European Medicines Agency
*Pre-authorisation Evaluation of Medicines for Human Use*

London, 31 August 2006
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**WORKSHOP ON REGULATORY AND SCIENTIFIC ISSUES RELATED TO THE INVESTIGATION OF MEDICINAL PRODUCTS INTENDED FOR NEONATAL USE**

# NEONATES WORKSHOP
# AGENDA

Wednesday, 11 October 2006, 09:00-17:00, room 3A
EMEA, 7 Westferry Circus, Canary Wharf, London E14 4 HB, UK

**Chairperson**: Prof. John van den Anker

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| **Welcome and Introduction**<br>(John van den Anker) | 9.00-9.30 |
| **Impact of organ immaturity on the investigation of medicinal products in the neonate (with a view on future guidelines)**<br>(John van den Anker) | 9.30-10.15 |
| **Drug formulations for neonates: lessons learnt, present status and needs**<br>(Joerg Breitkreutz) | 10.15-11.00 |
| ***Coffee Break*** | ***11.00-11.30*** |
| **Specific aspects of pharmacokinetics and pharmacodynamics in neonates (enzyme and receptor maturation / early development of drug metabolism)**<br>(Greg Kearns) | 11.30-12.15 |

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| **Invasiveness and non-invasive methods with specific regard to prevention and management of pain in neonates**<br>(Vineta Fellman) | 12.15-13.00 |
| ***Lunch Break*** | ***13.00-14.00*** |
| **Ethical aspects, recruitment and informed consent**<br>(Pieter Sauer) | 14.00-14.45 |
| **Methodology, study design and statistical approaches**<br>(Gerard Pons) | 14.45-15.30 |
| ***Coffee Break*** | ***15.30-16.00*** |
| **Pharmacovigilance and safety aspects**<br>(Dirk Mentzer) | 16.00-16.45 |
| **Closing remarks**<br>(John van den Anker) | 16.45-17.00 |



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