EMA/138312/2016

European Medicines Agency decision

P/0060/2016

of 18 March 2016

on the acceptance of a modification of an agreed paediatric investigation plan for rituximab (MabThera) (EMEA-000308-PIP02-11-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.

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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/0068/2012 issued on 4 April 2012,

Having regard to the application submitted by Roche Registration Limited on 6 November 2015 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 29 January 2016, 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 rituximab (MabThera), concentrate for solution for infusion, intravenous 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 agreed PIP covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/235/2011 issued on 30 September 2011, including subsequent modifications thereof.

Article 3

This decision is addressed to Roche Registration Limited, 6 Falcon Way, Shire Park, AL7 1TW - Welwyn Garden City, United Kingdom.

Done at London, 18 March 2016

For the European Medicines Agency
Zaïde Frias
Head of Division
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/796011/2015
London, 29 January 2016

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

EMEA-000308-PIP02-11-M01

Scope of the application

Active substance(s):

Rituximab

Invented name:

MabThera

Condition(s):

Treatment of granulomatosis with polyangiitis (Wegener's)

Treatment of microscopic polyangiitis

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Concentrate for solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

Roche Registration Limited

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, Roche Registration Limited submitted to the European Medicines Agency on 6 November 2015 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/0068/2012 issued on 4 April 2012.

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

The procedure started on 30 November 2015.

Scope of the modification

Some measures and timelines 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 to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee members 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 annexes and appendix.

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(s):

Treatment of granulomatosis with polyangiitis (Wegener's), Treatment of microscopic polyangiitis

The waiver applies to:

- Children from birth to less than 2 years of age;
- for concentrate for solution for infusion, intravenous use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

1.2 Condition(s):

Treatment of granulomatosis with polyangiitis (Wegener's), Treatment of microscopic polyangiitis

1.2.1 Indication(s) targeted by the PIP

Treatment of granulomatosis with polyangiitis (Wegener's)

Treatment of microscopic polyangiitis

1.2.2 Subset(s) of the paediatric population concerned by the paediatric development

From 2 to less than 18 years of age

1.2.3 Pharmaceutical form(s)

Concentrate for solution for infusion

1.2.4 Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	1	Study 1: Multicentre, open-label, uncontrolled study to evaluate the safety and pharmacokinetics of rituximab in paediatric patients from 2 to less than 18 years old with severe granulomatosis with polyangiitis (Wegener's) or microscopic polyangiitis

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By May 2018
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. Treatment of follicular lymphoma

Authorised indication(s):

- MabThera is indicated for the treatment of previously untreated patients with stage III-IV follicular lymphoma in combination with chemotherapy.
- MabThera maintenance therapy is indicated for the treatment of follicular lymphoma patients responding to induction therapy.
- MabThera monotherapy is indicated for treatment of patients with stage III-IV follicular lymphoma who are chemoresistant or are in their second or subsequent relapse after chemotherapy.

2. Treatment of diffuse large B-cell lymphoma

Authorised indication(s):

- MabThera is indicated for the treatment of patients with CD20 positive diffuse large B cell non-Hodgkin lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) chemotherapy.

3. Treatment of chronic lymphocytic leukaemia

Authorised indication(s):

- MabThera in combination with chemotherapy is indicated for the treatment of patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia. Only limited data are available on efficacy and safety for patients previously treated with monoclonal antibodies including MabThera or patients refractory to previous MabThera plus chemotherapy.

4. Treatment of autoimmune arthritis

Authorised indication(s):

- MabThera in combination with methotrexate is indicated for the treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies.

4. Treatment of granulomatosis with polyangiitis (Wegener's)

Authorised indication(s):

- MabThera, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener’s) and microscopic polyangiitis.

5. Treatment of microscopic polyangiitis

Authorised indication(s):

- MabThera, in combination with glucocorticoids, is indicated for the induction of remission in adult patients with severe, active granulomatosis with polyangiitis (Wegener’s) and microscopic polyangiitis.