EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2011
EMA/204912/2011

Agenda – 6th Workshop for micro, small and medium-sized enterprises (SMEs) organised by the SME office "*Focus on Scientific and Regulatory Advice*"

26 May 2011, 9.00-16.30

7, Westferry Circus, Canary Wharf, London E14 4HB

2nd floor, Conference Room – 2A

~ Registration and Coffee ~

8.30 - 9.00

Chairperson: Prof. Spiros Vamvakas – Head of Section, Scientific Advice, EMA

1.	**Introduction**	**9.00 – 9.35**
1.1	**Introductory remarks** *Prof. Spiros Vamvakas, Chairperson*	
1.2	**Update from SME office** Topic: Feedback on SMEs experience at MAA, Why seek scientific and regulatory advice, When, Where from, and How *Ms. Melanie Carr, SME Office, EMA*	
1.3	**SME's perspective on scientific and regulatory advice** Topic: SME's experience of seeking scientific and regulatory advice *Dr. Lene Rose Arfelt, Head of QA and RA Europe, ThromboGenics NV*	

2.	**Scientific advice**	**9.35 – 11.10**
2.1	**Scientific advice on quality aspects – key considerations** Topic: Highlights from recent scientific advice and protocol assistance on quality issues *Prof. Dieter Deforce, Faculteit Farmaceutische Wetenschappen Universiteit Gent, Belgium* *Member of Scientific Advice Working Party*	

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2.	Scientific advice	9.35 – 11.10
2.2	**Recent experience in non-clinical scientific advice** Topic: Highlights from recent scientific advice in non-clinical area *Dr. Jan-Willem van der Laan, Rijksinstituut voor Volkgezondheid en Milieu, The Netherlands* *Vice-Chair of CHMP Safety Working Party*	
2.3	**Scientific advice on clinical aspects – key considerations** Topic: Highlights from recent scientific advice in clinical area including biomarker qualifications *Dr. Bertil Jonsson, MPA, Sweden* *Vice-Chair of Scientific Advice Working Party*	
2.4	**Questions and discussion moderated by SME representative** *Dr. Wilfried Dalemans, Tigenix N.V.*	

~ Coffee Break ~

11.10-11.25

3.	Specific measures for orphan, paediatric and innovative medicines	11.25 – 13.15
3.1	**Innovation task force (ITF)** Topic: overview of sort of products discussed through ITF, practical experience on advice given with examples *Dr. Marisa Papaluca Amati, Head of Section, Scientific Support & Projects, EMA*	
3.2	**Orphan designation – key concepts and evaluation criteria** Topic: overview of orphan designation application process and its practical implications based on recent examples *Dr. Jordi Llinares, Head of Section, Orphan Medicines, EMA*	
3.3	**Paediatrics** Topic: practical examples of advice on paediatric development programme, presentation of various case studies *Dr. Matthew Thatcher, MHRA, United Kingdom* *Member of Paediatric Committee*	
3.4	**Advanced therapy medicinal products (ATMPs)** Topic: Specific considerations for ATMPS, recent experience with classification, scientific advice and certification *Prof. Jean-Hugues Trouvin, Afssaps, France* *Member of Committee on Advanced Therapies*	

3.	Specific measures for orphan, paediatric and innovative medicines	11.25 – 13.15
3.5	**Questions and discussion moderated by SME representative** *Dr. María Pascual Martinez, Cellerix S.A.*	

~ Lunch ~

13.15-14.20

4.	Veterinary SME experience	14.20 – 14.45
4.1	**Veterinary experience with scientific and regulatory advice** *Dr. Karen Quigley, Scientific Administrator, Veterinary Medicines, EMA*	
4.2	**Questions**	

5.	How to seek advice on regulatory matters prior to submission	14.45 – 16.30
5.1	**Advice on regulatory strategy** Topic: how to develop a sound regulatory strategy optimizing the use of the various incentives and tools *Ms. Zaide Frias, Head of Section, Regulatory Affairs, EMA*	
5.2	**Meeting rapporteur/co-rapporteur prior to filing** Topic: an overview of opportunities for dialogue with assessment teams nationally, including national scientific advice and pre-submission dialogue *Dr. Bertil Jonsson, MPA, Sweden* *Vice-Chair of Scientific Advice Working Party*	
5.3	**Support available to SMEs nationally and internationally** Topic: brief intervention from Afssaps, PEI and FDA *5.3.1 Dr. Stephane Palies, Afssaps, France* *5.3.2 Ms. Bettina Ziegele, Paul Ehrlich Institute, Germany* *5.3.3 Ms. Brenda Stodart, FDA*	
5.4	**Questions and discussion moderated by SME representative** *Speaker: Dr. Farid Benhammou, Novagali Pharma SA*	

~ Closing remarks by chairperson ~