



European Confederation of
Pharmaceutical Entrepreneurs AISBL

**EUCOPE
Regulatory/Pharmacovigilance/Medical Device
Working Group Meeting**

Date: 13 November 2018
2 pm – 3:30 pm

Venue: Teleconference

**Rue Marie de Bourgogne 58
1000 Brussels
www.eucope.org**

Telephone: +32 2 842 6982
Telefax: +32 2 842 6983
Date: 27 Sept 2018

TOP 1 Welcome / Next Events / Working Groups

TOP 2 Brexit implications on Regulatory Affairs

- Report from the CMDh meeting with Interested Parties (IPs)
- Outcome of the EMA Brexit meeting with stakeholders

TOP 3 Medical Devices

- Report from the Medical Device Coordination Group (MDCG); Notified Bodies – challenges (Jörg Plessl, Norgine)
- NAKI – national approach: German working group on the implementation of the new EU Medical Device and In-vitro diagnostic Regulations (Thomas Brückner, BPI)

TOP 4 AOB / Next meeting dates / Closure of meeting