MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time: **29 March 2022** (09:30 – 13:00)

Venue: **Audio meeting**

1. Opening, minutes from last meeting and adoption of the agenda

COM welcomed participants to the first NBO meeting of 2022.

Participants were informed that the commenting period for the draft minutes of the last NBO meeting is up to 19 April 2022.

The agenda was adopted with no changes in content.

2. Update MDCG 2019-6 – priority issues

Among the several work items linked to the update of MDCG 2019-6, the Commission identified priority issues to be urgently discussed with NBO members and a preparatory document was sent in advance to the meeting.

Concerning revision of question III.6 on the meaning of the term "employed", a new proposal was submitted by the Commission. The group generally agreed on the revised text but concerns were raised on possible misunderstanding. In particular, several authorities asked to clarify in the text that the practice of so-called "secondary contracts" would not fulfil the requirement of "employed by the notified body itself". Concerning the meaning of the term "internal activities", the group agreed to keep the current approach in the guidance and make the reference to Section 4.1, Annex VII to MDR/IVDR clearer. A new text will be circulated to NBO for feedback prior to consult notified bodies.

In addition, the meaning of "adequate experience in conformity assessments under this Regulation or previously applicable law in a notified body" in the context of qualification criteria established in Section 3.2.3 of Annex VII to MDR /IVDR was discussed and the group will be further consulted on the matter.

3. NBCG-Med meeting 5-7 April 2022

Invitation to the 66th NBCG-Med meeting which will take place on 5-7 April 2022 was circulated to NBO members. All NBO members are invited and COM encouraged participation.

4. State of play NBO Task Forces

Agenda item not covered due to time constrain. The presentation prepared by leaders of NBO TFs will be shared with the group.

5. Notified Bodies evaluation of Periodic Safety Update Reports (PSUR)

The group was updated on the latest development concerning the PSUR guidance, currently under consultation. NBO members recognised that the discussion on PSUR is complex and a number of unclear points were raised. Despite NBO acknowledged that this guidance should be handled as a matter of urgency, it was recognised that further discussion is needed on the requirements for notified bodies.

The group agreed to ask the PMSV WG for an extension of the consultation period in order to develop a NBO position on a number of key issues.

6. Status of Team-NB position papers

Team-NB published various position papers under the MDR as well as the IVDR with content which has not been discussed and agreed in any of the MDCG subgroups. Examples of such documents are the "Team-NB Position Paper Implant Card" and "Team-NB Position paper on Dental Implants-20200311-V1". Especially the latter raised concerns on conclusions drawn in respect to the applicability of the exemption rule to endosseous dental implants and dental implant abutments, why it would be appropriate for NBO to come to an agreement in respect to the status of such positions papers, especially which position designating authorities should take in respect to their "applicability" or "non-applicability" for notified bodies.

It was acknowledged that Team-NB position papers could be an important practical tool for notified bodies but there was also a general agreement on the very specific and limited status of these documents that are not agreed neither endorsed by MDCG.

Members were invited to send their position after the meeting. Based on this feedback, a common position will be developed. The applicability of the exemption rule should be followed up by the MDCG Borderline & Classification Group.

7. Pre-application or qualification of SWMD (separate modules) – experience from the Swedish authority

The matter for manufacturers of SWMD (Medical Devices Software) having difficulties to be accepted as manufacturers of medical devices by notified bodies was raised, as experienced in one Member State. NBO members have not experienced similar situations. The matter will be brought to the attention of the MDCG New Technology Group in case any specific follow up is needed.

8. Article 120(3) MDR and possible solutions for effective use of transitional provisions

COM informed about cases where manufacturers hold a valid EC design-examination certificate issued under MDD Annex II, section 4, while their Full Quality Assurance (FQA) system certificate issued under MDD Annex II (with the exception of section 4) will expire before the expiry of the EC design-examination certificate. The group discussed about the possibility during the transition period for manufacturers to "combine", under certain conditions, the MDD EC design-examination certificate with and EU QMS certificate issued in accordance to MDR. There was a general agreement on this approach, considered as a pragmatic application of the legislation, with only one MS raising concerns about this possibility.

NBCG-Med will be informed about this possible approach and MDCG guidance will also refer to that, when relevant.

9. AOB

No additional points were brought to the attention of the NBO WG members.

List of participants

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

Observers: NO, TR.

COM: SANTE B6, SANTE F5.