



European Medicines Agency

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23 October 2009

4th EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)
“Paediatric Medicines”

AGENDA

23 October 2009, 9.00-13.30

7, Westferry Circus, Canary Wharf, London E14 4HB
EMEA 2nd floor, Conference Room –2A

~ Registration +Coffee ~

8.30-9.00

Chairperson: Dr. Agnes Saint-Raymond

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| 9.00-9.10 | Welcome and Introductory remarks
<i>Chairperson</i> |
| 9.10-9.30 | Getting started – overview of paediatric regulation and sources of information
<i>Paolo Tomasi, EMEA</i> |
| 9.30-10.00 | How to prepare a PIP/waiver/deferral dossier - practical aspects, advice and step by step explanation
<i>Anu Tummavuori-Liemann, Celgene, Switzerland</i> |
| 10.00-10.30 | Public funding opportunities from the European Commission
<i>Fergal Donnelly, DG Research, European Commission</i> |
| 10.30-11.00 | Questions & Discussion |
| - Coffee Break -
11.00-11.30 | |
| 11.30-11.50 | A short overview of procedural aspects, the roles of the EMEA and the PDCA?
<i>Cecile Ollivier, EMEA</i> |
| 11.50-12.20 | Experience of PIP/waiver/deferral process from an SME perspective
<i>Simon Bryson, Auralis, United Kingdom</i> |
| 12.20-12.50 | Presentation and discussion of various case studies
<i>Matthew Thatcher, MHRA, United Kingdom</i> |
| 12.50-13.20 | Questions & Discussion |
| 13.20-13.30 | Closing Remarks |