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Human Medicines Research and Development Support Division

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

Rosuvastatin / acetylsalicylic acid for treatment of cardiovascular disease

On 20 June 2014, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for rosuvastatin / acetylsalicylic acid for the treatment of cardiovascular disease (EMEA-001269-PIP02-14).

What is rosuvastatin / acetylsalicylic acid, and how is it expected to work?

Rosuvastatin / acetylsalicylic acid is not authorised in the European Union. This medicine is proposed in adults for the substitution therapy in patients with high cardiovascular risk, adequately controlled with the individual products given concurrently at the same dose level as in the combination, but as separate products.

This medicine is expected to lower the lipid (fat) levels in blood as well as to prevent thrombotic events resulting from increased coagulation of the blood. The product contains two active ingredients in one capsule, both of which are widely used separately.

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 of an expected lack of significant benefit for the paediatric population. Therefore, the applicant requested an exemption (waiver*) from the obligation to study the medicine in any children, in the condition(s) treatment of cardiovascular disease.

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 the Committee concluded that this medicinal product does not seem to have a potential significant benefit over existing treatments for the treatment of cardiovascular disease.

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The Committee came to this conclusion because although the fixed-dose combination of the two active ingredients is more convenient for the patients to take than taking two separate tablets, it would be impossible to adjust the doses of the separate ingredients independently from the other one, which is especially important in paediatric patients.

What happens next?

The applicant has now received the EMA Decision (P/0201/2014)* 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.
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).