MDCG Subgroup Notified Bodies Oversight (NBO)
MINUTES

Date & time: **07 October 2020** (10:00 – 13:00)

Venue: **Videoconference - WebEx**

1. Introduction and adoption of the agenda

COM welcomed participants to the third and last NBO meeting of this year – no other plenary meeting is scheduled for the rest of the year for the time being, however NBO taskforces will still be running via meetings, consultations and e-mails. COM informed that the minutes of the meetings held in June (16th and 22nd) have been agreed upon and are in the process to be published. The agenda was adopted.

2. Work Programme and Task Forces

The co-chair presented the latest version of the Work Programme, amended following the feedback received during the last NBO consultation. Participants agreed upon the Work Programme. COM also presented the state of play of the NBO taskforces, and invited Member States to volunteer for those currently lacking leadership. Following this discussion, COM considered presenting the agreed Programme to the MDCG for information.

3. Q&A on MDCG 2020-4

The Q&A relating to the MDCG guidance 2020-4 *on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions* was discussed to address operational implementation. A number of Member States provided their opinions on the calls from notified bodies and industry for initial audits to be conducted under the MDR, under certain conditions, and a discussion followed. COM emphasized the importance of having clear indications from Member States about their views, and invited NBO members to send their positions on the matter via email by the end of the following week. The matter will be then moved to MDCG.

4. New set of Q&A on requirements relating to notified bodies (MDCG 2019-6)

COM updated participants on the proposed new set of questions to be added to MDCG 2019-6. Proposed questions covers: (1) verification performed by final reviewers and decision makers and how impartiality is ensured, (2) meaning of "permanent availability" for clinical evaluation reviewers, (3) requirements for surveillance audits, (4) monitoring of internal personnel, (5) meaning of type of devices under Art. 46(8) IVDR and (6) definition

of subsidiaries. Next steps: new consultation to be launched, involving also notified bodies and IVD WG.

5. Follow up questions from NBO meeting held on 22nd June, 2020

COM provided participants with feedback relating to three follow-up questions, raised during the last NBO meeting. They related to (1) application of code MDT 2013, (2) application of code MDS 1001 and (3) submission of the Periodic Safety Update Report in the transitional period.

Consensus was found among Member States (all replies in agreement) on point (2): notified bodies do not need to be designated under code MDS 1001 to perform activities according to Art. 117, which require instead the notified body to be designated for the type of device in question.

Work remains to be done on the two other points. In particular, COM informed participants on the intention to establish a task force on re-processing of single-use devices – point (1) – and to follow up point (3) under the task force on appropriate surveillance according to Article 120(3).

6. Re-assessment of notified bodies – follow up NBO meeting held on 22nd June, 2020

COM presented advancements relating to the re-assessment of notified bodies, as required by Art. 44(10) MDR and Art. 40(10) IVDR, namely on elements such as processes, steps and timelines in line with the Regulations. COM raised a number of questions/aspects for discussion intended to be tackled by the relevant task force, chaired by COM.

7. Medical device – medical product combinations – Interface with Directive 2001/83/EC

COM introduces new obligations concerning the interrelation between the medical devices legislation and Directive 2001/83/EC on medicinal substance. A task force has been established to address those aspects, with the involvement of the European Medicines Agency (EMA). The EMA presented its considerations on the interface within the medical devices Regulations and Directive 2001/83/EC. A number of areas of uncertainties for which cooperation between medical devices and pharmaceutical authorities would be envisaged were mentioned. EMA also mentioned draft guidance in the field of combination products, and invited NBO members to attend the EMA webinar on MDR Article 117 scheduled on 27th November. Following a discussion with Member States, COM concluded that some terms and definitions regarding combination products needed to be tackled first within the NBO task force on Article 117, in order to ensure a common understanding.

8. Establishment of Notified Body Coordination Group (NBCG)

COM informed participants of the envisaged and needed cooperation between the NBO and the NBCG, consisting, among others, of bi-annual meetings to which COM and authorities representatives are invited. The next meeting will take place on the 8th of October 2020 and Member States, if interested, are invited to inform COM if they are willing to attend.

9. AOB

Due to time constraints, COM shortly updated participants on the follow-up from EUDAMED NB & Certificates Working Group's meeting from the 5th of October 2020. COM will send participants, per writing, points needing clarification, with particular reference to aspects relating to certificates to be issued in accordance with Art. 22(3).