MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time: **18 June 2021** (10:00 – 13:30)

Venue: **Audio meeting**

1. Opening, adoption of the agenda and minutes from the meeting held on 16 March

COM welcomed participants to the third NBO meeting of 2021.

The agenda was adopted with one additional point under AOB concerning EU-CH relations (see agenda item 6.c) below) upon request from one Member State (MS). Minutes of the meeting held on 16 March 2021 were also adopted.

2. Application Forms and Applied-for-Scope Forms – for NBO endorsement

The NBO task force on the designation process finalised updates of the MDR & IVDR[1] Applications Forms and Applied-for-Scope Forms. The documents were sent to the group in advance of the meeting. All the documents were endorsed during the meeting with some further editorial changes and will be submitted to MDCG for endorsement.

3. Certification activities according to Article 17 MDR

Following questions received by notified bodies on certification activities according to Article 17 MDR, COM drew to the attention of NBO members a number of issues related to such a certification process. In particular, requirements to be met by notified bodies to issue the certificate of compliance to the Common Specifications according to Article 17(5) were discussed by the group.

It was acknowledged that the MDR does not establish designation requirements for notified bodies to enable them to issue certificates according to Article 17. In addition, such activities are not covered by Chapter IV of the MDR. In was also noted that code MDT 2013 "Devices that have undergone reprocessing" of Commission Implementing Regulation (EU) 2017/2185 cannot then be used to that purpose. Those MSs allowing for reprocessing of single-use devices can decide how to regulate the relevant requirements for notified bodies

[1] MDR: Medical Devices Regulation (EU) 2017/745; IVDR: *In vitro* Diagnostic Medical Device Regulation (EU) 2017/746

by means of national legislation. There was a general agreement on the need to find a harmonised approach, and COM proposed to clarify the matter in a Q&A to be added to MDCG 2019-6.

Further elements were discussed relating to the "annual independent external audit of the reprocessing activities" in accordance with Article 22 of Commission Implementing Regulation (EU) 2020/1207. The possibility to make use of an external auditor from outside of the notified body was considered not appropriate by a number of MSs.

4. Work programme – state of play and update

COM provided an update of the state of play of the different work items included in the NBO Work Programme 2021. The group agreed that priority should be given to the following items:

- Update of the NBO BPG 2017-1, including re-assessment and extension to scope
- Guidance on certification according to Article 16 MDR/IVDR
- Guidance on "appropriate surveillance" according to Article 120(3) MDR

The group also agreed on the possible need to develop guidance on conformity assessment activities, to be discussed after priority files are closed.

5. Task force updates

COM provided an update on the work of the following task forces, all of them lead by COM:

- Article 16 certification activities: NBO/MSs/Stakeholders consultation completed, revised text to be agreed with the task force before NBO/MSs endorsement;
- Appropriate surveillance according to Article 120(3) MDR: waiting for feedback from the MDCG task force on transitional provisions;
- Activities to be performed according to Article 117 MDR: EMA Q&A on MDR/IVDR implementation updated and expected to be published soon[2];
- Designation process: documents under review/draft, next meeting scheduled on 30 June;
- Batch verification: NBO/IVD WG/Stakeholders consultation completed, timing (and content) to be aligned with Implementing Act on EU Reference Laboratories;
- Explanatory note on IVDR codes: text sent to MDCG for endorsement.

6. AOB – Any Other Business

a) Certification of class I sterile devices, requirements for notified bodies

On request of one MS, requirements for notified bodies relating to certification activities for class I sterile devices were discussed. The designation codes that the notified body has to possess were discussed in particular. The group agreed on the need for the notified body to have the required competence to assess the technical documentation and perform the appropriate verification of the sterilisation process developed for the concerned devices.

[2] See https://ec.europa.eu/health/md_sector/new_regulations/guidance_en under "Other guidance documents".

Some questions remained unsolved and the COM proposed to further follow-up the matter addressing the issue in a possible question to be added to MDCG 2019-6.

b) Pre-certification services – clarification on trainings provided by notified bodies

Upon proposal prepared by one MS, the group discussed a revised text for question I.6 of MDCG 2019-6 concerning pre-certification activities. The group generally agreed on the need to further clarify the training that notified bodies are allowed to provide and on the draft proposal that was submitted in advance of the meeting. The text will be sent out for NBO written consultation. It will also be sent to notified bodies for comments.

c) Update on EU-CH relations

COM confirmed that all the necessary information is available from the Press Release https://ec.europa.eu/commission/presscorner/detail/en/IP_21_2684 and the "Notice to stakeholders" issued by COM on 26 May 2021. From that day, CH became a third country to the EU and as such, all the requirements of the MDR apply to CH manufacturers intending to place devices on the EU market. Nevertheless, COM and CH are still working for a possible agreement on a limited update of the MRA that would cover some transitional provisions on certificates and authorised representatives in order to prevent problems or disruptions in supplies as most as possible. COM will provide more specific information when available and in the meantime invited MSs authorities to follow up the situation adopting a common pragmatic approach, looking forward to possible positive developments.

List of participants

NBO members: AT, BE, CY, CZ, DE, EE, ES, FI, FR, HR, HU, IE, IT, LV, MT, NL, PL, PT, SE, SI, SK.

Observers: IC, NO, TK.

COM: SANTE B6, SANTE F5.