EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Directorate D – Consumer, Environmental and Health Technologies
Unit D4. – Health Technology and Cosmetics

Brussels, 23 June 2020

Minutes

Meeting of the MDCG Subgroup Notified Bodies Oversight (NBO)
Brussels, 15 November 2019

1) Adoption of the agenda and minutes of the meeting held on 24th June 201

COM welcomed the participants and highlighted the ambitious agenda of the meeting which fully reflects the intensive job performed in the area of Notified Bodies. The agenda was adopted.

The minutes of the meeting held on 24th June this year has been circulated and NBO members will be given 2 weeks to provide feedback.

COM announced the intention to appoint a NBO co-chair as representative of MSs (Member States). NBO members are invited to volunteer, decisions will be taken during next meeting

2) NBO Work programme

A draft work programme has been drafted to reflect needs and priorities. NBO members will requested to provide comments through written consultation. Result of the consultation will be discussed during next NBO meeting.

3) Implementation – state of play

COM provided an update of the rolling plan as well as the recently published list of on-going guidance documents, highlighting the key role played by NBO in developing essential guidance for the implementation of the Regulations.

4) Notified bodies under MDR/IVDR – state of play

COM made a presentation on the state of play as regards the joint assessment process.

COM stressed the need for designating authorities to submit nominations and availability of national experts in order to plan joint assessments.

5) Guidance on Sampling of devices for the assessment of the technical documentation and Explanatory note on MDR codes – for agreement

Both drafts have been subject to several rounds of consultation, including stakeholders. Texts resulted from the consultation have been provided to NBO. A discussion on contents followed and some additional improvements were made to the text. Both documents have been agreed by consensus and NBO agreed to submit them to MDCG for endorsement.

6) Document on Significant changes under Article 120(3) - results of consultation of NBO WG

Comments received by NBO members on the draft have been reviewed and presented by COM. Few additional changes were made on the text. NBO members will be given one more week for additional comments. The text will be then sent for consultation of stakeholders and relevant MDCG Subgroups.

7) Consultation procedure in case of devices incorporating a medicinal substance and/or utilising/incorporating substances of animal origin - result of consultation of NBO and B&C WGs

As result of the first consultation of the NBO and B&C Subgroups the draft text was reviewed, main outcome of the consultation was the need to clarify that notified bodies must repeat the consultations performed for certification under the Directives, though the relevant authority/EMA may decide to shorten the procedure under certain conditions.

A new version of the text will be sent for consultation to the relevant MDCG subgroups and stakeholders.

8) Open session with NB MED and Team NB – discussion with notified bodies

COM welcomed notified bodies representatives who have been invited to attend a dedicated session of the NBO meeting in order to enhance cooperation between regulators and notified bodies towards the implementation of the new Regulations. COM will try to organise such kind of meetings on a regular basis.

Notified bodies thanked NBO for the invitation and welcomed the possibility to discuss about implementation with regulatory authorities. Notified bodies made a presentation on main challenges identified. Topics discussed were especially interpretation of significant changes and appropriate surveillance in accordance with Article 120(3) of the MDR and provisions established in Art. 16 MDR.

9) New set of Q&A – for discussion

Concerning document MDCG 2019-6 "Questions and answers: Requirements relating to notified bodies", following the suggestion from one MS, it was decided to keep track of changes made into the document.

COM presented a new set of Q&A, mainly related to outstanding issues. Following the discussion during the meeting, a new version of the document will be sent to NBO for consultation.

10) Update of document MDCG 2019-3 on interpretation of Article 54(2)b of MDR – results of consultation of NBO and CIE WGs

Document MDCG 2019-3 has been updated by the NBO task force on Art. 54(2)b. The document does not modify the position of the MDCG but clarifies procedural aspects to be considered by the notified body in order to assess whether an MDD Class III implantable or a Class IIb active device to administer medicines should be subject to the Clinical Evaluation Consultation Procedure.

The document has been subject to consultation to the NBO and CIE Subgroups, relevant changes have been incorporated and the current version will be sent to stakeholders for consultation.

11) Designation and notification process - procedures and forms – for discussion

COM listed a number of documents and templates relating to the process for designation and notification that would need an update or to be developed in the near future. COM is looking for volunteers to work on the different subjects, including NBOG BPG 2017-1, form for Corrective Actions and Preventive Actions, forms NBOG F 2017-3/4 on applied for scope, forms NBOG F 2017-5/6 on preliminary assessment review templates.

12) Extension of scope and peer reviews – for information/next steps

COM is currently discussing both issues internally.

For extensions of scope, the intention would be to develop a text to be added in NBOG BPG 2017-1. With regard to peer review, COM is currently assessing resources needed for the next two years and would need to understand how many MSs are in principle interested in carrying these out as part of the surveillance activities.

13) AOB

This Agenda item was not covered because of lack of time.

List of participants

AT, BE, CZ, DE, DK, EE, IE, ES, FR, HR, IT, LV, HU, MT, NL, PL, PT, RO, SK, FI, SE, UK, CH, TR.

Commission: GROW / D4, SANTE / F5

Invited exceptionally only for this meeting: NB MED, Team-NB