



EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

25 June 2019

11.00-16.00 CET

EUCOPE offices
Rue Marie de Bourgogne, 58
1000 Brussels, Belgium

EUCOPE MEMBERS MEETING

AGENDA

- TOP 1 Welcome / New Members / Next Events / Working Groups**
- TOP 2 The Implementation of the MDR – an Update from the European Commission**
(Salvatore D'Acunto, Head of Unit & Salvatore Scalzo, Legal Assistant, Unit D4 - Health Technology and Cosmetics, DG GROW, European Commission)
- TOP 3 The Outcome of the European Parliament Elections** (Petra Wilson, FTI)
- Predictions of the election's effect on healthcare legislation and non-legislative EU politics
- TOP 4 HTA Collaboration beyond 2020**
- What will happen to the proposal for an EU HTA Regulation?
 - Joint HTA: Establishing harmonised methods on the verge of legislation (Nina Seiler & Alexandra Thiele, AMS Europe)
- TOP 5 The European Medicines Agency's Priorities and Regulatory Strategy** (EMA)
- TOP 6 The EU Pharma Incentives Review**
- Preliminary findings of the EUCOPE study on the value of OMPs (The Office of Health Economics, OHE Consulting Ltd)
 - An analysis of orphan medicine expenditure in Europe: is it sustainable? (Jorge Mestre Ferrandiz, economics consultant)
- TOP 7 France: Recent Developments in Compliance and Drug Assessment**
(Alexandre Regniault, France Biotech)
- Clinical trials : a new system for selecting French Ethics Committees ("CPPs")
 - Refresh on the "anti-kickback" legislation
 - Reform of HTA criteria: "watch this space"
- TOP 8 Digital Health and AI: Overview & Outlook**



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TOP 9 Germany: The bill on Safety in the Supply of Medicinal Products (“GSAV”)

- The core provisions of the adopted text

TOP 10 AOB / End of meeting