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Human Medicines Research and Development Support Division

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

Human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein for prevention of infection by human papillomavirus

On 12 December 2014, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein for prevention of infection by human papillomavirus (EMEA-000234-PIP02-14).

What is Cervarix, and how is it expected to work?

Cervarix (human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1) is a vaccine currently authorised in adults and children from the age of 9 years for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer causally related to certain oncogenic human papillomavirus (HPV) types.

Studies in adults and children are currently on-going. This medicine is now proposed in adults and children for the prevention of premalignant anal lesions and anal cancer.

Papillomaviruses are viruses that cause warts and abnormal tissue growth. There are more than 100 types of papillomavirus, some of which like HPV types 16 and 18 are associated with genital and anal cancers.

All papillomaviruses have a shell or 'capsid', which is made up of distinctive proteins called 'L1 proteins'. Cervarix contains purified L1 proteins for HPV types 16 and 18. The proteins are assembled in 'virus-like particles' (structures that look like HPV, so that the body can recognise them easily).

When a patient is given the vaccine, the immune system produces antibodies against the L1 proteins. The antibodies help to destroy the virus. After vaccination, the immune system is able to produce antibodies more quickly when it is exposed to the real viruses. This will help to protect against the diseases caused by papillomaviruses.

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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, in the condition prevention of infection by human papillomavirus.

Is there a need to prevent the infection caused by human papillomavirus in children?

Taking into account the proposed indication in adults, and the characteristics of the medicine, the Paediatric Committee considered this vaccine is not expected to be of significant therapeutic benefit over existing treatment or 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, because the Committee concluded that this medicinal product does not seem to have a potential significant benefit over existing treatments for the prevention of infection caused by human papillomavirus.

The Committee came to this conclusion because a quadrivalent HPV vaccine (which protects also against HPV-6 and HPV-11 related diseases) is already licenced in the EU in males and females from the age of 9 years for the prevention of premalignant genital lesions (cervical, vulvar and vaginal), premalignant anal lesions, anal lesions and anal cancer and genital warts (condyloma acuminata).

What happens next?

The applicant has now received the EMA Decision (P/0008/2015)* 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).