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Human Medicines Research and Development Support Division

Public summary of the evaluation of the proposed paediatric investigation plan

Solothromycin for treatment of bacterial pneumonia and treatment of gonococcal infection

On 15-August 2014, the Paediatric Committee of the European Medicines Agency agreed a Paediatric Investigation Plan* (PIP) for solothromycin for treatment of bacterial pneumonia and treatment of gonococcal infection (EMA-001581-PIP01-13).

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

Solothromycin is not authorised in the European Union. Studies in adults and children are currently ongoing. This medicine is proposed in adults for the treatment of bacterial pneumonia and treatment of gonococcal infection.

This medicine is an antibiotic of the macrolide group with improved antimicrobial effectiveness and is expected to inhibit bacterial development by suppressing cell viability, protein synthesis, and growth rate.

What was the proposal from the applicant?

For children, the applicant proposed:

To study the medicine in children from birth to 18 years old affected by bacterial pneumonia and gonococcal infection in a paediatric investigation plan*. The future indications proposed for children are: treatment of bacterial pneumonia and treatment of gonococcal infection. The plan includes the development of a specific pharmaceutical form to be used in children*, powder for oral suspension. It also includes a proposal to determine the right dose and to show efficacy and safety of the medicine in clinical studies.

Is there a need to treat children affected by bacterial pneumonia or gonococcal infections?

Taking into account the proposed indication in adults, and the characteristics of the medicine, the Paediatric Committee considered this medicine of potential use for the treatment of bacterial pneumonia and for the treatment of gonococcal infections. These conditions occur also in children.

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

At present, some treatments are available for the treatment of bacterial pneumonia and for the treatment of gonococcal infections in children in the European Union, such as amoxicillin for bacterial pneumonia or ceftriaxone for gonococcal infections are known to work. Therefore, the Committee considered that new data are required to decide whether the use of this medicine will bring a benefit to the children affected by these conditions, and to understand any potential risks.

The Committee considered that there is also a need to develop a specific pharmaceutical form* of this medicine, which would allow to use the medicine safely and accurately in young children (powder for oral suspension), and whose composition* must only include components that are known to be safe in children.

Because there is a need for more medicines for the treatment of bacterial pneumonia and for the treatment of gonococcal infections in children, and this medicine has a potential interest for children, the Committee considered that non-clinical and clinical studies were necessary.

What is the content of the Plan after evaluation?

The Paediatric Committee considered that:

- In the paediatric population from birth to less than 12 years studies for the treatment of gonococcal infections are not necessary, because clinical studies with the specific medicinal product are not expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).
- A pharmaceutical form* such as a powder for oral suspension will be developed by the applicant.
- Studies in animals need to be performed, to identify any risk before the medicine is used in children.
- It is necessary to study if the medicine is efficacious to treat bacterial pneumonia in children or to treat gonococcal infections in children. This will be done in studies for both, bacterial pneumonia and gonococcal infections, comparing the medicine to the respective active controls.

What happens next?

The applicant has now received the EMA Decision* on this medicine. The Decision itself is necessary for the applicant to request in the future a marketing authorisation* for this medicine in adults and in children.

The Decision* on the agreed Paediatric Investigation Plan means that the applicant is bound to perform the studies and trials with children in the next months or years. In case of difficulties, or a change in current knowledge or availability of new data, the applicant may request changes to the plan at a later stage. This can be done through a modification of the PIP.

The agreed completion of all the studies and trials included in the Paediatric Investigation Plan is February 2018.

Trials in the Paediatric Investigation Plan will be listed in the public EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu/>) as soon as they have been authorised to be started, and their results will have to be listed in the register within 6 months after they have completed.

The results of the studies conducted in accordance with the agreed Paediatric Investigation Plan will be assessed, and any relevant information will be included in the Product Information (summary of product characteristics, package leaflet). If the medicine proves to be efficacious and safe to use in children, it can be authorised for paediatric use, with appropriate recommendations on the dose and on necessary precautions. The product information will also describe which adverse effects are expected with the medicine, and wherever possible, how to prevent or reduce these effects.

***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 18 th 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).