EMA/330874/2010

European Medicines Agency decision

P/84/2010

of 1 June 2010

on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi) (EMEA-000265-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8409
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi) (EMEA-000265-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/58/2010 issued on 26 March 2010,

Having regard to the application submitted by Centocor B.V. on 4 February 2010 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 16 April 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for golimumab (Simponi), solution for injection in a pre-filled syringe, solution for injection in a pre-filled pen, solution for infusion, subcutaneous use, intravenous use are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Centocor B.V., Einsteinweg 101, 2333 CB Leiden, The Netherlands.

Done at London, 1 June 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/147279/2010

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000265-PIP01-08-M01

Scope of the application

Active substance(s):

Golimumab

Invented name:

Simponi

Condition(s):

Juvenile idiopathic arthritis
Psoriatic arthritis
Ankylosing spondylitis
Rheumatoid arthritis

Pharmaceutical form(s):

Solution for injection in a pre-filled syringe
Solution for injection in a pre-filled pen
Solution for infusion

Route(s) of administration:

Subcutaneous use
Intravenous use

Name/corporate name of the PIP applicant:

Centocor B.V.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Centocor B.V. submitted to the European Medicines Agency on 4 February 2010 for modification of the agreed paediatric investigation

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
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E-mail info@ema.europa.eu **Website** www.ema.europa.eu

plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/58/2010 of 26 March 2010. The application for modification proposed changes to the pediatric investigation plan.

The procedure started on 18 February 2010.

Scope of the modification

Change of the design of the clinical study in JIA, change of the end point definition, statistical plan and timelines. Change in the condition and indication terminology and corresponding grounds for a waiver.

Opinion

The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree to changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan in the scope set out in the Annex I of this opinion.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex and appendix(ces).

London, 16 April 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

Annex I

The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

1. Condition(s)

Juvenile idiopathic arthritis

Psoriatic arthritis

Ankylosing spondylitis

Rheumatoid arthritis

2. Waiver

2.1. Condition

Juvenile idiopathic arthritis

The waiver applies to:

- Children from birth to less than 2 years, for the solution for injection in a pre-filled syringe and solution for injection in a pre-filled pen for subcutaneous use and for the solution for infusion for intravenous use

on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset of the paediatric population.

2.2. Condition

Psoriatic arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 12 years of age for the solution for injection in a pre-filled syringe and solution for injection in a pre-filled pen for subcutaneous use and for the solution for infusion for intravenous use

on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset of the paediatric population.

2.3. Condition

Ankylosing spondylitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age for the solution for injection in a pre-filled syringe and solution for injection in a pre-filled pen for subcutaneous use and for the solution for infusion for intravenous use,

on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

2.4. Condition

Rheumatoid arthritis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age for the solution for injection in a pre-filled syringe and solution for injection in a pre-filled pen for subcutaneous use and for the solution for infusion for intravenous use,

on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations

3. Paediatric Investigation Plan

3.1. Condition to be investigated

Juvenile idiopathic arthritis (including Psoriatic arthritis)

3.1.1. Indication targeted by the PIP

Treatment of children with moderately to severely active polyarticular-course juvenile idiopathic arthritis (defined as one of: rheumatoid factor positive or negative polyarticular JIA , systemic JIA with no systemic symptoms but with polyarthritis , extended oligoarticular JIA, or polyarticular juvenile psoriatic arthritis) in combination with methotrexate, in whom the response to methotrexate has been inadequate

3.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years

3.1.3. *Pharmaceutical form(s)*

Solution for injection in a pre-filled syringe for subcutaneous use

3.1.4. Studies

Area	Number of studies	Description
Quality	1	Solution for injection for subcutaneous use in age-appropriate pre-filled syringe
Non-clinical		Not applicable.
Clinical	1	Double-blind, randomised withdrawal, multi-centre; two phase placebo controlled study to evaluate pharmacokinetics, safety and efficacy of golimumab in combination with methotrexate in children from 2 years to less than 18 years of age with inadequate response to methotrexate

4. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	**Yes**
Date of completion of the paediatric investigation plan:	By September 2013
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

EU Number	(Invented) name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content (concentration)	Package size
EU/1/09/546/001	Simponi	50 mg	Solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (glass)	0.5 ml	1 pre-filled pen
EU/1/09/546/002	Simponi	50 mg	Solution for injection in pre-filled pen	Subcutaneous use	pre-filled pen (glass)	0.5 ml	3 (3 x 1) pre-filled pens
EU/1/09/546/003	Simponi	50 mg	Solution for injection in pre-filled syringe	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe
EU/1/09/546/004	Simponi	50 mg	Solution for injection in pre-filled syringe	Subcutaneous use	pre-filled syringe (glass)	0.5 ml	3 (3 x 1) pre-filled syringes