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, 05 June 2019

Minutes

Meeting of the MDCG Subgroup Notified Bodies Oversight (NBO)
Brussels, 29 March 2019

1) Opening, adoption of the agenda

This was the first meeting in a new setting. i.e. as the MDCG subgroup. Commission will take care of the secretariat and for the time being will also chair the subgroup. Tour de table followed to introduce new members. Additional item was added under AOB.

2) UK withdrawal from the EU – state of play

COM recalled the guidance published on its website. In the case of 'no deal' scenario, the reference in the guidance to the UK's withdrawal from the EU on 29/3/2019 is to be read as the reference to 12/4/2019.

3) NB designation status under MDR/IVDR – state of play

COM made a presentation on the state of play as regards the joint assessment process. The updated information will be presented at MDCG meeting of 9-10 April.

4) Q&A on NB designation process

An updated version of the Q&A document incorporating suggestions for changes and comments from Member States was discussed. The majority of Q&As were agreed upon and the outstanding questions were identified for further discussion in future meetings. The agreed questions will be presented for endorsement in the MDCG meeting in April. This guidance will be a 'living document' that will incorporate the already endorsed MDCG positions related to notified bodies and will be updated as new issues are identified and resolved.

For questions related to the role of the internal/integrated clinician in the NB's assessment and decision-making process as well as requirements for re-certification of quality systems NBO members didn't reach consensus. The outcome of the discussion that took place will be presented in the MDCG meeting in April in a separate document, presenting the different views expressed.

5) NB feedback at MDCG on 14/2/2019

A number of questions raised by the notified bodies both in the MDCG meeting and to the CAMD Executive group were presented. Most of these questions are already covered in the Q&A document and possible additional questions will be discussed for future incorporation in that document.

6) Corrigendum

The corrigendum has been approved by co-legislators and awaits OJ publication. The content of the corrigendum was outlined, with focus on Annexes VII and IX.

7) Significant changes to certificates during the grace period

The position paper prepared by the industry was discussed. In principle, the document is a step in the right direction, whereas NBO will consider setting up a task force for the preparation of a guidance to be prepared by the NBO and endorsed by the MDCG. In the drafting process of such guidance, as well as for guidance documents referred to in point 8(a), representatives from notified bodies and other stakeholders concerned should generally be involved at an early stage.

8)

(a) Guidance development

A draft document 'key information form' has been presented on the basis of the document used for MDD designations and one of the final assessment reports sent by one designating authority. NBO members were asked to provide comments.

(b) Task forces for specific topics

COM invited Members to express their interest in the taskforces, aimed at developing guidance on the following topics: (i) explanatory note on the designation codes; (ii) sampling rules for technical files of Class IIa and IIb devices and Class C and B *in vitro* diagnostic devices; (iii) batch release of IVDs (in close cooperation with IVD TG). Circabc message with timelines will follow.

9) Status of NBs designated under the Directives after the repeal date

COM explained the intention to keep notified bodies designated and notified in NANDO under the Medical Device Directives after May 2020 with a 'marking' indicating that they cannot issue new certificates, but only carry out surveillance for the certificates which remain valid under the Directives. Some Member States expressed certain legal concerns related to this approach and COM committed to work on a position paper for discussion in the next NBO meeting in order to clarify COM's views and address the concerns raised.

10) Prolongation of issued certificates prior to completion of re-certification process

NBO members agreed that certificates can only be renewed when the re-certification process is completely finalised as otherwise the notified body will not have evidence of compliance with the relevant legislation. Therefore, notified bodies need to make sure that the re-certification is finalised on time prior to renew a certificate. For this reason, re-certification applications should be submitted sufficiently on time.

11) IMDRF (International Medical Device Regulators Forum)

COM presented the state of play as regards definition of criteria for pre-market approval auditing organisations and Regulated Product Submission (RPS).

12) **Update from other MDCG subgroups**

COM briefly updated on the latest developments and future work planning as regards the clinical investigation and evaluation WG as well as the Eudamed NBs and certificates WG.

For the notified bodies' activities in respect to the Summary of Safety and Clinical Performance (SSCP) clarification is still needed. The Commission informed that the SSCP would be presented for endorsement on the next CIE and invited the members to liaise with their CIE representative for any questions

13) Draft standardisation request under MDR / IVDR – state of play

European Standardisation Organisations do not support the draft, which lists specific standards and focuses on horizontal standards only.

The final text of the mandate will depend on the text of the parallel mandate in another sector (PPE – Personal Protective Equipment), whereas the focus on horizontal standards results from MDCG discussions.

14) AOB, rolling agenda items

(a) content of certificates for class I sterile devices

The group discussed about the actual case of a certificate covering a range of devices in a sterile condition without specifying the scope of intervention of the notified body. Following the discussion, for the content of certificates the NBO members referred to NBOG 2010-3 "Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC". It was suggested to contact the respective designating authority for further clarification with the notified body..

(b) NB certification activities under Article 16 MDR/IVDR and Article 17 MDR

These activities will be discussed in future NBO meetings.

List of participants

AT, BE, CZ, DE, DK, EE, IE, ES, FR, HR, IT, LV, HU, NL, PL, PT, SK, FI, SE, UK, NO, CH.

Commission: JRC / F2, SANTE /F5, GROW / D4