European Medicines Agency

London, 2 February 2009
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3rd EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)

"Focus on Non-clinical Aspects"

AGENDA

2 February 2009, 9.30-16.00
7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA 2nd floor, Conference Room –2A

~ Registration +Coffee ~
9.00-9.30

Chairperson: Dr. Beatriz Silva Lima

1.	**INTRODUCTION**	9:30-10:00 (30')

1.1 *Introductory remarks*
Dr. Beatriz Silva Lima, CHMP member and Chair of Safety Working Party
Ms. Melanie Carr, SME Office, EMEA

1.2 *Global development challenges – for classical and advanced therapy medicinal products*
Dr. Beatriz Silva Lima, CHMP member and Chair of Safety Working Party

2.	**PRE-CLINICAL SAFETY & TRANSLATIONAL ASPECTS**	10:00-11:15 (75')

Panellists/Presenters:
Dr. Klaus Olejniczak, Expert to CHMP Safety Working Party
Dr. David Jones, Member of CHMP Safety Working Party
Dr. Charmian Wells, Pangenetics BV (SME Representative)

2.1 *Safety pharmacology (30')*
Dr. Klaus Olejniczak

2.2 *Requirements for the first-in-human clinical trials (30')*
Dr. David Jones

2.3 *Questions and Discussion moderated by SME Representative (15')*
Ms. Charmian Wells

~ Coffee Break ~
11:15-11:35

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3. MEETING REQUIREMENTS FOR EU MARKETING AUTHORISATION 11:35-13:00 (85')

Panellists/Presenters:

Dr. Jan-Willem van der Laan, Vice-Chair CHMP Safety Working Party
Dr. Peter Kasper, Expert to CHMP Safety Working Party
Dr. Kerstin Wickström, Swedish Medical Products Agency
Dr. Spiros Vamvakas, EMEA Scientific Advice & Orphan Drugs Sector, ICH Co-ordinator
Dr. Jean-Pierre Gotteland, PregLem (SME Representative)

3.1 *General toxicity study designs for small molecules and biopharmaceuticals. Similarities and differences (20')*
Dr. Jan-Willem van der Laan

3.2 *Genotoxicity and Carcinogenicity (25')*
Dr. Peter Kasper

3.3 *Reprotoxicity (20')*
Dr Kerstin Wickström

3.4 *Questions and Discussion moderated by SME Representative (20')*
Dr. Jean-Pierre Gotteland

~ Lunch in Lobby Area kindly sponsored by EBE and EuropaBio ~
13.00-14.15

4. KEY CONSIDERATIONS FOR THE MAA 14:15-15:50 (95')

Panellists/Presenters:

Dr. Beatriz Silva Lima, CHMP member and Chair of Safety Working Party
Dr. Jean-Marc Vidal, Safety and Efficacy Sector, EMEA
Dr. Brendan Cuddy, Inspections Sector, EMEA
Dr. Klaus Olejniczak, Expert to CHMP Safety Working Party
Dr. Thore Nederman, Active Biotech (SME Representative)

4.1 *Non-clinical documentation – Overview of requirements, Common Technical Document, Guidelines for vaccines, anti-cancer, biotech, paediatric medicines (30')*
Dr. Jean-Marc Vidal

4.2 *GLP compliance (15')*
Dr. Brendan Cuddy

4.3 *Recent experience in Non-clinical Assessment – Scientific advice and Applications for marketing authorisation (30')*
Dr. Beatriz Silva Lima

4.4 *Questions and Discussion moderated by SME Representative (20')*
Dr. Thore Nederman

~ Closing Remarks by Chairperson ~
15:50-16:00