European Medicines Agency

London, 2 February 2007
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1st EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)
"Navigating the Regulatory Maze"

DRAFT AGENDA

2 February 2007, 9.30-17.00
7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA 3rd floor, Conference Room –3A

~ Registration +Coffee ~
9.00-9.30

Chairperson: Dr. Patrick Le Courtois, Head of Pre-Authorisation Human Unit

1. INTRODUCTION 9:30-10:20

1.1 *Introduction to the EMEA*
Mr. Martin Harvey, Head of Sector, Executive Support

1.2 *Update from the SME Office*
Ms. Melanie Carr, SME Office

2. ORPHAN & PAEDIATRIC INCENTIVES 10:20-11:15

2.1 *Orphan Designation - Key Concepts and Evaluation Criteria*
Dr. Jordi Llinares-Garcia, Scientific Administrator

2.2 *Implementation of the Paediatric Regulation*
Dr. Nathalie Seigneuret, Scientific Administrator

2.3 *Questions and Discussion moderated by SME Representative*
Ms. Marie-Christine Fortun, Director of Regulatory Affairs, Orphan Europe and Member of the EBE Regulatory & Technical Affairs Committee

~ Coffee Break ~
11:15-11:35

3. EARLY ADVICE FROM THE EMEA 11:35-12:30

3.1 *Scientific Advice*
Dr. Marco Cavaleri, Scientific Administrator
Dr. Karen Quigley, Scientific Administrator

3.2 *Innovation Task Force*
Dr. Marisa Papaluca, Deputy Head of Sector Safety & Efficacy

3.3 *Questions and Discussion moderated by SME Representative*
Ms. Anita Osbourne, Director of Regulatory Affairs, Rheoscience and Chairperson of the EBE Regulatory & Technical Affairs Committee

~ Lunch in EMEA's Self-Service Restaurant ~
12.30-13.45

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4. REGULATORY ISSUES IN THE RUN UP TO MARKETING AUTHORISATION 13:45-15:00

4.1 *Pre-submission Issues and EMEA meeting opportunities*
Ms. Hilde Boone, Scientific Administrator
Dr. Karen Quigley, Scientific Administrator

4.2 *Submission of the dossier, update on Electronic Submissions and PIM*
Mr. Paul Kershaw, Communications and Networking

4.3 *Compliance Issues – Preparing for Inspections*
Mr. Brendan Cuddy, Scientific Administrator from EMEA Inspections Sector

4.4 *Questions and Discussion moderated by SME Representative*
Mr. Jean-Pierre Girre, Innate Pharma, Chair of Developers and Chief Medical Officers (CMOs) Working Group, France Biotech

~ Coffee Break ~
15:00-15:20

5. MARKETING AUTHORISATION & BEYOND 15:20-16:35

5.1 *Marketing Authorisation Review Process*
Dr. Evdokia Korakianiti, Scientific Administrator

5.2 *Maximum Residue Limits for Veterinary Products*
Dr. Jordi Torren Edo, Scientific Administrator

5.3 *Pharmacovigilance & Risk Management*
Dr. Francois Maignen, Principal Scientific Administrator

5.4 *Questions and Discussion moderated by SME Representative*
Dr. Johan Vanhemelrijck, Secretary General of EuropaBio's Emerging Enterprise Council

~ Closing Remarks by Chairperson ~
16:35-16:50