



22 September 2015
EMA/589180/2015
Human Medicines Research and Development

Draft agenda - Expert meeting on paediatric development of fixed-dose combinations for treatment of HIV infection

10 November 2015, room 2F

Chair: Dirk Mentzer

| Item | Agenda | Time | Speaker |
|------------------------------------|--|-----------------|---------------------------|
| 1. | Arrival and registration | 10.00 | |
| Introduction and Background | | | |
| 2. | Welcome and introduction of participants Objectives of the meeting Declaration of conflict of interest Requirements of the Paediatric Legislation | 10.30- 10.50 | Dirk Mentzer |
| 3. | HIV therapies – current regulatory requirements | 10.50- 11.05 | Sabrina Spinosa Guzman |
| 4. | Overview of agreed Paediatric Investigation Plans for HIV therapies | 11.20- 11.30 | Andrea Ecker |
| Discussion of questions | | | |
| 5. | Criteria for drug prioritisation for development in children | | All |
| Lunch break | | | |
| 6. | Appropriate dosing for young children | | All |
| 7. | Development of fixed-dose combinations in adolescents | | All |
| 8. | Formulation development in children | | All |
| Coffee break | | | |
| 9. | Wrap-up and conclusions | 16.30 | Dirk Mentzer |
| 10. | End of the meeting | 17.00 | |

