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Press Office

Press release

European Medicines Agency recommends suspension of Octagam in all EU Member States

CHMP recommendation based on risk of thrombo-embolic reactions

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.

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 reviewed Octagam because Germany and Sweden had 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, due to the recent increase in thromboembolic events, 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.

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

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Notes

1. A question-and-answer document with more information is available

2. Octagam is authorised in the following EU Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom.

3. The review was initiated under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a decentralised authorised medicine as a result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.

4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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