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Human Medicines Research and Development Support Division

Public summary of the evaluation of a proposed product-specific waiver

Azithromycin for treatment of bacterial conjunctivitis

On 17 January 2015, the Paediatric Committee of the European Medicines Agency did not agree a Paediatric Investigation Plan* (PIP) for Azithromycin for the treatment of bacterial conjunctivitis (EMEA-001777-PIP01-15) but agreed a product-specific waiver* on own motion instead.

What is Azithromycin, and how is it expected to work?

This particular formulation of Azithromycin is not authorised in the European Union, but other Azithromycin formulations including topical eye drops for eye infections are available in the European Union. This medicine is proposed in adults for the same condition as in children.

This medicine is a topical antibiotic expected to treat bacterial conjunctivitis which is an infection of the eye.

What was the proposal from the applicant?

The applicant proposed to conduct studies in children. However the PDCO considered that studies in children were not necessary on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients. This was based on the fact that other Azithromycin eye drops are already available in the European Union for children.

What did the Paediatric Committee conclude on the potential use of this medicine in children?

The Committee disagreed with the plan proposed by the applicant, and granted an exemption (waiver*) from conducting studies, instead. This is because the Committee concluded that this medicinal product does not seem to have a potential significant benefit over existing treatments.

What happens next?

The applicant has now received the EMA Decision (P/0203/2015)* on this medicine. The Decision itself is necessary for the applicant to request in the future a marketing authorisation* for this medicine in adults and/or in children.

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*Definitions:

Applicant	The pharmaceutical company or person proposing the Paediatric Investigation Plan or requesting the Product-Specific Waiver
Children	All children, from birth to the day of the 18th birthday.
Paediatric investigation plan (PIP)	Set of studies and measures, usually including clinical studies in children, to evaluate the benefits and the risks of the use of a medicine in children, for a given disease or condition. A PIP may include "partial" waivers (for example, for younger children) and/or a deferral (see below).
Waiver	An exemption from conducting studies in children, for a given disease or condition. This can be granted for all children (product-specific waiver), or in specific subsets (partial waiver): for example, in boys or in children below a given age.
Deferral	The possibility to request marketing authorisation for the use of the medicine in adults, before completing one or more of the studies /measures included in a PIP. The Paediatric Committee may grant a deferral to avoid a delay in the availability of the medicine for adults.
Opinion	The result of the evaluation by the Paediatric Committee of the European Medicines Agency. The opinion may grant a product-specific waiver, or agree a PIP.
Decision	The legal act issued by the European Medicines Agency, which puts into effect the Opinion of the Paediatric Committee.
Pharmaceutical form	The physical aspect of the medicine (the form in which it is presented), for example: a tablet, capsule, powder, solution for injection, etc. A medicine can have more than one pharmaceutical form.
Placebo	A substance that has no therapeutic effect, used as a control in testing new drugs.
Active control	A medicine with therapeutic effect, used as a control in testing new drugs.
Historical control	A group of patients with the same disease, treated in the past and used in a comparison with the patients treated with the new drug.
Route of administration	How a medicine is given to the patient. For example: for oral use, for intramuscular use, for intravenous use, etc. The same medicine, or the same pharmaceutical form, may be given through more than one route of administration.
Patent	A form of protection of intellectual property rights. If a medicinal product is protected by a patent, the patent holder has the sole right to make, use, and sell the product, for a limited period. In certain circumstances, a patent for a medicinal product may be extended for a variable period by a Supplementary Protection Certificate.
Marketing Authorisation	When a Marketing Authorisation is granted, the pharmaceutical company may start selling the medicine in the relevant country (in the whole European Union, if the procedure was a centralised one).