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Human Medicines Research and Development Support Division

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

Torsemide / lisinopril for treatment of hypertension and treatment of heart failure

On 17 July 2015, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for torsemide / lisinopril for treatment of hypertension and treatment of heart failure (EMA-001759-PIP01-15).

What is torsemide / lisinopril, and how is it expected to work?

Torsemide / lisinopril is not authorised in the European Union. Studies in adults are currently ongoing. This medicine is proposed in adults for treatment of hypertension and / or heart failure as substitution therapy in adult patients whose blood pressure and / or symptoms of heart failure, including oedema, are adequately controlled on the combination of lisinopril and torsemide given concurrently.

This medicine is expected to decrease blood pressure and to improve heart function. Torsemide is a diuretic working by increasing the elimination of salt and water in the urine. This decreases the overall blood volume and blood pressure, reducing the effort needed for the heart to pump blood and thereby improving its function. Lisinopril is an ACE inhibitor that decreases blood pressure in patients with hypertension by relaxing vascular smooth muscle.

What was the proposal from the applicant?

For children, the applicant proposed:

Not to do any study in children (from birth to less than 18 years of age), because this medicine does not have a potential significant benefit over existing treatments of hypertension and heart failure.

Is there a need to treat children affected by hypertension and heart failure?

Taking into account the proposed indication in adults, and the characteristics of the medicine, the Paediatric Committee considered this medicine of no potential use for treatment of hypertension and

treatment of heart failure. These conditions occur also in children; however the combination of torasemide / lisinopril is not considered appropriate for use in children for these conditions.

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

The Committee agreed with the request of the applicant to be exempt from performing studies in children from birth to less than 18 years of age, because this medicinal product does not seem to have a potential significant benefit over existing treatments of hypertension and heart failure.

What happens next?

The applicant has now received the EMA Decision (P/0199/2015)* 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 18 th 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).