EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2013
EMA/CHMP/38042/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

HyQvia

Human normal immunoglobulin

On 21 March 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product HyQvia, 100 mg/ml, solution for infusion for subcutaneous use intended for:

Replacement therapy in adults (≥ 18 years) in primary immunodeficiency syndromes such as:

- congenital agammaglobulinaemia and hypogammaglobulinaemia
- common variable immunodeficiency
- severe combined immunodeficiency
- IgG subclass deficiencies with recurrent infections

Replacement therapy in adults (≥ 18 years) in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections.

The applicant for this medicinal product is Baxter Innovations GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of HyQvia is human normal immunoglobulin, an immune sera and immunoglobulins: immunoglobulins, normal human, ATC code: J06BA.

Human normal immunoglobulin contains mainly immunoglobulin G (IgG) with a broad spectrum of opsonising and neutralizing antibodies against infectious agents. Human normal immunoglobulin contains the IgG present in the normal population. It is usually prepared from pooled human plasma from not fewer than 1,000 donations. It has a distribution of IgG subclasses closely proportional to that in native human plasma. Adequate doses of human normal immunoglobulin may restore abnormally low IgG levels to the normal range.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

The benefits with HyQvia are its ability to lower the rate of validated, acute, serious bacterial infections per year. HyQvia is administered subcutaneously with an initial infusion of an excipient recombinant human hyaluronidase which facilitates the dispersion and absorption of IG 10% every 3 to 4 weeks.

The most common side effects are local reactions (discomfort/pain, erythema, swelling/oedema, and pruritus), fatigue and headache. Specific safety issues regarding the risk of antibodies against the recombinant human hyaluronidase, pregnancy and fertility have been evaluated and addressed in the Summary of Product Characteristics (SmPC) and in the Risk Management Plan.

A pharmacovigilance plan for HyQvia will be implemented as part of the marketing authorisation.

The approved indication is:

Replacement therapy in adults (≥ 18 years) in primary immunodeficiency syndromes such as:

- congenital agammaglobulinaemia and hypogammaglobulinaemia
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Replacement therapy in adults (≥ 18 years) in myeloma or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections.

It is proposed that HyQvia be prescribed by physicians experienced in the treatment of immunodeficiency.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made 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 there to be a favourable benefit-to-risk balance for HyQvia and therefore recommends the granting of the marketing authorisation.