



**EUCOPE**

European Confederation of  
Pharmaceutical Entrepreneurs AISBL

16 October 2019

11.00-16.00 CET

EUCOPE offices, 2<sup>nd</sup> floor  
Rue Marie de Bourgogne, 58  
1000 Brussels, Belgium

## **EUCOPE MEMBERS MEETING AGENDA**

- TOP 1 Welcome / New Members / Next Events / Working Groups**
- TOP 2 The FDA Europe Office** (Ritu Nalubola, FDA Europe Office Director)
- Mission and Objectives
  - Update on the US/EU collaboration
- TOP 3 The strategic and long term political agenda of the EU**
- Challenges and opportunities for the pharmaceutical industry (external speaker, FTI)
  - EUCOPE Advocacy Group's recommendations to members for their engagement strategy
- TOP 4 EU-Proposal on Joint HTA**
- Expected Shortcomings
  - EUCOPE Positioning
  - Outlook on the German EU Presidency 2020
- TOP 5 Priorities of the Croatian EU Presidency in the health care sector** (tbc)
- TOP 6 Third parties' access to Clinical Trials Data** (Peter Bogaert, Covington)
- Update on the EMA's transparency policy
  - Pending court cases
  - Broader context
- TOP 7 The European Commission's evaluation of the EU [Blood](#) and [Tissues and Cells](#) legislation** (European Commission, tbc)
- TOP 8 Latest updates from the EMA – stakeholder interaction**
- Regulatory Science Strategy 2025
  - Status of the [Clinical Trials Information System](#)
  - Qualification of digital methodologies for medicine development
  - Parallel consultation with regulators and HTA bodies
- TOP 9 Pricing & Reimbursement Country Updates**
- TOP 10 AOB / End of meeting**