EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical Devices

Brussels, 22 September 2020

Minutes

Meeting of the MDCG Subgroup Notified Bodies Oversight (NBO)
Brussels, 22 June 2020

1) Adoption of the agenda and minutes of the meeting held on 15th November 2019

Commission (COM) welcomed the participants and reminded that this meeting, originally planned for mid-March, had to be rescheduled to this day due to the pandemic. COM thanked NBO members for their support and contribution to the several initiatives driven by this MDCG Subgroup, both on the side of the implementation and lately also on the response against Covid-19. Taking into account the several relevant projects yet on-going or to be started, COM called MS for their active participation in the working items pursued by the group, including the many task forces (TFs) in place and to be set up requiring active participation and a lead.

COM presented the agenda of this meeting and the minutes stemming from the meeting held on 15th November, 2019. Both were adopted by the group.

2) Organisation matters

COM announced two news with respect to the co-chairmanship of the NBO:the replacement of the co-chair representing SANTE F and the new German co-chair representing MS, as agreed by the group. The two co-chairs were welcomed by the group.

3) Notified bodies under MDR/IVDR – state of play

COM made a presentation on the state of play as regards the joint assessment process. COM reminded participants about the obligation and importance of ensuring the availability of national experts to allow joint assessments to take place and the subsequent designations of notified bodies. COMencouraged MS to submit nominations and accept the call to take part in joint assessments when needed. The need for availability of national experts is particularly relevant in case of joint assessments carried out under the IVDR.

4) Follow-up NBO meeting with NBCG held on 16th June 2020

COM summarised the main topics discussed with notified bodies' representatives on 16th June 2020, and a number of them were covered in details. Concerning the possibility to perform

remote audits for initial MDR/IVDR certification, the matter will be discussed by the NBO TF on temporary alternative measures for notified bodies. In order to better tackle a number of issues raised by notified bodies, TFs will be set up on: appropriate surveillance according to Article 120(3) MDR, certificates to be issued in accordance with Article 16 (jointly with the MDCG Market Surveillance working group), template on standard fees (Article 50 MDR/Article 46 IVDR), provisions established by Article 117 MDR (involving also EMA representatives) and the designation process (including notification, re-assessment, extension to scope).

A document listing 14 questions raised by notified bodies was provided in advance to the meeting and presented by COM with the proposed replies. Replies have been agreed by the group and will be provided back to notified bodies.

COM also introduced another topic coming from previous discussions with notified bodies, namely the interpretation of codes MDT 2013 (for multiple use/reusable devices) and MDS 1001 (and its link to activities performed in accordance with Article 117). As a follow up of the meeting, COM will send specific questions to consult NBO members on these topics.

5) Work programme, priorities and taskforces

Feedback on the work programme from the end of November was taken into account and a new proposal was presented by the NBO co-chair, considering also the list of on-going MDCG guidance documents and the CAMD roadmap. The NBO was informed that the list of on-going MDCG guidance documents will be updated according to the discussion from today's meeting and MS were encouraged to send their feedback on the proposal presented.

The list of TFs in place was presented and NBO members were called on to volunteer in taking the lead. New TFs were also proposed by COM, including the ones described under item n.4 of the Agenda and one additional TF on the use of standard (to be set up jointly with the Standard working group). A call for expression of interests to take part and possibly lead the several TFs will be launched in the coming days. COM stressed the need for the MSs to take the lead of the TFs in order to ensure the work on the needed deliverable can be performed.

6) Process for designation, notification and re-assessment of notified bodies

COM put forward two topics to be clarified, also commonly raised by notified bodies, enquiring about the process for re-assessment of notified bodies and the extension of the scope of the designation. COM proposes either to review the best practice guidance on designation and notification, or to create a new guidance. As mentioned under agenda item n. 5, a TF will be established to tackle these topics.

7) New set of Q&A: feedback from the last NBO consultation

Following a consultation of the NBO on a new set of Q&A, COM is processing comments received. The updated document will be provided back to the NBO and to notified bodies for a new round of consultation.

8) AOB

MS are required to check if the list of contact points, including contact points for TSE, published on COM website is updated and communicate any needed change to the SANTE-MED-DEV functional mailbox.

List of participants

AT, BE, CZ, DE, EE, IE, ES, FR, HR, IT, CY LV, HU, MT, NL, PL, PT, SK, FI, SE, IS, NO, CH, TR.

Commission: B6/F5 SANTE,