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

London, 17 December 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
ImmunoGam

Common name: ***human hepatitis B immunoglobulin***

On 17 December 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product ImmunoGam, 312 IU/ml, Solution for injection, intended for the Immunoprophylaxis of Hepatitis B. The applicant for this medicinal product is Cangene Europe Limited.

The active substance of ImmunoGam is human hepatitis B immunoglobulin (HBIG), a specific immunoglobulin medicinal product (J06BB04). The mechanism of action of hepatitis B immunoglobulin is a passive immunisation against infection with the hepatitis B virus (HBV).

The benefits with ImmunoGam are its ability to maintain protective anti-HBs serum levels in line with those required for hepatitis B immunoglobulin preparations (> 10 IU/l) for immunoprophylaxis after intramuscular administration. The pharmacokinetic profile of ImmunoGam was characterised in two studies in healthy adults comparing ImmunoGam with other HBIG licensed products. Furthermore, the efficacy of ImmunoGam administered concomitantly with HBV vaccine was demonstrated in a clinical study with 178 infants and 23 adults. The most common side effects are injection site reactions (local pain or tenderness) as well as headache, nausea, hypersensitivity, diarrhea, pain and pyrexia.

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

The approved indication is: “Immunoprophylaxis of Hepatitis B:
- In case of accidental exposure in non-immunised subjects (including persons whose vaccination is incomplete or status unknown).
- In haemodialysed patients, until vaccination has become effective.
- In the newborn of a hepatitis B virus carrier-mother.
- In subjects who did not show an immune response (no measurable hepatitis B antibodies) after vaccination and for whom a continuous prevention is necessary due to the continuous risk of being infected with hepatitis B.”

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 ImmunoGam and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive 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.

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