MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time: **16 March 2021** (10:00 – 12:30 & 13:30 – 16:30)

Venue: **Audio meeting**

1. Opening, adoption of the agenda

COM welcomed participants to the second NBO meeting of 2021.

COM proposed the addition of two agenda points under AOB (see below). The agenda was adopted.

2. Temporary extraordinary measures during Covid-19 exceptional circumstances and Commission Notice 2021/C 8/01

Following the agreement at NBO on 5th February, COM set up a dedicated CIRCA BC Workspace to allow MS to share information about temporary extraordinary measures taken by individual notified bodies.

Feedback from stakeholders raised concerns about possible diverging positions among the Member States on application of Commission Notice 2021/C 8/01. However, no diverging views were raised by NBO members. At the same time, during the MDCG meeting on 5th March, few MS asked for further exchanges on the matter. NBO members agreed to work on a common set of information to be provided when uploading information in CIRCA BC and to develop a common template. NL agreed to share their template to be used as a basis for discussion. The template will be sent to NBO members for consultation.

3. CECP practical aspects - follow-up meeting with notified bodies on 11th March

COM informed about the opening of the expert panels as from April 2021. In view of the opening, COM organised a meeting with notified bodies on CECP (Clinical Evaluation Consultation Procedure) on 11th March, NBO members were also invited. During the meeting, work instructions prepared by COM were discussed. Members suggested to limit the document to what is actually needed. The document will be revised and NBO members are invited to send their possible comments.

During the meeting, some concerns were raised by notified bodies in respect to changes in design and the possibility to trigger a CECP if the change is significant in term of clinical impact. It appeared that NBO members didn't share notified bodies' concerns and that

comments raised by notified bodies may be not fully in line with clarifications provided so far.

COM also informed to be about to launch an update of the notified bodies' survey on CECP and invited NBO members to encourage their notified bodies to reply.

4. Joint Assessments – state of play

COM shared an overview of notified bodies' activities at each stage of the joint assessment/designation process. COM informed that a total of 50 applications for the MDR and 14 for the IVDR are progressing at various stages throughout the joint assessment process. COM encouraged MSs to engage with their notified bodies that have not yet applied, in particular those who plan on applying for the IVDR. In addition, COM informed that it is awaiting submission from MSs of a number of preliminary assessment reports (PARs). COM encouraged their submission in as timely a manner as possible. There have been 47 on-site assessments completed to-date; in addition, 3 preliminary remote assessments have been performed. A further 2 assessments have been scheduled to be conducted. MSs were reminded to continue their efforts in the review of CAPA plans (as DAs and National Experts). At the time of the meeting, a total of 23 notified bodies were notified.

COM also informed that the number and availability of National Experts is at a critical low (particularly for IVDR) and reminded MSs of their legal obligations in the joint assessment process. MSs were also asked to respond to requests for participation as National Experts in as timely a manner as possible as JAT appointments have a legal timeline.

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: draft text provided to notified bodies for feedback with specific questions on surveillance activities and requests for examples;
- Appropriate surveillance according to Article 120(3) MDR: specific questions sent to the task force, feedback is currently being processed, next meeting scheduled on 25th March;
- Activities to be performed according to Article 117 MDR: bi-weekly calls scheduled with the participation of EMA; task force currently focusing on the revision of EMA documents (Q&A on MDR/IVDR implementation and Drug Device Combination guidance);
- Use of standards: draft guidance on use of standards for medical devices circulated for comments in February and sent for agreement of the concerned MDCG Sub-groups;
- Designation process: several on-going work items, including update BPG on designation and notification, define process for re-assessment and extension-to-scope and limitations – templates to be sent for NBO agreement;
- Batch verification: draft guidance on verification of manufactures batches of class D IVDs circulated to stakeholders consultation after comments received by the NBO and IVD Sub-groups;

- Explanatory note on IVDR codes: draft text circulated for comments and contribution in February, feedback received is currently reviewed by the task force.

6. Requirements to be met by notified bodies – Q&As – Update of MDCG 2019-6

A new set of questions was sent to NBO and notified bodies for consultation in October 2020. Due to other priorities, the work on most of the new questions as well as updates of existing questions has been temporary put on hold.

COM informed that the question concerning definition of type of devices will be followed up separately outside of the Q&A MDCG 2019-6 and handled with as a priority file. NBO will be consulted on a new text in the coming weeks.

7. System and Procedure Packs - certification activities according to Article 22(3)

COM informed about the agreement reached at the level of NBO following a consultation launched last October on aspects relating to certificates issued according to Article 22(3) of the MDR. The matter raised on the need to define specification in EUDAMED. In particular, the system will allow for the registration of such certificates either in coherence with the workflow already defined in EUDAMED for other quality system certificates or as stand-alone registration only for Article 22(3) certificates.

A discussion followed, with particular reference to the scope of those certificates. COM informed that a discussion is on-going with notified bodies to clarify their practice under both the MDD and the MDR. The matter will be further followed up when time allows for it.

8. IMDRF – Regulated Product Submission (RPS)

COM updated NBO members on the work of the IMDRF groups on either Good Regulatory Review Practice (GRRP), referencing recently published documents including documents for consultation, and RPS.

Concerning RPS, COM informed that the IMDRF Table of Contents (ToC) of pre-market submission is yet to be updated to include MDR/IVDR. Notified bodies have already been working on a draft update to be reviewed by NBO. The work is currently performed by COM with the support of DE. It is worth noting that the IMDRF ToC is not fully aligned with application for certification under MDR/IVDR and further discussion will be needed. Especially the question if notified bodies would use such a structure should be clarified upfront. COM asked other NBO members to support the work, nobody volunteered.

9. DA Surveillance activities

NBO Members have asked for harmonisation of documents to be provided by DAs under the MDR. It was explained that those activities are already contained in the NBO work programme but due to resource constraints not as current activities.

Communication processes in the absence of EUDAMED were discussed as a follow-up of the last MDCG meeting. NBO members were asked to liaise with their MDCG representatives to make sure that the DA perspective is adequately reflected in the processes to be set up.

Modalities of the upcoming monitoring activities in respect to the notified body's activities under the transitional provisions (Art. 120(3) MDR) have been discussed. It was agreed that – in line with MDCG 2019-10 rev.1 – the extent will vary over the time. In the beginning, special attention should be put on the implementation of new requirements resulting from Art. 120(3) MDR.

10. AOB

10.1 Notified Bodies survey on certifications and applications

COM informed that a request of data on notified bodies' certifications and applications was sent in January. Replies have been received by several notified bodies and are in the process of being processed.

10.2. EU Technical documentation assessment certificate for self-testing, near-patient testing and companion diagnostic devices

COM informed that MDCG has been recently consulted on the issuance of EU Technical documentation assessment certificate for self-testing, near-patient testing and companion diagnostic devices. The following common position was agreed: in case of class B, class C and class D devices intended for self-testing and/or near-patient testing and/or that are companion diagnostics, as an outcome of the multiple procedures mentioned in Article 48, the notified body should issue a single EU technical documentation assessment certificate. The certificate should be explicit in its scope, referencing the procedures in Article 48 that it covers.

List of participants

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

Observers: CH, IC, NO, TR.

Commission: SANTE B6, SANTE F5.