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Press Office

Press release

European Medicines Agency gives second positive opinion for a paediatric-use marketing authorisation

Hemangiol recommended for the treatment of proliferating infantile haemangioma

The European Medicines Agency's Committee for Medicinal Products for Human use (CHMP) has recommended granting a paediatric-use marketing authorisation (PUMA) for Hemangiol for the treatment of proliferating infantile haemangioma. This is the second time that the CHMP has granted a positive opinion for a PUMA since their introduction by the Paediatric Regulation, which came into force in 2007.

Infantile haemangioma are abnormal growths (benign tumours) involving blood vessels, that develop in the skin or internal organs. They typically appear during the first four to six weeks of life, characteristically exhibit early rapid growth and then usually start to shrink spontaneously. Around 3% to 10% of children are affected. Although usually uncomplicated, haemangioma can produce painful ulceration and scarring, and some are associated with life-threatening complications, such as breathing difficulties and heart problems.

Hemangiol is to be used in patients with serious complication requiring systemic therapy (treatment which aims to have an effect on the whole body). Treatment should be initiated in infants aged five weeks to five months. In most European countries, there are currently no approved treatment options, although corticosteroids are authorised for severe cases in France and Germany.

PUMAs can be granted for medicines which are already authorised, but no longer under patent protection, and that have been developed specifically for children. Prerequisite for a PUMA is a paediatric investigation plan (PIP) which sets out the development of the medicine in children and has to be approved by the Agency's Paediatric Committee (PDCO).

As an incentive to stimulate research of existing products in children, medicines that have been granted a PUMA benefit from ten years of market protection. However, industry and academic networks have so far not embraced this opportunity as fully as the Regulation intended. This was also highlighted by the European Commission in its five-year report on the impact of the Paediatric Regulation. As a further incentive, the EMA now accepts PIPs for a PUMA that covers only certain age groups and not the entire paediatric population.

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Hemangiol is an oral solution of propranolol, a well-known medicine which has been used since the 1960's in adults for cardiovascular therapies and is commonly prescribed in several clinical situations, including control of hypertension.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing-authorisation applicant for Hemangiol is Pierre Fabre Dermatologie.
3. The first paediatric use marketing authorisation (PUMA) was granted in September 2011 to Buccolam (midazolam) for the treatment of prolonged, acute, convulsive seizures in paediatric patients from the age of three months to 18 years. More information is available here: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2011/06/WC500107995.pdf
4. More information on PUMAs is available in this questions and answers document: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/09/WC500112071.pdf
5. The European Commission's five-year report on the impact of the Paediatric Regulation is available here: http://ec.europa.eu/health/files/paediatrics/2013_com443/paediatric_report-com(2013)443_en.pdf
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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