIP was revised and sent back to delegations.

1) Approval of the agenda

Agenda was approved.

2) Joint Implementation Plan (JIP) – Discussion and endorsement

The Commission appreciated the input and comments received by competent authorities in preparation of the JIP and noted that the intention is to ensure delivery of actions in priority areas identified:

- EUDAMED database
- Ensure placement of safe devices on the market and combat potential shortages
- Clinical evaluations and expert panels
- Implementing acts.

At the same time, European Commission contacted relevant main European associations prior to the meeting (MedTech Europe, COCIR, AESGP) and Notified Bodies associations requesting information / data regarding market situation on certificates and devices.

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

Based on the information received so far, from the previously mentioned EU associations and 33Notified Bodies, it seems that most manufacturers have either already recently received a certificate under the current legislation or are in the end phase of this. According to figures provided by a majority of the notified bodies designated for the existing legislation, on average 93% of the devices that have recently been submitted to them for a new certification or re-certification under the current legislation are likely to have obtained a new certificate by 26 of May 2020, while for 7% additional information from the manufacturer is still pending. It was, however, underlined that the results should be interpreted with caution as not all actors replied and some replied with non-quantified data.
The Commission confirmed that monitoring will be continued and asked MDCG members to liaise with all actors in their national markets and share any available data or other information.

MDCG members were generally supportive of the JIP and decided to endorse it as a pragmatic approach considering the short deadlines and limited resources. The recent developments due to the corona virus situation was underlined and it was agreed to carefully monitor the situation and its potential impact on the implementation of the plan, including additional constraints on resources. MDCG decided to strengthen in collaboration with the European Commission the monitoring of implementation. MDCG at a more operational level will continue examination of new relevant guidance documents as appropriate in relation to JIP. Furthermore, compilation of data is a key issue and the European Commission could take a coordinating role facilitating the exchange of information between national competent authorities and economic operators as appropriate.

3) EUDAMED

The Commission stressed that the development of EUDAMED, as reflected in the Joint Implementation Plan, is one of the highest priorities and that there is strong intention to achieve full functionality by May 2022. The main points highlighted were the following:

- The Commission committed to making the development of EUDAMED a transparent process, ensuring that all relevant parties stay updated along the way. The development of EUDAMED is a joint project that requires the input and support of all parties, in particular on the second set of modules (clinical investigations, vigilance, and market surveillance).
- Participants were informed about a newly established MDCG Subgroup on EUDAMED to facilitate the link between policy and IT discussions and to streamline communication between all parties. MS were encouraged to nominate representatives. In a second step, stakeholders would be invited to participate as well.
- The Commission committed to making available to Member States the six different EUDAMED modules on a gradual basis, that is, as soon as they are ready. This would allow all parties to gradually adjust their systems and practices to the new modules and, at the same time, leverage the benefits of each module already prior to May 2022.
- Participants were reminded that the first module on Actor Registration will be made available to Member States by May this year. It was stressed that this module builds the foundation for all other modules and that therefore it is crucial that MS agree on taking a common approach to using it. Next modules in line are on device registration (UDI) and certificates.

- The Commission highlighted that achieving full functionality of EUDAMED by May 2022 is an ambitious task and that it is necessary to focus on the essential elements of the different modules, which means a basic functional system that will enable all parties to meet their obligations under the new Regulations.
- The Commission mentioned that it was in the process of redrafting guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional. The document would follow a slightly revised approach focusing in particular on solutions and practices that bring 'added value' and minimise potential additional burden on the parties.

MDCG members overall supported the intended approach to roll out modules gradually and, although they expressed regret of the postponed launch of EUDAMED, participants agreed on the need to collaborate in order to meet the target of May 2022. Some concerns were raised regarding the legal status of the actor registration and other modules. The Commission stressed that it would make available each module to national authorities and that it was for the latter to decide and ensure full use of modules by economic operators on their territory. MDCG members also supported the proposed approach on guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional. The Commission suggested that operational measures in relation to these topics could be further discussed at the ordinary MDCG meeting, which takes place the following day.

4) AOB

Corona Virus [COVID -19]

Recent developments have been rapid and have added additional burden on public health systems and patients in general. At EU level there have been a number of crisis management meetings and there is a call for better cooperation across Europe in particular as regards medicinal products and medical devices. The Commission asked for exchange of information and specific proposals by Member States on how to improve collaboration and information sharing.
At the same time the Commission informed that the dedicated MDCG subgroup on IVD (In vitro diagnostics) focuses at present on exchange of information on available diagnostic tests therefore participants were asked to provide input through this network.
MDCG members noted that the corona virus public health crisis adds an extra burden on the already limited available resources.

Next meeting:

Next MDCG meeting: **12 March 2020**

List of participants:

MDCG members: AT, BE, BG, HR, CY, CZ, DK, EE, FI, FR, DE, GR, HU, IE, IT, LU, LT, LV, MT, NL, PL, PT, RO, SI, SK, ES, SE.

Observers: CH, LI, NO, TR

Commission: SANTE B6, SANTE A4, SANTE F5, JRC F2, EMA (European Medicines Agency)