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Questions and answers on the suspension of the marketing authorisations for Octagam (human normal immunoglobulin 5% and 10%)

Outcome of a procedure under Article 107 of Directive 2001/83/EC

The European Medicines Agency has completed a review of Octagam triggered by reports of serious thromboembolic events. The Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that all marketing authorisations for the medicine be suspended throughout the European Union (EU) and that Octagam currently on the market be recalled.

What is Octagam?

Octagam is a solution for infusion (drip into a vein) that contains human normal immunoglobulin extracted from blood as the active substance. Human normal immunoglobulins are antibodies (types of protein) normally found in the blood that help the body to fight infections and other diseases.

Octagam is used in patients who are at risk of infection because they do not have sufficient antibodies 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 and in patients who have had a bone marrow transplant.

Octagam is made by Octopharma. It is authorised in 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.

Why was Octagam reviewed?

In September 2010, the German and Swedish medicines regulatory agencies suspended marketing authorisations for Octagam. This follows an unexpectedly high number of reports of serious thromboembolic events (problems due to the formation of blood clots in the blood vessels) in patients taking the medicine. These events were thought to be related to problems with the medicine's manufacture, and included stroke, myocardial infarction (heart attack) and pulmonary embolism (clot in a blood vessel supplying the lungs).

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As required by Article 107, the German and Swedish agencies informed the CHMP of their actions so that the Committee could prepare an opinion on whether the marketing authorisations for Octagam should be maintained, changed, suspended or withdrawn across the EU.

Which data has the CHMP reviewed?

The CHMP reviewed the reported thromboembolic events and looked at evidence related to the medicine's safety.

What are the conclusions of the CHMP?

The CHMP noted that, based on the available information, there was clear evidence of a recent increase in thromboembolic events associated with Octagam but that the exact cause of the problems could not be identified with certainty. The CHMP therefore recommended that, because of the safety concerns with Octagam, the marketing authorisations for the medicine be suspended in the EU. While the marketing authorisations are suspended, Octagam will not be available. The suspension will remain in place until the problem has been rectified.

What are the recommendations for prescribers and patients?

- Doctors should stop using Octagam and switch their patients to the most appropriate alternative treatment.
- Patients who have any questions should speak to their doctor or pharmacist.

The European Commission issued a decision on this opinion on 23 May 2011.