Agenda

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EUCOPE Board Meeting

Date: February 8th, 2012;
11:00 a.m. to 4:30 p.m.

Venue: EUCOPE Offices
Rue d'Arlon 50
1000 Brussels

Rue d'Arlon 50
1000 Brussels
www.eucope.org

Telephone: +32 2 282 04 75
Telefax: +32 2 282 05 98

E-Mail: natz@eucope.org
Reference: AN
Date: 21.12.2011

TOP 1 **Welcome**

TOP 2 **New Members**

TOP 3 **Outlook on Commission - EMA proposals / EUCOPE topics for 2012**

TOP 4 **Revision of Directive 89/105/EEC (Transparency Directive)**

- Impact Assessment Roadmap: http://ec.europa.eu/governance/impact/planned_ia/docs/2011_entr_005_national_health_insurance_en.pdf
- EUCOPE submission on the consultation paper (incl. questionnaire): http://www.eucope.org/en/files/2011/09/EUCOPE_submission_transparency_directive.pdf
- Specifics on medical devices, orphan drugs
- Managed entry agreements / HTA / International Reference Pricing / Timelines / Binding effect of MA / Tacit inclusion

TOP 5 **Revision of Directive 2001/20/EC (Clinical Trials Directive)**

- EU public consultation paper: http://ec.europa.eu/health/files/clinicaltrials/docs/2009_10_09_public-consultation-paper.pdf
- EUCOPE submission on the consultation paper: http://ec.europa.eu/health/files/clinicaltrials/ctresp_2011-06/eucope.pdf
- Specific needs in the field of rare diseases and personalized medicine / Single submission process / Tacit approval / NIS / Ethic committees

TOP 6 **The EU's current and changing Medical Device Regulations and the impact on Pharma Companies** (Shayesteh Fürst-Ladani, SFL)

TOP 7 **Review of Directive 98/79/EC (IVD) and Directives 90/385/EEC + 93/42/EEC (Medical Devices)**

- EU public consultation paper: http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=5918
- Council conclusions: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF
- Commission Roadmap: http://ec.europa.eu/governance/impact/planned_ia/docs/2008_sanco_081_proposal_medical_devices_en.pdf
- Transfer of responsibilities from Notified Bodies to Regulatory Authorities / Potential EMA responsibilities / Demarcation guideline

TOP 8 **State of play of EU pharma legislation in the European Parliament**
2:30 pm (Dr. Antonyia Parvanova MEP)

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TOP 9 Orphan Drugs

- First early benefit assessment in Germany (Esbriet/Pirfenidone)
- Next EUCOPE Working Group Orphan Drugs / Incremental Research

TOP 10 Country Updates on Pricing and Reimbursement

TOP 11 Delegated / implementing acts Directive 2011/62/EU (Falsified Medicines Directive)

- GMP-/ production-related measures
- EU public consultation paper on safety features: http://ec.europa.eu/health/files/counterf_par_trade/safety_2011-11.pdf
- German Pilot project (www.securPharm.de)
- Outcomes of the Commission Stakeholder Meeting 20.12.2011

TOP 12 Implementation EU pharmacovigilance legislation

- Art. 57(2) : Submission obligations to EMA (Markus Ambrosius (Sträter Law Firm))
- EU public consultation paper: http://ec.europa.eu/health/files/pharmacovigilance/2011-09_concept-paper.pdf
- EUCOPE submission on the consultation paper: http://www.eucope.org/en/files/2011/11/PhV-Implementation.pdf

TOP 13 Update on EU Competition Law

(Dr. Werner Berg (Crowell & Moring Law Firm)

TOP 14 AOB; Next Board Meeting: Dates and Topics