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, 17 December 2019

Minutes

Meeting of the MDCG Subgroup Notified Bodies Oversight (NBO)
Brussels, 24 June 2019

1) Opening, adoption of the agenda

COM welcomed the participants and highlighted the ambitious agenda of the meeting which fully reflects the intensive job performed in the area of Notified Bodies.

It was specifically asked to include in the agenda aspects related to the EUDAMED module for notified bodies and certificates to be covered under point 12. The Agenda was approved.

2) Adoption of the minutes of the meeting on 29 March 2019

Comments received on the draft minutes were discussed. COM highlighted that minutes of the MDCG WGs are intended to be drafted in accordance to common principles, providing the essential information concerning topics discussed and decisions. The updated version of the minutes will circulate after the meeting for approval and then be published in the Registry for Commission Expert Groups for transparency reasons.

3) Rolling plan

Taking the Rolling plan and also the CAMD Roadmap of the MDR/IVDR implementation as a basis, the NBO will develop its work programme identifying priorities and a tentative timeline.

Starting from the different guidance documents already under development, the work programme should identify which are the areas the group will have to focus on and where the work needs to be intensified. Currently no additional items should be added.

4) Validity of the certificates issued according to the Directives after the repeal date

It is essential to give clarity on the conditions for validity of certificates issued in accordance to the Directive during the transitional period (i.e. May 2024). In particular, Article 120 of the MDR allows validity of these certificates under certain conditions.

A draft position paper was prepared by COM and sent to the group in advance of the meeting. Following the discussion, a new version of the text will be sent to the group for written consultation.

5) NB designation status under MDR/IVDR – state of play

COM made a presentation on the state of play as regards the joint assessment process. The updated information was presented at MDCG meeting of 20 June.

COM stressed the challenges found in process of designation and it proposed to organise a meeting for ex-change of experiences with designating authorities (Das) in order to facilitate the review of different actors.

6) Diverging opinions

In order to address the three remaining diverging opinions between the joint assessment team and the designating authority raised during joint assessments, COM proposed three background documents for discussion. The three remaining diverging opinions are concern the following topics:

- Tasks to be carried out in accordance to Art. 36 (Art. 32) and Section 4.1 of Annex VII of the MDR (IVDR)
- Re-certification activities
- Employment linked to the internal clinician

The intention is to address the abovementioned issues in Q&As to be presented for endorsement at the next MDCG.

Following the discussion held during the meeting, the background documents will be modified and sent back to the group for written consultation.

7) Q&A on NB designation process

A new set of Q&A was sent to the group for written consultation in advance of the meeting. COM thanked those Member States who sent comments for the valuable contribution provided. The modifications performed following the written consultation were discussed and further additional changes were made.

The modified version of the document will be sent again to the group and also to associations of notified bodies for written consultation. The intention is to agree on a new set of Q&A to be submitted to the MDCG for endorsement and then be added to the published document MDCG 2019-6.

8) Guidance documents and possible areas to work on

Key information form. A draft template was sent the group for written consultation. The vast majority of comments received have been incorporated in the document. Further comments were raised and addressed during the meeting. The agreed text will be sent to the group and submitted for endorsement at the next MDCG.

Procedure on significant changes in accordance to Art. 120 of the MDR. COM encouraged the group to send comments on the joint industry position on significant changes. The plan is to incorporate any future comments and then send the document for stakeholder consultation.

Applicability of the clinical evaluation consultation procedure. COM pointed out the need to provide clarification on the application of Art. 54(2)b and intends to set up a task force, jointly with the CIE WG. A call for interest will be launched in the coming days. Such task force is also expected to work on an update of the document MDCG 2019-3.

9) Task forces – state of play

COM informed the group about the state of play of the NBO task forces. In particular, three task forces are currently in place for the development of: (a) guidance on sampling of devices on a representative basis, (b) explanatory note on MDR codes and (c) guidance on batch verification on class D IVDs. Drafts of the first two documents are expected to be sent for consultation of both NBO and stakeholders in the coming weeks. The draft guidance on sampling will be also sent to the IVD WG for written consultation.

10) Notified bodies tasks under Article 16 and Article 17

Such kinds of activities are not covered by Chapter IV and Annex VII of the Regulations but require notified bodies to issue individual certificates. In order to ensure the application of a common approach, the group suggested proposing to NB MED to work on a draft of agreed requirements such certification activities should comply with.

11) IMDRF

COM stressed the importance of the involvement of the EU in the MDSAP (Medical Device Single Audit Program). There will be a TC on the next days and documents can be sent to MSs should they wish to provide comments within the short deadline.

12) Updates from other WGs/Stakeholders

COM informed the group about the NB MED meeting held on the 2nd April 2019, where notified bodies raised a number of questions related to the interpretation of the requirements laid down in the Regulations, some of which have been addressed in the Q&A presented under point 6.

Following the MDR EUDAMED NBs & Certificates WG held on the 21st June 2019, COM drew a number of issues to the attention of the group. The following decisions were taken: (a) a modification of the name of the device/group of devices cannot be reflected in an amended certificate; (b) EUDAMED should register as metadata information related to specific aspects of the device, including indications about sterility and the presence of tissue of animal origin; (b) the assessment report referred to in Art. 55 of the MDR should be interpreted as the clinical evaluation assessment report.

13) Draft Standardisation request under MDR/IVDR

COM provided an update of the state of play of the standardisation request. In particular, COM informed the group that the consultation of the internal services of the Commission will be launched in the coming days.

14) AOB, Rolling Agenda Item

This Agenda item was not covered because of lack of time.

List of participants

AT, BE, CZ, DE, DK, EE, IE, ES, FR, HR, LV, HU, NL, PL, PT, SK, FI, SE, UK, NO, CH.

Commission: GROW / D4, SANTE / F5, GROW / B1