



**EUCOPE**

European Confederation of  
Pharmaceutical Entrepreneurs AISBL

12 February 2020

EUCOPE offices  
Rue Marie de Bourgogne  
58 – 1000 Brussels

# **EUCOPE**

## **REGULATORY / PV / MEDICAL DEVICE**

### **WORKING GROUP MEETING**

EUCOPE offices Brussels 11am – 4pm CET

#### **Meeting agenda**

TOP 1 **Welcome / next events**

TOP 2 **Priorities 2020**

- Focus groups – composition and topic leads

TOP 3 **EMA Regulatory Science Strategy 2025**

- Follow up on the EMA stakeholder meeting (Lucia D'Apote, Amgen)

TOP 4 **Pharmacovigilance**

- Current status of discussion envisioning ICH review process (Wendy Huisman, Seattle Generics, tbc)

TOP 5 **Promoting RWE for regulatory purposes**

- Innovative approach for regulatory decision making (Jill Morell, Biomarin)

TOP 6 **Medical Devices – latest updates**

- Latest update on the activities of the Medical Device Coordination Group (MDCG) and working groups (Jörg Plessl, Norgine)

TOP 7 **AOB / End of meeting**