19th April 2011

Circular No: P04/2011

Dear Healthcare Professional,

Re: European Medicines Agency's recommends lifting of suspension of Octagam

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. In Malta, the marketing authorisation for Octagam has been suspended since October 2010. Prior to this, Octagam 10% was available for hospital use

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. In Malta, no adverse drug reactions involving Maltese patients treated with Octagam 10% were reported.

The 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

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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 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.

The Medicines Authority is participating in the discussions held at the EMA and is in agreement with the full **press release** and **question-and-answer** document as issued by the EMA, and attached here for your perusal.

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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