EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 October 2011
EMA/838645/2011
Human Medicines Development and Evaluation

Closed Workshop on biosimilar monoclonal antibodies and immunogenicity of monoclonal antibodies

Monday 24th October 2011, European Medicines Agency, London, United Kingdom

Chair: Christian Schneider

Time	Item	Speakers:
09.15-09.20	**Welcome**	
09.20-09.30	Presentation of draft guideline on biosimilar monoclonal antibodies	Christian Schneider (DKMA)
09.30-09.40	Presentation of draft guideline on Immunogenicity assessment of monoclonal antibodies intended for *in vivo* clinical use	Robin Thorpe (NIBSC/HPA)
09.40-10.00	**General presentation by stakeholders**	
09.40-09.50	Presentation by Innovator industry	Anne-Marie Li-Kwai-Cheung (Genzyme)
09.50-10.00	Presentation by Biosimilars industry	Joerg Windisch (EGA/Sandoz Biopharmaceuticals)
10.00-11.00	**SESSION 1 Non-Clinical Issues (Chair: Leon van Aerts)**	
10.00-10.05	Introduction (5 min)	
10.05-10.35	Questions (Session 1)	
Off-target toxicity - does it occur and how should we detect it?		
1.1	Presentation by Innovator industry (5 min)	Sven Kronenberg (Roche)
1.2	Presentation by Biosimilars industry (5 min)	Antonio Da Silva (Sandoz

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Time	Item	Speakers:
		Biopharmaceuticals)
1.3	Presentation by an EU regulator (5 min)	Gabriele Reichmann (PEI)
A risk-based approach - rationale and decision points		
1.4	Presentation by Innovator industry (5 min)	Sven Kronenberg (Roche)
1.5	Presentation by Biosimilars industry (5 min)	Karl Heinz Emmert (EGA/Teva Global Branded Products)
1.6	Presentation by an EU regulator (5 min)	Karen De Smet (AFMPS)
10.35-11.00	Panel discussion	
11.00-11.15	**Coffee break**	
11.15-12.00	**SESSION 2 Clinical Issues** **Equivalence versus Non-Inferiority (Chair: Martina Weise)**	
11.15-11.20	Introduction	
11.20-11.35	Questions (Session 2)	
Could we accept non-inferiority instead of equivalence trials in specific situations?		
2.1	Presentation by Innovator industry (5 min)	Frank Scappaticci (Roche)
2.2	Presentation by Biosimilars industry (5 min)	Ildiko Aradi (Gedeon Richter Plc.)
2.3	Presentation by an EU regulator (5 min)	Martina Weise (BfArM)
11.35-12.00	Panel discussion	
12.00-12.45	**SESSION 3 Clinical Issues** **Indication/Product-specific guidance (Chair: Christian Schneider)**	
12.00-12.05	Introduction	
12.05-12.20	Questions (Session 3)	
Is product/indication specific guidance already necessary and meaningful?		
3.1	Presentation by Innovator industry (5 min)	John Medich (Abbott)
3.2	Presentation by Biosimilars industry (5 min)	Nicole Filser (Mylan)

Time	Item	Speakers:
3.3	Presentation by an EU regulator (5 min)	Christian Schneider (DKMA)
12.20-12.45	Panel discussion	
12.45-14.15	**Lunch**	
14.15-15.15	**SESSION 4 Immunogenicity of monoclonal antibodies (Chair: Robin Thorpe)**	
14.15-14.20	Introduction	
14.20-14.45	Questions (Session 4)	
How should antibodies against mAb therapeutics be assessed?		
4.1	Presentation by an EU regulator (10 min)	Meenu Wadhwa (NIBSC/HPA)
Risk-based approach – What are the risk factors? Is there anything special for mAbs as compared to other biologicals?		
4.2	Presentation by stakeholder (5 min)	Thomas B. May (Hospira)
4.3	Presentation by stakeholder (5 min)	Mike Moxness (Amgen)
4.4	Presentation by an EU regulator (5 min)	Christian Schneider (DKMA)
14.45-15.15	Panel discussion	
15.15-16.15	**SESSION 5 Pharmacovigilance (Chair: Thijs Giezen)**	
15.15-15.20	Introduction	
15.20-15.35	Questions (Session 5)	
What data/studies could be deferred to the post-authorisation phase?		
5.1	Presentation by Innovator industry (5 min)	John Orloff (Novartis)
5.2	Presentation by Biosimilars industry (5 min)	Marc McCamish (Sandoz)
5.3	Presentation by an EU regulator (5 min)	Thijs Giezen (CBG-MEB)
15.35-16.00	Panel discussion	
16.00-16.15	**Coffee break**	
16.15-17.00	**CONCLUSIONS OF THE WORKSHOP**	Christian Schneider (DKMA)