



Worldwide Orphan Medicinal Designation Workshop 10 March 2014

European Medicines Agency, London, United Kingdom

Morning

9:00 Welcome Remarks

Introduction and Opening Remarks

9:10 Plenary Session

First Session: Orphan Designation around the World

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| 9:10-9:40 | European Orphan Designation |
| 9:40-10:10 | FDA Orphan Designation |
| 10:10-10:40 | MHLW/PMDA Orphan Designation |

10:40-11:00 Panel Discussion 20 minutes

11:00-11:30 Coffee break

Second Session: Orphan Designation Incentives and Grants around the World

11:30-12:15 Grant Frameworks:

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| • Situation in Europe and IRDIRC (Global) | 15 min |
| • Situation in USA | 15 min |
| • Situation in Japan | 15 min |

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12:15- 13:15 Incentives and Regulatory Considerations:

- Situation in Europe 20 min
- Situation in USA 20 min
- Situation in Japan 20 min

13:15-13:30 Panel Discussion 20 minutes

13:30-14:30 Lunch

Afternoon

Three Agencies Face to Face Consultations

(Can be joint depending on the sponsors preference at registration)

14:30- 16:30

- Separate 40minute consultations sessions (2h in total)

Break

17:00-19:00

- Separate 40minute consultations sessions (2h in total)