04 March 2015
EMA/712433/2014
Human Medicines Research and Development Support Division

Summary of the evaluation of the proposed product-specific waiver

Amlodipine / perindopril (erbumine) for treatment of hypertension and for treatment of stable coronary artery disease

On 12 December 2014 the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for the fixed drug combination amlodipine / perindopril (erbumine) for the treatment of hypertension and for treatment of stable coronary artery disease (EMEA-001669-PIP01-14).

What is amlodipine / perindopril (erbumine), and how is it expected to work?

The fixed drug combination amlodipine / perindopril (erbumine) is not authorised in the European Union. Studies in adults are currently on-going. This medicine is proposed for the treatment of hypertension and for the treatment of stable coronary artery disease as substitution therapy in adult patients adequately controlled with the individual products given concurrently at the same dose level as in the combination, but as separate tablets.

This medicine is expected to control high blood pressure and as a consequence to reduce the risk for coronary artery disease.

What was the proposal from the applicant?

For children, the applicant proposed:

Not to do any study in children (from birth to 18 years of age), because the fixed dose combination product does not represent a significant therapeutic benefit over existing treatments. Therefore, the applicant requested an exemption (waiver*) from the obligation to study the medicine in any children, in the condition “treatment of hypertension”.

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

The Committee agreed with the request of being exempt from performing studies in children, because the Committee concluded that this fixed drug combination does not seem to have a potential significant benefit over existing treatments for the treatment of hypertension and for the treatment of stable coronary artery disease.

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The Committee came to this conclusion because there are insufficient data on the safety and efficacy of perindopril monotherapy in children available yet. Consequently, a fixed-dose combination, of which one of the components has not yet been proved as safe and efficacious in children, is not recommended.

Stable coronary artery disease does not occur in the paediatric population.

What happens next?

The applicant has now received the EMA Decision* (P/0028/2015) on this medicine. The Decision itself is necessary for the applicant to request in the future a marketing authorisation* for this medicine in adults.

*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.
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).