



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/589434/2011

European Medicines Agency decision P/197/2011

of 30 August 2011

on the acceptance of a modification of an agreed paediatric investigation plan for golimumab (Simponi) (EMA-000265-PIP01-08-M02) 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.



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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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/58/2010 issued on 26 March 2010, the decision P/84/2010 issued on 1 June 2010,

Having regard to the application submitted by Janssen Biologics B.V. on 2 May 2011 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 15 July 2011, 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 infusion / solution for injection in a pre-filled pen, 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 Janssen Biologics B.V., Einsteinweg 101 (P.O. Box 251), 2333 CB – Leiden, The Netherlands.

Done at London, 30 August 2011

For the European Medicines Agency
Andreas Pott
Acting Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/473211/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000265-PIP01-08-M02

Scope of the application

Active substance(s):

Golimumab

Invented name:

Simponi

Condition(s):

Treatment of juvenile idiopathic arthritis

Treatment of psoriatic arthritis

Treatment of ankylosing spondylitis

Treatment of rheumatoid arthritis

Authorised indication(s):

See Annex II

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:

Janssen Biologics 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, Janssen Biologics B.V. submitted to the European Medicines Agency on 2 May 2011 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/58/2010 issued on 26 March 2010, the decision P/84/2010 issued on 1 June 2010.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 18 May 2011.

Scope of the modification

Some measures of the paediatric investigation plan have been modified.

Opinion

1. 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

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

London, 15 July 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of 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.

1.2. Condition: Treatment of 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.

1.3. Condition: Treatment of 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.

1.4. Condition: Treatment of 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.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of juvenile idiopathic arthritis

2.1.1. Indication(s) 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

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

From 2 years to less than 18 years

2.1.3. Pharmaceutical form(s)

Solution for injection in a pre-filled syringe

Solution for injection in a pre-filled pen

Solution for infusion

2.1.4. 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 with JIA from 2 years to less than 18 years of age with inadequate response to methotrexate

2.2. Condition: Treatment of psoriatic arthritis

2.2.1. Indication(s) 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

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

From 12 years to less than 18 years

2.2.3. Pharmaceutical form(s)

Solution for injection in a pre-filled syringe

Solution for injection in a pre-filled pen

Solution for infusion

2.2.4. 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 with JIA from 2 years to less than 18 years of age with inadequate response to methotrexate

Follow-up, completion and deferral of PIP

Concerns on potential long term safety issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2014
Deferral for some or all studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):**1. Treatment of rheumatoid arthritis**

Authorised indications:

Simponi, in combination with methotrexate (MTX), is indicated for:

- treatment of moderate to severe, active rheumatoid arthritis in patients when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate.
- treatment of severe, active and progressive rheumatoid arthritis in patients not previously treated with MTX.

Simponi, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

2. Treatment of psoriatic arthritis

Authorised indication:

Simponi, alone or in combination with MTX, is indicated for the treatment of active and progressive psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. Simponi has been shown to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease (see section 5.1) and to improve physical function.

3. Treatment of ankylosing spondylitis

Authorised indication:

Simponi is indicated for the treatment of severe, active ankylosing spondylitis in patients who have responded inadequately to conventional therapy.

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