9 December 2015
EMA/833251/2015

Agenda “Emerging Medicinal Products – from laboratory to patient use”. The fourth annual regulatory seminar organised by EBE and the European Medicines Agency (EMA)

14 December 2015, De Vere Venues, 1 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom

Item	Agenda item	Time
1.	**Welcome & Introduction** • Guido Rasi/EMA • Roberto Gradnik/EBE	10:00-10:15
2.	**Session 1: Emerging medicinal products – a look to the future** What types of new products are under development and what are the challenges in bringing these to the market? • Market Scan: types of new products that are likely to emerge in the next 5 years Presenter: Keith Thompson, UK Catapult (15 min) • Development challenges and bringing science to the market Four short presentations of 10 min each. Presenters: - Eduardo Bravo, Tigenix - Paul-Peter Tak, GSK - Tomas Boran, CAT Member - Steve Bloor, Videregen • Panel discussion (20 min) Moderator: Paul-Peter Tak GSK Panellists: All presenters and Paula Salmikangas (CAT Chair)	10:15-11:30
3.	**Session 2: Translating science into medicinal products** How do regulators respond to the challenges posed by innovative medicines, and how can regulators and developers work together early in the development process. • EMA early dialogue platforms with regulators; Innovation Task Force, SME office.	11:30-12:30

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	Presenter: Melanie Carr, EMA (15 min) • Collaborative input on the optimum development pathway: do adaptive pathways offer a model for the future? Presenter: Francesca Cerreta, EMA (15 min) • EU early medicinal product access tools: what's new? Presenter: Michael Berntgen, EMA (15 min) • Panel discussion (15 min) Moderator: Jordi Llinares Garcia, EMA Panellists: All presenters and Corinne De Vries, EMA	
4.	**Lunch**	12:30-13:30
5.	**Session 3: Attracting investment for innovative medicines** Communication of the value of innovation in risk-averse atmosphere of unconventional business models. • Overview presentation on current situation and market trends Presenter: Joep Muijrers, Life Science Partners - LSP (20 min) • What funds are available, how is the decision made? Five presentations from different fund providers of 10 min each. Presenters: - A health-care investment perspective: Vincent Ossipow, Omega Funds - An 'asset-centric' VC company: Kevin Johnson, Index Ventures - European Investment Bank: Milena Messori - J&J Innovation Funding: Jeanne Boger, J&J - EBE IFM WG funding gap analysis: Emil Pot, Actogenix • A case study from a user of funds Presenter: Holger Schmoll, AiCuris (10 min) • Panel discussion (20 min) Moderator: Joep Muijrers Panellists: All presenters	13:30-15:10
6.	**Coffee break**	15:10-15:30
7.	**Session 4: Listening to the users of innovative medicinal products** Innovative products address areas of high unmet medical need: what access would the users of innovative products regard as appropriate? • When in the development process should users be involved in risk/benefit discussions, definition of end points, risk level acceptability. • Early access to innovative products: clinical trials, compassionate use, national access programmes. Five presentations of 10 min each: Presenters: - Representative from a patient organization: David Haerry, PCWP co-Chair - Representative from a physician organization: Pieter A. Doevendans, ESC	15:30-16:45

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	- Representative from a patient organization: Robert Johnstone, EPF - National authority early access scheme: Dan O'Connor, MHRA - Patient involvement in the development process & early access – an industry perspective: Lode Dewulf, UCB • Panel discussion (25 min) Moderator: Isabelle Moulon, EMA Panellists: All presenters	
8.	Closing remarks Guido Rasi/Roberto Gradnik	16:45-17:00