EMA/278824/2011

European Medicines Agency decision

P/87/2011

of 8 April 2011

on the acceptance of a modification of an agreed paediatric investigation plan for Japanese encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells) (Ixiaro), (EMEA-000559-PIP01-09-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 726/2004[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/10/2010 issued on 29 January 2010, the decision P/74/2010 issued on 5 May 2010,

Having regard to the application submitted by Intercell AG on 3 December 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 18 February 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 and to the deferral.

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

[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 Japanese encephalitis vaccine (inactivated, adsorbed) (Ixiaro), suspension for injection, intramuscular use, including changes to the deferral 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 Intercell AG, Campus Vienna Biocenter 3, 1030 Vienna, Austria.

Done at London, 8 April 2011

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

EMA/PDCO/57886/2011

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

EMEA-000559-PIP01-09-M02

Scope of the application

Active substance(s):

Japanese encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells)

Invented name:

Ixiaro

Condition(s):

Prevention of Japanese encephalitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Intercell AG

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Intercell AG submitted to the European Medicines Agency on 3 December 2010 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/10/2010 issued on 29 January 2010 and the decision P/74/2010 issued on 5 May 2010.

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

The procedure started on 22 December 2010.

Scope of the modification

The scope of the modification relates to changes in some measures and timelines of the Paediatric Investigation Plan.

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 and to the deferral 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 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, 18 February 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

Prevention of Japanese encephalitis

The waiver applies to:

- from birth to less than 2 months,
- for suspension for injection,
- on the grounds that the specific medicinal product is likely to be ineffective.

2. Paediatric Investigation Plan

2.1. Condition: Prevention of Japanese encephalitis

2.1.1. Indication(s) targeted by the PIP

Active immunization against Japanese encephalitis in children aged 2 months to <18 years.

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

From 2 months to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Suspension for injection.

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Development of a marked pre-filled syringe allowing accurate administration of half dose.
Non-clinical		Not applicable.
Clinical	4	Study 1: Uncontrolled, open-label phase 3, Immunogenicity and safety study in children aged ≥2-month to < 18 years in non-endemic countries Study 2: Open-label, randomized, active-controlled to assess safety and immunogenicity of the Japanese encephalitis vaccine IC51 (IXARO®) in a paediatric population from endemic countries Study 3: Long-term follow-up of study 1 to assess immunity for up to 3 years. Study 4: Long-term follow-up of study 2 to assess immunity for up to 3 years and effect of a booster dose at 12-15 months in 150 children of all age groups.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2015
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of Japanese encephalitis

   Authorised indications:

Ixiaro is indicated for active immunization against Japanese encephalitis in adults. IXIARO should be considered for use in individuals at risk of exposure through travel or in the course of their occupation.

EU Number	**Invented name**	**Strength**	**Pharmaceutical Form**	**Route of Administration**	**Packaging**	**Content (concentration)**	**Package size**
EU/1/08/501/001	Ixiaro	6 µg	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe + 1 needle
EU/1/08/501/002	Ixiaro	6 µg	Suspension for injection	Intramuscular use	pre-filled syringe (glass)	0.5 ml	1 pre-filled syringe