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

London, 21 February 2008
Doc.Ref. EMEA/CHMP/97213/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF OPINION*
for
PRIVIGEN

International Nonproprietary Name (INN): ***human normal immunoglobulin (IVIg)***

On 21 February 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Privigen 100 mg/ml, solution for infusion, intended for

Replacement Therapy in
Primary Immunodeficiency Syndromes such as:
- congenital agammaglobulinaemia and hypogammaglobulinaemia
- common variable immunodeficiency
- severe combined immunodeficiency
- Wiskott Aldrich syndrome

Myeloma or chronic lymphocytic leukaemia (CLL) with severe secondary hypogammaglobulinemia and recurrent infections.

Children with congenital AIDS and recurrent infections.

Immunomodulation
- Idiopathic thrombocytopenic purpura (ITP), in children or adults at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome
- Kawasaki disease

Allogeneic Bone Marrow Transplantation

The applicant for this medicinal product is CSL Behring GmbH.

The active substance of Privigen is Human normal immunoglobulin (IVIg), an immune sera and immunoglobulin medicinal product.
ATC code: J06BA02.
Human normal immunoglobulin contains mainly functionally intact immunoglobulin G (IgG) with a broad spectrum of antibodies against infectious agents.
Human normal immunoglobulin contains the IgG antibodies present in the normal population. It is usually prepared from pooled plasma from not fewer than 1000 donations. It has a distribution of immunoglobulin G subclasses closely proportional to that in native human plasma. Adequate doses of human normal immunoglobulin may restore abnormally low immunoglobulin G levels to the normal range.
The mechanism of action in indications other than replacement therapy is not fully elucidated, but includes immunomodulatory effects.

---

* Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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

The clinical studies with Privigen have shown comparable results to that reported in literature and are consistent with acceptable efficacy of the product in these indications. The most common side effects are chills, headache, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain.

A pharmacovigilance plan for Privigen, as for all medicinal products, will be implemented as part of the marketing authorisation.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Privigen and therefore recommends the granting of the marketing authorisation.