Medical Device Coordination Group (MDR/IVDR)
DRAFT AGENDA

Date & time: **11 March 2020** (14:30 – 18:00); and
12 March 2020 (14:30 – 17:00)

Venues: 11 March: **CHARLEMAGNE building (CHAR)**
room: **Lord Jenkins**
address: **170 Rue de la Loi, 1040 Brussels, Belgium**

12 March: **Conference Centre Albert Borschette (CCAB) –**
room: **CCAB 0.A**
address: **36 rue Froissart, 1040 Brussels, Belgium**

Please note points for endorsement: 4.3(a), 4.3(b), 4.4 & 6.1

1. Opening, adoption of the agenda
2. Adoption of the minutes of the meeting held on 13 December 2019
3. MDR / IVDR Implementation – wrap up from the High Level meeting
4. Notified bodies under MDR/IVDR

   4.1. Joint Assessments Progress Report

   4.2. MDCG recommendation on the draft designation of a notify body:

   a) Final assessment report of the designating authority and draft designation – summary presentation by the competent authority
   b) Final opinion of the joint assessment team – summary presentation by SANTE
   c) MDCG recommandation under Article 39(9) MDR

   4.3. Transitional provisions

   a) Guidance on significant changes [Art. 120.3 (EU) 2017/745] with regard to devices covered by certificates according to 90/385/EEC or 93/42/EEC – for endorsement
   b) Class I transitional provisions in Article 120 (3)(4) – for endorsement
   c) Guidance on transitional provisions for consultations of authorities on devices containing ancillary medicinal products and on devices manufactured using TSE susceptible animal tissues – for information

   4.4. Addendum to guidance document MDCG-2019-3 on interpretation of application of Article 54(2)b (EU) 2017/745 – for endorsement

5. Implementing Acts – for information

6. Clinical Evaluation

   6.1. Guidance on clinical evaluation and performance evaluation of medical device software – for endorsement

   6.2. Guidance on clinical evidence requirements needed for medical devices previously certified under Directives 93/42/EEC and 90/385/EEC (legacy medical devices) – for information

   6.3. Guidance on Equivalence – state of play

7. Expert Panels

   - State of play on the setting up of Expert Panels

8. Information Note on Transparency obligations – state of play

9. EUDAMED – conclusions and next steps

10. Exchange of views on market situation in the EU

    - Roundtable by MDCG members

11. IVDR specific topics (update)

    11.1. EU Reference Laboratories

    11.2. Common Specifications

12. International Matters

    12.1. EU Participation in the IMDRF (International Medical Devices Regulators Forum)

    12.2. Developments with regard to guidance on MDSAP (Medical Device Single Audit Programme)

13. AOB

    - CAMD (Competent Authorities for Medical Devices) – Update on activities by the Chair of CAMD

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