MDCG-NBO (Notified Bodies Oversight) Working Group

MINUTES

Date & time: **13 June 2021** (09:30 – 13:00)

Venue: **Audio meeting**

1. Opening, adoption of the agenda

The agenda was adopted. One Member State (MS) asked to discuss certificates to be issued by notified bodies for reprocessing of single use devices. COM proposed to cover the issue under Agenda item 3, where a specific question on designation requirements for Article 17(5) will be discussed.

2. EUDAMED – Deployment of NBs&Certificate module

COM announced that the EUDAMED UDI/Devices registration and NBs & Certificates modules have been successfully deployed in the Production environment beginning of October and are available for use. Notified bodies (NBs) designated under the MDR/IVDR are already registered in EUDAMED from NANDO. To start acting in EUDAMED, NBs need to have a first LAA (Local Actor Administrator), to be validated by their designating authority (DA). Member States asked for detailed information about the features being currently available / not available in the NBs & Certificates modules.

3. Update 2019-6

In advance to the meeting, COM circulated a proposal for a new set of questions. Individual questions were discussed. Concerning update of current question III.6 on the meaning of the term "employed" (MDR Article 36(1) / IVDR Article 32(1)), as proposed by COM taking into account concerns raised by notified bodies, NBO members expressed their views, requesting the proposed wording to be changed, preferred the current wording of the MDCG 2019-6 to be kept to a great extent and modifying it only where needed and justified.

Questions will be revised on the basis of the discussion and a new text will be sent for NBO consultation.

4. NBO Work Programme

a) Update on the designation process and re-assessment of notified bodies

COM summarised the work performed by the task-force on the designation process, highlighting revision of BPG 2017-1, including the re-assessment process, as priority matter. NBO as well as NBCG-Med will be soon consulted on the text prepared by the task-force.

b) Guidance Appropriate Surveillance

The need for a guidance on "Appropriate surveillance under Article 120(3) MDR" was identified as a priority by NBO. COM informed that a draft text has been finalised by the task-force on appropriate surveillance, with the involvement of notified bodies, and taking into account MDCG 2021-25. After agreement of the task-force, the text will be sent for NBO and MDCG & Stakeholders consultation.

c) Interfaces with other WGs (Guidance on PSURs)

Requirements for notified bodies are discussed in different fora, given that notified bodies' tasks are covered by several work streams. It is important to ensure that a coherent and consistent approach is taken. As an example, the draft guidance on Periodic Safety Update Report (PSUR) was mentioned which contains detailed specifications for notified bodies. NBO decided to propose in the upcoming PMSV WG Task Force meeting to take over the sections of the guidance concerning the evaluation to be performed by notified bodies into the notified bodies' template for the technical documentation assessment report.

d) 2022 Work Programme

COM informed that the NBO chair and co-chairs are working on the 2022 Work Programme and a first NBO consultation will be launched in the coming days. The group was informed that all MDCG Subgroup Work Progammes should be submitted for MDCG endorsement in March.

5. AOB

d) International matters – update from the Commission

The group was updated about several activities performed at International level. Main activities are related to the IMDRF working Group on Regulated Products Submissions (RPS) and Good Regulatory Review Practice (GRRP). In addition, exchanges with MDSAP authorities are regularly taking place.

e) Information on NBCG meeting 7 October 2021 10

On 07/10/2021 the NBO chair and co-chairs were invited to the bi-annual NBCG-Med meeting. CAMD co-chairs also attended. Main concerns raised by notified bodies were consultation of medicinal authorities for ancillary substance and need for a consistent application of COM Notice 2021/C 8/01.

f) Notification according to Commission Notice 2021/C 8/01 10

COM reminded about the agreement on CIRCA BC notifications concerning the use of temporary extraordinary measures as referred to in COM Notice 2021/C8/01 and thanked those DAs that regularly notify. All DAs are invited to make use of CIRCA BC to notify temporary extraordinary measures their notified bodies are applying and to flag any need for further reflections they may identify, including hybrid audits.

List of participants

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

Observers: NO, TK.

COM: SANTE B6, SANTE F5.