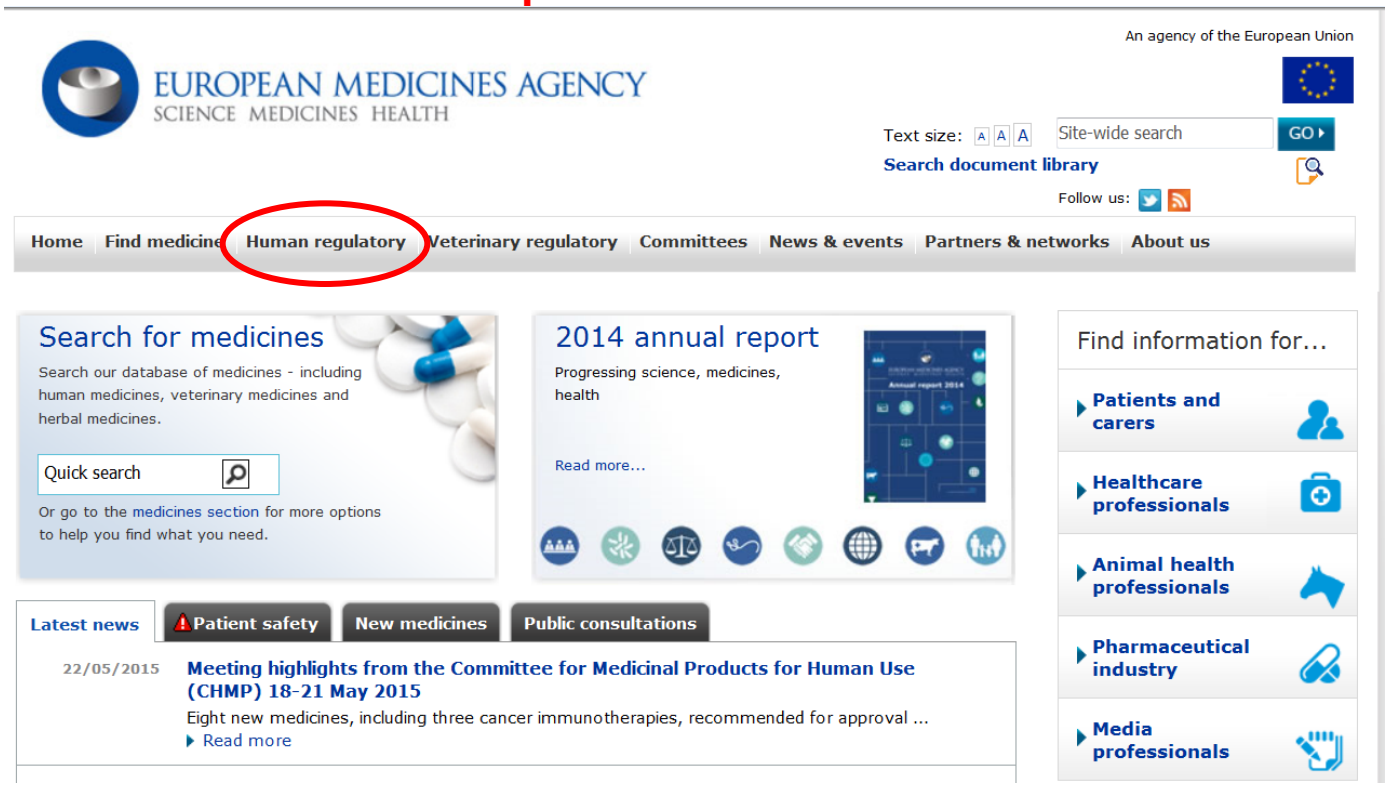
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Public summaries of PDCO opinions on agreed PIPs and waivers

Irmgard Eichler

Public summaries of PDCO opinions

- Since almost a year the paediatric team publishes public summaries of the PDCO opinions on agreed PIPs and waivers for the general public.
- To be found on the PIP decision webpage to the right hand side, under related information: **www.ema.europa.eu**



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Post-opinion
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Paediatric medicine
Geriatric medicine
Orphan designation

Human medicines: regulatory information

This section of the website provides information for companies and individuals involved in developing and marketing medicines for human use in the European Union (EU).

For further information on EU legislation and procedures for the regulation of human medicines, see volumes 1-4 and 9-10 of the rules governing medicinal products in the EU.

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Paediatric-medicine development

The European Medicines Agency has a number of important tasks and responsbilities relating to the development of paediatric medicines. These were brought in by the Paediatric Regulation in January 2007.

This legislation concerns the development and authorisation of medicines for use in children aged up to 17 years and introduced sweeping changes into the regulatory environment for paediatric medicines, designed to better protect the health of children in the European Union (EU). The main change introduced was the creation and operation of the Paediatric Committee within the Agency to provide objective scientific opinions on development plans for medicines for use in children.

This section of the website provides information for companies or individuals wishing to develop a paediatric medicine and requiring guidance for the approval of a paediatric investigation plan (PIP), together with other information relating to paediatric medicines.

More information

- Paediatric Regulation
- Application guidance
- Opinions and decisions on paediatric-investigation-plan applications
- Post-assessment guidance
- Supporting information
- Paediatrics: Regulatory and procedural guidance

Related information

- Opinions and decisions on paediatric investigation plans
- Paediatric Committee
- European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
- Medicines for children: Background information
- Better medicines for children (18/05/2015)

All Microsoft Office documents submitted to the European Medicines Agency must be in a format compatible with MS Office 2003. Office 2007 and Office 2010 formats cannot currently be accepted. PDF certified electronic application forms require Adobe Reader 10.0 or higher. Please visit eSignature for more information on digitally signed electronic documents.

