



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/914967/2011

European Medicines Agency decision P/288/2011

of 2 December 2011

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant L-asparaginase (EMA-000013-PIP01-07-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/7/2008 issued on 1 February 2008 and the decision P/2/2009 issued on 27 January 2009,

Having regard to the application submitted by medac Gesellschaft für klinische Spezialpräparate on 26 August 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 14 October 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 recombinant L-asparaginase, powder for solution for injection or infusion, intravenous use, intramuscular 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 medac Gesellschaft für klinische Spezialpräparate mbH, Fehlandtstrasse 3, 20354 Hamburg, Germany.

Done at London, 2 December 2011

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/786672/2011

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-000013-PIP01-07-M02

Scope of the application

Active substance(s):

Recombinant L-asparaginase

Condition(s):

Treatment of acute lymphoblastic leukaemia

Treatment of lymphoblastic lymphoma

Pharmaceutical form(s):

Powder for solution for injection or infusion

Route(s) of administration:

Intravenous use

Intramuscular use

Name/corporate name of the PIP applicant:

medac Gesellschaft für klinische Spezialpräparate

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, medac Gesellschaft für klinische Spezialpräparate submitted to the European Medicines Agency on 26 August 2011 an application for modification of the agreed paediatric investigation plan as set out in the European Medicines Agency's decision P/7/2008 issued on 1 February 2008 and the decision P/2/2009 issued on 27 January 2009.

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

The procedure started on 14 September 2011.



Scope of the modification

The timeline of a measure in the paediatric investigation plan was changed.

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 to 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.

2. The measures and timelines of the paediatric investigation plan 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, 14 October 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

Not applicable.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of acute lymphoblastic leukaemia

2.1.1. Indication(s) targeted by the PIP

Treatment of acute lymphoblastic leukaemia.

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Powder for solution for injection or infusion.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Randomised, parallel-group, blinded, single-centre, multiple-dose, comparative PK/PD and safety phase 2 study. Non-controlled, multi-centre, PD, activity and safety phase 2 study of recombinant L-asparaginase. Randomised, multi-centre, double-blind, pharmacodynamic equivalence / comparative efficacy and safety phase 3 study.

2.2. Condition: Treatment of lymphoblastic lymphoma

2.2.1. Indication(s) targeted by the PIP

Treatment of lymphoblastic lymphoma.

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

From birth to less than 18 years of age.

2.2.3. Pharmaceutical form(s)

Powder for solution for injection or infusion.

2.2.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	3	Study 1: same as for condition treatment of acute lymphoblastic leukaemia. Study 2: same as for condition treatment of acute lymphoblastic leukaemia. Study 3: same as for condition treatment of acute lymphoblastic leukaemia.

3. 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 November 2012
Deferral for one or more studies contained in the paediatric investigation plan:	No