27 February 2025
EMA/CHMP/2527/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Deqsiga

human normal immunoglobulin

On 27 February 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Deqsiga, intended for replacement therapy in people with primary or secondary immunodeficiencies and immunomodulation in people with certain autoimmune diseases. The applicant for this medicinal product is Takeda Manufacturing Austria AG.

Deqsiga will be available as a 100 mg/ml solution for infusion. The active substance of Deqsiga is human normal immunoglobulin, (ATC code: J06BA02). Deqsiga contains mainly immunoglobulin G (IgG), with a broad spectrum of antibodies against infectious agents. Adequate doses of Deqsiga may restore abnormally low IgG levels to normal levels. Deqsiga also has immunomodulatory effects in patients with autoimmune diseases, although the mechanism of action is not fully understood.

Deqsiga is a duplicate of Kiovig (human normal immunoglobulin), which was authorised in the EU on 19 January 2006. Deqsiga and Kiovig have the same pharmaceutical form, active substance and indications, but Deqsiga contains lower levels of immunoglobulin A (IgA) and may therefore be more suitable for people with IgA deficiency who have a higher risk of hypersensitivity to immunoglobulin products that contain higher levels of IgA.

Because Deqsiga is a duplicate of Kiovig, its benefits and risks are expected to be the same as those of Kiovig. Therefore, the benefits of Deqsiga are expected to be normalising IgG levels in patients with primary or secondary immunodeficiencies, and relieving the symptoms of certain autoimmune diseases. Side effects with Deqsiga include chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain, reversible haemolytic reactions.

The full indication is:

Replacement therapy in adults, children and adolescents (0 to 18 years) in:

- Primary immunodeficiency syndromes (PID) with impaired antibody production.

[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

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- Secondary immunodeficiencies (SID) in patients who suffer from severe or recurrent infections, ineffective antimicrobial treatment and either **proven specific antibody failure (PSAF)*** or serum IgG level of < 4 g/L.

*PSAF = failure to mount at least a 2-fold rise in IgG antibody titre to pneumococcal polysaccharide and polypeptide antigen vaccines

Immunomodulation in adults, children and adolescents (0 to 18 years) in:

- Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count.
- Guillain Barré syndrome.
- Kawasaki disease (in conjunction with acetylsalicylic acid; see section 4.2).
- Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP).
- Multifocal Motor Neuropathy (MMN).

Treatment with Deqsiga should be initiated and supervised by physicians experienced in the treatment of immune system disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.