European Medicines Agency

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Questions and answers on the referral for Uman Big

Human Hepatitis B Immunoglobulins, 180 IU/ml, solution for injection

The European Medicines Agency (EMEA) has completed a referral procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Uman Big 180 IU/ml, solution for injection. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Uman Big outweigh its risks, and that the marketing authorisation granted in Italy can be recognised in other Member States of the European Union and the European Economic Area. The review was carried out under an 'Article 29' referral[1].

What is Uman Big?
Uman Big is a solution of human hepatitis B immunoglobulins. Immunoglobulins are blood proteins that have been extracted from donor plasma. Hepatitis B immunoglobulins contain high levels of antibodies against the hepatitis B virus. Uman Big is given as an intramuscular (into the muscle) injection to prevent hepatitis B in the following cases:

- in case of accidental exposure in people who have not been vaccinated against the hepatitis B virus; including those whose vaccination is incomplete or status unknown;
- in haemodialysed patients (patients whose kidneys have failed and who rely on a blood purification technique called haemodialysis), until vaccination has become effective;
- in the newborn of a hepatitis B virus carrier-mother;
- in subjects who did not show an immune response after vaccination (and for whom a continuous prevention is necessary due to the continuous risk of being infected with hepatitis B.

Why was Uman Big reviewed?
Kedrion S.p.A. submitted Uman Big for mutual recognition on the basis of the initial authorisation granted by Italy on 2 June 1979. The company wanted the authorisation to be recognised in Austria, Denmark, Germany, Greece, Hungary, Poland, Portugal and Sweden (the concerned Member States). These member states were not able to reach an agreement. On 31 October 2008, the Italian medicines agency, Agenzia Italiana del Farmaco, referred the matter to the CHMP.

The grounds for the referral were concerns over the insufficiency of the clinical data submitted to establish the efficacy of the product. In addition, the absence of product specific safety data or post-marketing safety data was raised as a concern.

What are the conclusions of the CHMP?
Based on evaluation of the currently available data and the scientific discussion within the Committee and at the CHMP's Blood Products Working Party, the CHMP concluded that the benefits of Uman Big outweigh its risks, and that therefore the marketing authorisation for Uman Big should be granted in all concerned member states.

The European Commission issued a decision on 06 March 2009.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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