The European Medicines Agency

# CONFERENCE ON ENVIRONMENTAL RISK ASSESSMENT FOR HUMAN AND VETERINARY MEDICINAL PRODUCTS

## To be held at the European Medicines Agency, London on 27-28 October 2005

### Programme

**Thursday 27th October 2005**

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| 12:00 | • Registration at the ground floor<br>• Coffee and conference materials at meeting room 3A, 3rd floor | |
| 13:00 | Moderator's Opening Address | Moderator: Annika Wennberg, FAO, Italy |
| **Session I:** | **Exposure of the environment to veterinary and human medicinal products.** | |
| | Chair: Kornelia Grein, EMEA | |
| 13:15 | • Pharmaceuticals in the environment (abstract) | Mark Crane, member SETAC, UK (40') |
| | • Questions | (10') |
| | • Current 'state of the art' and challenges in Exposure Assessment for Pharmaceuticals (ERAPharm) (abstract) | Kathrin Fenner, Eawag, Switzerland (40') |
| | • Questions | (10') |
| **Session II:** | **Environmental Risk Assessment and the Regulatory aspects of ERA for pharmaceuticals** | |
| | Chair: Per Spindler, University of Copenhagen<br>(co) Chair: Joseph Robinson, Pfizer Inc. | |
| 14:55 | • European Regulatory Situation – Veterinary Medicinal Products (abstract) | Kornelia Grein, EMEA (10') |
| | • VICH guidelines/ Technical Guidance Documents (abstract) | Joop de Knecht, RIVM, the Netherlands (40') |
| 15:45 | Tea and Coffee | |
| 16:10 | • European Regulatory Situation – Human Medicinal Products | Jean-Marc Vidal, EMEA (10') |
| | • CHMP Guideline (abstract) | Innes Rönnefahrt, Federal Environmental Agency, Germany (30') |
| 16:50 | • Comments from industry – Veterinary Medicinal Products (abstract) | Gregor Scheef IFAH Europe (15') |
| | • Questions | (5') |
| 17:10 | • Comments from industry – Human Medicinal Products (abstract) | David Taylor, EFPIA (15') |
| | • Questions | (5') |
| 17:30 | Discussion with panel | (45') |

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| **Session III** | **Risk management / Mitigation – Too much or not enough?** | |
| | Chair: Hans Hoogland, CVMP<br>(co) Chair: Martin van der Graaff, EFPIA | |
| 09:00 | **Regulators - National Competent Authority's perspective** | |
| | • NCA Germany (abstract) | Jan Koschorreck, Federal Environmental Agency (15') |
| | • NCA UK (abstract) | Alex Tait, Veterinary Medicine Department (15') |
| | • NCA The Netherlands | Mark Montforts (15'), RIVM, The Netherlands (15') |
| | • Questions | |
| **Session IV** | **Future Developments / Impacts** | |
| 10:00 | • Environmental risk assessment for pharmaceuticals - challenges from a scientific point of view (abstract) | Thomas Knacker, ECT, ERAPharm (20') |
| | • Questions | (10') |
| 10:30 | Tea and coffee | |
| 10:55 | • Water Framework Directive - implications for pharmaceuticals - INERIS, on behalf of the European Commission (abstract) | Vincent Bonnomet, INERIS DRC/ECOT, France (20') |
| | • Questions | (10') |
| 11:25 | Discussion with panel | (45') |
| **Conference conclusions** | | |
| 12:10 | Conference Summary | Moderator: Annika Wennberg, FAO, Italy |
| 12:25 | Conference Conclusions | Thomas Lönngren, Executive Director, EMEA |
| 12:40 | Close | |