EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

6 February 2019
11.00 – 16.00 CET

EUCOPE offices
Rue Marie de Bourgogne, 58
1000 Brussels

EUCOPE OMP WORKING GROUP

Meeting agenda

	SESSION TOPIC	SPEAKER
1	**Welcome / Introduction / Meeting agenda and objectives**	Chairs
2	**OMP Working Group 2019 priorities, meetings and action plan**	Chairs
3	**Assessment of the ORPH-VAL principles: Presentation of the final report**	**Adam Hutchings**, Dolon
4	**2016 Notice on the application of Articles 3, 5 and 7 of Regulation n° 141/2000** • Maintenance of an orphan drug designation by showing significant benefit over magistral and officinal preparations: practical case and lessons learned	**Jean-Pierre Anzévui**, Santen (tbc) and **Geneviève Michaux**, Mayer Brown (tbc)
5	**Community Advisory Boards (CABs):** • Feedback and lessons learned on a company experience	**Flaminia Macchia**, Vertex
6	**European Reference Networks – the role for industry** • Presentation by the EU Commission • EURORDIS' views on the future of ERNs and challenges ahead • EUCOPE's views	**Enrique Terol,** EU Commission (tbc) **Matt Bolz-Johnson**, EURORDIS (tbc)
7	**Analysis of the EU OMP Regulation: an update** • Technopolis study • EUCOPE 2019 study and advocacy activities	Secretariat
8	**EURORDIS multi-stakeholder symposium** • Programme and objectives • Draft roadmap • EUCOPE preparations	Chairs
9	**Market access for orphan drugs in the UK** • New Scottish definition for ultra-rare diseases and implications for (ultra) orphan drugs • Update on the NICE Highly Specialised Technologies guidance	**Josie Godfrey**, JG Zebra Consulting

SESSION TOPIC		SPEAKER
	• Update on the Single Technology Appraisal (STA) process and 2019 planned activities	
9	**Germany: Cabinet draft on the Draft Law for More Safety in the Supply of Medicinal Products (GSAV)** • Implications regarding proposals on mandatory registries for most OMPs, conditional approval and OMP thereshold.	Speaker tbc
10	**A.O.B / Meeting conclusion**	Chairs