EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 July 2014
EMA/448345/2014
Human Medicines Research and Development Support Division

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

Aflibercept for the treatment of branch retinal vein occlusion and for the treatment of choroidal neovascularisation secondary to pathologic myopia

On 23 May 2014, the Paediatric Committee of the European Medicines Agency agreed a product-specific waiver* for aflibercept for the treatment of branch retinal vein occlusion and for the treatment of choroidal neovascularisation secondary to pathologic myopia (EMEA-000236-PIP04-14).

What is Eylea (aflibercept), and how is it expected to work?

Eylea is a medicine currently authorised in adults for the indications neovascular (wet) age-related macular degeneration (AMD) and visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO). Its safety and efficacy have not been studied in children.

This medicine is expected to decrease the permeability of the blood vessels in the eye that is a critical component in the development of vascular leakage and/or thickening and oedema of the retina, which are thought to contribute to vision loss.

What was the proposal from the applicant?

For children, the applicant proposed:

Not to do any study in children (from birth to 18 years of age), because the above described diseases do not occur in children. Therefore, the applicant requested an exemption (waiver*) from the obligation to study the medicine in any children, in the condition(s) treatment of branch retinal vein occlusion and for the treatment of choroidal neovascularisation secondary to pathologic myopia.

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

The Committee agreed with the request of being exempt from performing studies in children, because the condition for which the medicinal product could potentially be used does not exist in children.

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What happens next?

The applicant has now received the EMA Decision* 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.
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).