EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 November 2013
EMA/681302/2013

Draft programme – Workshop on biosimilars

Thursday 31st October 2013, room 3A

Time	Item	Speakers:
09.00-09.10	**Welcome**	Guido Rasi
09.10-10.50	**SESSION 1: Guideline on Similar biological medicinal products** **Chair: Martina Weise**	
09.10-09.20	Presentation of the draft guideline (10 min)	Martina Weise
Choice of reference product and three way comparability exercise		
09.20-09.30	Presentation by Innovator industry (10 min)	Eugene Corretge
09.30-09.40	Presentation by Biosimilars industry (10 min)	Karl Heinz Emmert
09.40-10.50	Panel discussion	
10.50-11.05	**Coffee break**	
11.05-12.45	**SESSION 2: Guideline on Similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues** **Chair: Niklas Ekman**	
11.05-11.15	Presentation of the draft guideline (10 min)	Niklas Ekman
Quality target product profile in the development of a biosimilar ***The use of different/novel expression systems compared to the originator***		
11.15-11.25	Presentation by Innovator industry (10 min)	Beverly Ingram
11.25-11.35	Presentation by Biosimilars industry (10 min)	Joerg Windisch
11.35-12.45	Panel discussion	
12.45-14.00	**Lunch**	

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

14.00-15.15	**SESSION 3: Guideline on Similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues** **Chairs: Hans-Karl Heim, Pekka Kurki**	
14.00-14.10	Presentation of the draft guideline (10 min)	Hand-Karl Heim, Pekka Kurki
Stepwise approach to non-clinical program ***Biosimilar specific clinical model and endpoints*** ***Extrapolation of indication***		
14.10-14.20	Presentation by Innovator industry (10 min)	Richard Markus
14.20-14.30	Presentation by Biosimilars industry (10 min)	Mark McCamish
14.30-15.45	Panel discussion	
15.45-16.00	**Coffee break**	
16.00-16.50	General discussion	
16.50-17.00	**CONCLUSIONS OF THE WORKSHOP**	Martina Weise