9 March 2016
EMA/48362/2016
Procedure Management and Committees Support Division

Workshop on immunogenicity assessment of biotechnology-derived therapeutic proteins

9th March 2016, 9.00-17.00 (Room 3A)

Background:

The CHMP Biosimilar Medicinal Products Working Party (BMWP) revised the 'Guideline on Immunogenicity Assessment of biotechnology-derived therapeutic proteins' (CHMP/BMWP/14327/06). The draft revised guideline was released in October 2015 for a four month external consultation ending on 31 January 2016.

This EMA Workshop is intended to complement the external consultation with a discussion among experts on the key issues relevant to the assays and methods used to explore and assess the immunogenicity of therapeutic proteins. It will focus on the following aspects:

- The development of adequate assays for detecting and measuring immune response in human including challenges in assessing relative immunogenicity
- Innovative non-clinical models that could better predict immunogenicity of biotechnology-derived therapeutic proteins in human
- Immunogenicity and Risks associated with the use of products containing therapeutic proteins including pharmacovigilance aspects

The Workshop is **by invitation only**.

Participants:

Experts from BMWP, BWP, other regulatory authorities, stakeholders who provided comments on the draft guideline and specifically invited interested parties.

Contact:

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Chair: Pekka Kurki (Finnish Medicines Agency - Fimea)

Time	Item	Speakers:
09.00-09.05	**Welcome**	Enrica Alteri (European Medicines Agency)
09.05-09.10	**Introduction**	Pekka Kurki (Finnish Medicines Agency - Fimea)
09.10-09.40	**Quality attributes impacting immunogenicity of therapeutic proteins**	Steffen Gross (Paul-Ehrlich-Institut - PEI) Susan Kirshner (FDA)
09.40-12.00	**SESSION 1: Assays and methods** Session coordinator: Robin Thorpe	
09.40-09.55	Presentation of the draft guideline and introduction of the topics for discussion	Meenu Wadhwa (NIBSC)
09.55-10.10	Target/drug interference considerations in immunogenicity assessment	Eric Wakshull (Genentech)
10.10-10.25	Neutralising assay methodology	Shalini Gupta (Amgen)
10.25-10.45	**Coffee break**	
10.45-11.00	Challenges in assessing relative immunogenicity (biosimilar and manufacturing change)	Paul Chamberlain (NDA)
11.00-12.00	Panel discussion Panellists: Robin Thorpe, Steffen Gross (Paul-Ehrlich-Institut - PEI), Susan Kirshner (FDA), Meenu Wadhwa (NIBSC), Shalini Gupta (Amgen), Eric Wakshull (Genentech), Paul Chamberlain (NDA), Meena Subramanyam (Biogen), Nanna Kruse (Danish Medicines Agency - DKMA), Martin Ullmann (Merck Serono)	All
12.00-13.00	**Lunch**	
13.00-14.00	**SESSION 2: Pre-clinical studies** Session coordinator: Leon van Aerts (Medicines Evaluation Board - MEB)	
13.00-13.10	Presentation of the draft guideline and introduction on the topic for discussion	Leon van Aerts (Medicines Evaluation Board - MEB)
13.10-13.30	Non-clinical approaches for immunogenicity assessment:	Frank Horling

Time	Item	Speakers:
	predictive models	(Baxalta) and Philippe Stas (ImmunXperts)
13.30-14.00	Panel discussion Panellists: Leon van Aerts (Medicines Evaluation Board - MEB), Frank Horling (Baxalta), Mark Fogg (Antitope Limited), Philippe Stas (ImmunXperts)	All
14.00-16.50	**SESSION 3: Clinical aspects** Session coordinator: Pekka Kurki (Finnish Medicines Agency - Fimea)	
14.00-14.40	Summary of immunogenicity program and risk assessment • General introduction on the topic • Presentation by stakeholder	Pekka Kurki (Finnish Medicines Agency - Fimea) Amy Rosenberg (FDA)
14.40-15.30	How to integrate risk assessment and risk stratification into a risk-based approach for immunogenicity assessment • General introduction on the topic • Presentation by stakeholder • Presentation by stakeholder	Christian Schneider (NIBSC) Florian Deisenhammer (Innsbruck Medical University) Gerrit Jan Wolbink (Jan van Breemen Institute, Sanquin)
15.30-15.45	Immunogenicity from pharmacovigilance point of view • General introduction on the topic	Thijs Giezen (Foundation Pharmacy for Hospitals in Haarlem; Medicines Evaluation Board)
15.45-16.00	**Coffee break**	
16.00-16.50	Panel discussion Panellists: Pekka Kurki (Finnish Medicines Agency - Fimea), Amy Rosenberg (FDA), Christian Schneider (NIBSC), Gerrit Jan Wolbink (Jan van Breemen Institute, Sanquin), Florian Deisenhammer (Innsbruck Medical University), Venke Skibeli (Norwegian Medicines Agency - NOMA), Thijs Giezen (Foundation Pharmacy for Hospitals in Haarlem; Medicines Evaluation Board), Niels Vermeer (European Medicines Agency)	All

Time	Item	Speakers:
16.50-17.00	**CONCLUSIONS OF THE WORKSHOP**	Pekka Kurki (Finnish Medicines Agency)