



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2013
EMA/551226/2013
Human Medicines Development and Evaluation

Orphan Medicines Development in Europe and Japan

Date 19 September 2013 / Time: 14:00-16:15 (Japanese Embassy, London)

Item	Preliminary draft agenda	Speaker
1	14:00 Registration	
2	14:15 Opening Remarks by Embassy of Japan in the UK	
3	14:20 <ul style="list-style-type: none">• Orphan Medicines Designation (80 min in total)<ul style="list-style-type: none">○ Orphan Designation in Europe : Dr Jordi Llinares (European Medicines Agency) 20minutes○ Orphan Designation in Japan : Dr Segundo Mariz (European Medicines Agency) 10minutes○ MHLW/PMDA-EMA collaboration : Dr Segundo Mariz (European Medicines Agency) 10minutes• Post designation considerations:<ul style="list-style-type: none">○ Incentives for development and marketing in Europe: Ms Melanie Carr (European Medicines Agency) 20 minutes○ Protocol assistance, Annual Reports and the review of the Orphan Designation at the time of Market Authorisation Application: Dr Segundo Mariz (European Medicines Agency) 20minutes	
4	15:40 Questions & Answers session (30 minutes)	
5	16:10 Closing Remarks by Embassy of Japan in the UK	
	16:15 End of Workshop	