28 May 2015 14:30 to 17:30

Plenary

1. Welcome and approval of agenda

2. Approval of minutes
   2.1. MDEG meeting 17 November 2014 – ‘Plenary’

3. Documents for approval
   3.1 MEDDEV 2.7.2 Rev. 2 – Guidelines for competent authorities in making an assessment of a clinical investigation application (endorsed by the Clinical Investigation and Evaluation (CIE) Working Group)
   3.2 MEDDEV 2.7.3 Rev. 3 – Guidelines on clinical investigations: serious adverse events reporting (endorsed by the Clinical Investigation and Evaluation (CIE) Working Group)

4. Regulatory issues
   4.1 Revision of MDD, AIMDD and of the IVD Directive – State of Play
   4.2 Harmonised Standards and Mandates – information on recent developments

5. PIP Action Plan – update
   5.1 Joint assessments of notified bodies - update
   5.2 Presentation of JRC report on analysis of incident reporting of Medical Devices in the EU, EFTA and Turkey and EU pilot on vigilance and trending

6. International issues
   6.1 Update on International Medical Device Regulators’ Forum (IMDRF)
   6.2 EU participation as observer in MDSAP (Medical Device Single Audit Program) pilot
6.3 RPS (Regulated Products Submission) IMDRF pilot

7. Update on on-going mandates to the Scientific Committee

8. Written progress reports from Working Groups
   *Short written overview of main activities and Work Programme for 2015-2016*
   
   8.1 Borderline and Classification Working Group
   8.2 IVD Technical group
   8.3 Notified Body Operations Group (NBOG)
   8.4 Clinical Investigation and Evaluation (CIE) Working Group
   8.5 MDEG Vigilance
   8.6 Eudamed Working Group
   8.7 Software Working Group
   8.8 UDI Working Group
   8.7 MD Compliance and Enforcement Group (COEN)
   8.8 New and Emerging Technologies (N&ET)
   8.9 NB-MED

9. Other Commission Initiatives impacting Medical Devices
   
   9.1 Information on public consultation on the respect of intellectual property in public procurement procedures
   
   9.2 Follow up to the green paper on m-health

10. AOB

11. Future Meetings