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Human Medicines Research and Development Support Division

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

Calcium (carbonate) / cholecalciferol (in combination with ibandronic acid) for combination treatment of osteoporosis

On 14 November 2014, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for calcium (carbonate) / cholecalciferol (in combination with ibandronic acid) for the combination treatment of osteoporosis (EMEA-001670-PIP01-14).

What is calcium (carbonate) / cholecalciferol (in combination with ibandronic acid), and how is it expected to work?

The combination pack calcium (carbonate) / cholecalciferol (in combination with ibandronic acid) is not authorised in the European Union. These medicines are proposed in adults for the indication combination treatment of osteoporosis in postmenopausal women at increased risk of fracture.

Calcium (carbonate) / cholecalciferol is a fixed combination, calcium (carbonate) is essential for a number of physiological functions and particularly bone mineralization whereas cholecalciferol, undergoes a biotransformation into 1,25 dihydroxycholecalciferol, a main active metabolite of vitamin D, which is necessary to promote the intestinal absorption of calcium.

Calcium (carbonate) and cholecalciferol are used in association with ibandronic acid if dietary intake is inadequate to avoid lower level of calcium in the blood.

Ibandronic acid is a bisphosphonate which stops the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells by ibandronic acid leads to less bone loss and could be of benefit for osteoporosis that occurs when not enough new bone grows to replace the bone that is naturally broken down.

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 lack of significant therapeutic benefit. Therefore, the applicant requested an exemption (waiver*) from the obligation to study the medicine in any children, for treatment of osteoporosis.

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Is there a need to treat children affected by osteoporosis?

Taking into account the proposed indication in adults, and the characteristics of the medicine, the Paediatric Committee considered this combination pack is not of potential use for the treatment of osteoporosis in children.

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, because clinical studies with the combination pack cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population for treatment of osteoporosis.

What happens next?

The applicant has now received the EMA Decision (P/0339/2014)* 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).