24th September 2010

Circular No. P12/2010

Dear Healthcare Professional,

Re: European Medicines Agency recommends suspension of Octagam in all EU member states

The European Medicines Agency has recommended the suspension of the marketing authorisations for Octagam (human normal immunoglobulin), from Octapharma GmbH and a recall of Octagam currently on the market in Europe. Octagam 10% has a marketing authorisation in Malta.

As the medicine will no longer be made available, the Agency recommends that doctors should stop using Octagam and should switch their patients to the most appropriate alternative treatment.

Octagam is an intravenous solution used to strengthen the body's immune system to lower the risk of infection in patients with a weakened immune system, including people with primary immunodeficiency syndrome, or children born with acquired immune deficiency syndrome (AIDS). It is also used in people with certain immune disorders such as idiopathic thrombocytopenic purpura (ITP) and in patients who have had a bone marrow transplant.

The CHMP suspended the marketing authorisations of these medicines following an unexpected increase in reports of thromboembolic reactions, including stroke, myocardial infarction and pulmonary embolism in patients receiving the medicine. This increase is thought to be related to problems with the medicine's manufacturing process.

Based on the available information the Committee recommended that, the marketing authorisations of the medicines in all EU Member States where Octagam is authorised should be suspended. The suspension will remain in place until the marketing authorisation holder has rectified the problem.

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The Committee's recommendation to suspend the marketing authorisation for Octagam will now be forwarded to the European Commission for the adoption of a binding decision.

The Medicines Authority has participated in the discussions held at the EMA and is in agreement with the full **press release** issued by the EMA, attached here for your perusal. A **question-and-answer** document with more information about the outcome of this assessment is also available.

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

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