European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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CHMP Blood Products Working Party (BPWP)
Stakeholder Meeting on IVIg guidance
Chairman: Prof. Dr. Rainer Seitz
Vice-chairman: Dr. Bengt Ljungberg

Start: Friday, 27 November 2009 at 9:30
End: Friday, 27 November 2009 at 13:00
EMEA, 2nd floor, Meeting Room 2G
7, Westferry Circus, Canary Wharf, E14 4HB

AGENDA - draft

The aim of this meeting is to provide an opportunity for BPWP and stakeholders to discuss the key comments raised during the written public consultation on the revised IVIg guidance.

1 Adoption of the Agenda

Agenda

a) Agenda (EMEA/CHMP/BPWP/652052/2009-draft)

2 Guideline on the clinical investigation of IVIg

2.1 Use of IVIg in certain auto-immune disorders (chronic myasthenia gravis, chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) and multifocal motor neuropathy (MNN)

2.2 Other aspects of the guideline

a) Published guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) (CPMP/BPWG/388/95 rev. 2, EMEA/CHMP/BPWP/94033/2007) released for public consultation, deadline for comments: 31.08.2009.

3 Guideline on the core SmPC for IVIg

a) Published core SmPC for human normal immunoglobulin for intravenous administration (IVIg) (CPMP/BPWG/859/95 rev. 3, EMEA/CHMP/BPWP/94038/2007) released for public consultation, deadline for comments: 31.08.2009.

4 Closing remarks from BPWP Chairperson

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

List of Participants

BPWP Members

BPWP Regular Expert

EMEA Secretariat