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Press Office

Press release

European Medicines Agency recommends lifting of suspension of Octagam

Recommendation follows implementation of improved manufacturing process and other preventive measures

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the lifting of the suspension of the marketing authorisations for Octagam (human normal immunoglobulin 5% and 10%) and associated names, and the re-introduction of the medicine onto the market in the European Union. The lifting of the suspension is subject to a change to the manufacturing process.

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.

The CHMP recommended the suspension of the marketing authorisations for Octagam in September 2010, following an unexpected increase in reports of thromboembolic reactions, including stroke, myocardial infarction (heart attack) and pulmonary embolism (clot in a blood vessel supplying the lungs) in patients receiving the medicine.

An in-depth review of all available data on the safety and quality issues identified previously has now been finalised. In the review, the CHMP concluded that the unexpected presence of a pro-coagulant, factor XIa, was the main cause of the thromboembolic events and that a number of critical steps in the manufacturing process could explain the presence of substances that triggered the thromboembolic events.

A number of corrective and preventive measures have now been implemented, including an improved manufacturing process and a test to be carried before batches of Octagam are released to the market to detect factor XIa or other substances that can trigger thromboembolic events. In addition the marketing authorisation holders are also required to perform post-marketing safety studies as soon as the medicine is back on the market to confirm the safety of the improved manufacturing process.

Following the review, which also included the findings of inspections carried out at two manufacturing sites, the CHMP was reassured that, with the conditions and safeguards in place, future production of

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Octagam would meet the required quality standards and therefore recommended lifting the suspension.

The Committee's opinion has now been forwarded to the European Commission for the adoption of a legally binding decision. It is expected that supply of Octagam will resume shortly after the adoption of the Commission decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Marketing authorisations for Octagam have been suspended since 4 October 2010 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 of Octagam was carried out under Article 31 of the Community code relating to medicinal products for human use (Directive 2001/83/EC), as amended. This type of procedure foresees that the CHMP makes a recommendation on whether the marketing authorisation for a medicine should be maintained, changed, suspended or revoked.
4. The September 2010 review of Octagam that led to the suspension of the medicine was carried out under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC), as amended. This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a nationally 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.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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