05 December 2014
EMA/757976/2014
Human Medicines Research and Development Support Division

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

Varicella-zoster virus (live, attenuated) for prevention of varicella-zoster-virus reactivation

On 10 October 2014, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for varicella-zoster virus (live, attenuated) for the prevention of varicella-zoster-virus reactivation (EMEA-001672-PIP01-14).

What is Zostavax (varicella-zoster virus (live, attenuated)), and how is it expected to work?

Zostavax (varicella-zoster virus (live, attenuated)) is a medicine currently authorised in adults 50 years of age or older for the prevention of herpes zoster ("zoster" or shingles) and herpes zoster-related post-herpetic neuralgia (severe long-lasting pain). Its safety and efficacy have not been studied in children.

This medicine is proposed in adults for the prevention of varicella-zoster virus reactivation with a new route of administration.

This medicine is a vaccine expected to 'boost' the specific immunity (protection) against shingles and to prevent the pain associated with varicella-zoster virus reactivation in people who have had chickenpox earlier in life. It appears that the risk of developing shingles is linked to a decline in the specific immunity against varicella-zoster virus, causing both chickenpox and shingles.

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 it was not expected that the vaccine could be of significant therapeutic benefit in children from birth to less than 18 years of age. Therefore, the applicant requested an exemption (waiver*) from the obligation to study the medicine in any children, in the condition prevention of Varicella-Zoster-Virus reactivation.

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Is there a need to treat children for the prevention of varicella-zoster-virus reactivation?

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 the prevention of Varicella-Zoster-Virus reactivation in children.

Prevention of Varicella-Zoster-Virus reactivation occurs occasionally also in children; however Zostavax is not expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population.

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 vaccine is not expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the paediatric population for the prevention of Varicella-Zoster-Virus reactivation.

What happens next?

The applicant has now received the EMA Decision (P/0309/2014)* on this medicine. The Decision itself is necessary for the applicant to request a new indication, a new route of administration* or a new pharmaceutical form*, as this medicine is already authorised and protected by a patent*.

*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).