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Product specific decisions

Opinions and decisions on PIP applications

In this section you can find information on decisions and opinions of the Paediatric Committee related to PIP applications including class waivers.

- Class waivers
- Product specific decisions

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Herbal medicines for human use

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Opinions and decisions on paediatric investigation plans

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This page allows you to find information on opinions and decisions adopted by the European Medicines Agency's (EMA) Paediatric Committee (PDCO) on Paediatric Investigation Plans (PIPs) including deferrals and waivers.

A PIP is a medicine development plan aimed at ensuring the necessary data are obtained through studies in children to support the medicine's authorisation for use in children. The plan is submitted by a pharmaceutical company to the PDCO, which is responsible for agreeing or refusing the plan and for publishing an opinion with its decision.

Decision types
P: decision agreeing on a Paediatric investigation plan, with or without partial waiver(s) and or deferral(s)
W: decision granting a waiver in all age groups for the listed condition(s)
PM: decision on the application for modification of an agreed PIP
RP: decision refers to a refusal on a proposed Paediatric Investigation Plan
RW: decision refers to a refusal on a request for waiver in all age groups for the listed condition(s)
RPM: decision refers to a refusal on the application for modification of an agreed PIP

Decisions replaced by the latest modification of an agreed PIP

When the latest modification of an agreed PIP is published, any previous decisions will no longer be displayed on the decision web page accessed through the below search. However, these decisions remain published and can be found by searching the document library or using the site-wide search bar featured at the top right of every page. If you cannot find the document you are looking for, you can make a formal request for access to documents using the online enquiry form.

Browse A-Z | Keyword search | Browse by therapeutic area

Browse for Paediatric investigation plans by first letter of active substance:

A B C D E F G H I J K L M N O P
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Search for keyword:

Enter keywords SUBMIT ▸

- (•) Invented name
- ( ) Active substance
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EMEA-001202-PIP02-13

Overview | Decision

Invented name	-
Active substance	Reslizumab
Decision number	P/0017/2015
PIP number	EMEA-001202-PIP02-13
Pharmaceutical form(s)	Concentrate for solution for infusion; Solution for injection
Condition(s)/indication(s)	Treatment of asthma
Route(s) of administration	Intravenous use; Subcutaneous use
PIP applicant	Teva Pharma GmbH Germany E-mail: arthur.merlindestreux@tevauk.com Tel. +44 (0)20 7540 7524
Decision type	P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s)

Related information

Public summary of the evaluation of a proposed paediatric investigation plan: Reslizumab for treatment of asthma (10/03/2015)

Public summary of the evaluation of a proposed paediatric investigation plan

Reslizumab for treatment of asthma

On 12 December 2014 the Paediatric Committee of the European Medicines Agency agreed a Paediatric Investigation Plan* (PIP) for reslizumab for the treatment of asthma (EMEA-001202-PIP02-13).

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

Reslizumab is not authorised in the European Union. Studies in adults are currently on-going. This medicine is proposed in adults as an add-on treatment to reduce exacerbations, relieve symptoms and improve lung function in uncontrolled adult patients with moderate-to-severe asthma who have a blood eosinophil count ≥ 400/µL.

The active substance is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) in the body. Reslizumab has been designed to attach to and neutralise interleukin-5 (IL-5). This molecule stimulates the production, activation and maturation of eosinophils, a type of white blood cells, which play an important role in asthma exacerbations. This causes a reduction in eosinophil number and reduces asthma symptoms and exacerbations.

What was the proposal from the applicant?

For children, the applicant proposed:

To study the medicine in children from 12 years to less than 18 years of age affected by asthma, in a paediatric investigation plan*. The future indication proposed for children is: Add-on treatment to reduce exacerbations, relieve symptoms and improve lung function in uncontrolled paediatric patients (12 to less than 18 years of age) with moderate-to-severe asthma who have a blood eosinophil count ≥ 400/µL. 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 asthma?

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 asthma in children. This condition occurs also in children and affects in particular preadolescent children and adolescents.

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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 asthma in children in the European Union, such as inhaled corticosteroids that 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 children from 6 years to less than 18 years affected by the condition, 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, 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 asthma in children, and this medicine has a potential interest for children, the Committee considered that clinical studies were necessary.

The Committee considered that it is more prudent to confirm that the medicine is effective and safe in adults, before starting the paediatric studies. The Committee agreed with the request of the applicant that the development of a specific pharmaceutical form to be used in children, and paediatric clinical studies should be deferred to avoid a delay in the availability of the medicine for adults.

What is the content of the Plan after evaluation?

The Paediatric Committee considered that:

- Studies are not necessary in children birth to less than 6 years of age because reslizumab does not represent a significant therapeutic benefit over existing treatments.
- A pharmaceutical form* such as solution for injection for subcutaneous use was needed for children aged from 6 years to less than 18 years of age. A new form will be developed by the applicant.
- Determination of the best dose should be done with 1 trial of the medicine's behaviour in the body and the body's reactions to it.
- It is necessary to study if the medicine is effective to treat the disease in children. This will be done in 2 studies comparing the medicine to placebo*.
- It is necessary to study the potential side effects of the medicine, to prevent them or to reduce the consequences if they occur. The main concern identified by the PDCO is the potential toxicity of the medicine for occurrence of parasitic infestations.
- Two modelling and simulation studies to support the dose selection of reslizumab in children before conducting clinical trials were considered necessary.

What happens next?

Published summaries of PDCO opinions

- Feedback important from people to whom this service is intended

? Are you aware that the EMA started publishing summaries of PDCO evaluation of PIPs/Waivers from July 2014, intended mainly for patients/parents?

? Do you find the public summaries useful?

? Do you think the language of public summaries is appropriate, e.g. too technical or too lay?