BMWP / BWP WORKSHOP ON IMMUNOGENICITY ASSESSMENT OF THERAPEUTIC PROTEINS

Chairperson: Pekka Kurki / Jean-Hughes Trouvin

4th September (10.00-18.00) (Room 2A)

EMEA, 7 Westferry Circus, Canary Wharf, London, E14 4HB

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Background:

The CHMP Biosimilar Medicinal Products Working Party (BMWP) drafted a 'Guideline on Immunogenicity Assessment of Biological/Biotechnology-Derived Proteins' (CHMP/BMWP/14327/06) which has been released for six month external consultation ending on 31 July 2007.

This 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:

- Impact of Immunogenicity on pre-clinical/clinical & post approval development.
- Immunogenicity and Risks associated with the use of products containing therapeutic proteins as well as points to design less immunogenic BioTherapeutics.

The Workshop will be followed by BMWP meeting for BMWP members and experts to discuss the highlights from Workshop and identify the input for the completion of draft GL.

Participants:

- **Invited speakers**
- **BMWP members** + **Drafting group on Immunogenicity**
- **Additional Experts from the CHMP Working Parties** and **from the EU network**

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Programme

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Tuesday 4 September 2007
10.00-18.00

10.00	Welcome and Keynote presentation (20')	**Jean-Hughes Trouvin** Agence Française de Sécurité, FR

SESSION 1 (**10.30- 13.00)**

10.30	Evaluation of immunity of biopharmaceuticals (30')	**Geoff Hale** Oxford University, UK
11.00	In vitro tests and experimental animal models for investigation of the allergenic potential of biotechnology-derived proteins (20')	**Attila Bacsi** University of Debrecen, School of Medicine, HU
11.20	Assays and assays' strategy (30')	**Steve Swanson** Amgen, US
11.50	Platform studies to standardize methods to evaluate the immunogenicity of r-h-Beta IFN: lesson learned (20')	**Huub Schellekens** Utrecht University, NL
12.10	Platform studies to standardize methods to evaluate the immunogenicity of r-h-EPO: progress report (20')	**Jean-Marc Spieser** Conseil de l'Europe, FR
12.30	Round table discussion (Chaired by J-H Trouvin)	

LUNCH BREAK (**13.00-14.00)**

SESSION 2 (**14.00 – 15.30)**

14.00	Immune-response and adverse reactions: Rare immune mediated complication OR Patient related risk factors for immunogenicity and clinical implications of antibody development (20')	**Nicole Casadevall** Laboratoire d'Hématologie, FR
14.20	Risk management of immunogenicity (20')	**Rainer Seitz** Paul-Ehrlich-Institut, DE
14.40	Rational design of less immunogenic biotherapeutics (30')	**Joy Cavagnaro** Access BIO, US
15.10	Round table discussion (Chaired by P. Kurki)	

COFFEE BREAK (15.30-16.00)

SESSION 3 (**16.00 -18.00)**

16.00	Contribution from EuropaBio: Immunogenicity studies in the pre-clinical development phase (20')	**Christian Ross Pedersen** Novo Nordisk, DA
16.20	Contribution from EGA: Immunogenicity: impact on the design of clinical trials for biosimilars (20')	**Alexander Berghout** Sandoz, DE
16.40	Contribution from EFPIA/EBE: Immunogenicity and the strategy of RMP (20')	**Adrian Thomas** J&J, US
17.00	General discussion (Co-chaired by Pekka Kurki and J-H Trouvin)	

CONCLUSIONS OF THE WORKSHOP