



European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 1 December 2008

**on the application for agreement of a Paediatric Investigation Plan for 3-(1H-indol-3-yl)-4-(2-(4-methyl-1-piperazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1),
EMEA-000093-PIP01-07, in accordance with Regulation (EC) No 1901/2006 of
the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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EMEA-000093-PIP01-07, in accordance with Regulation (EC) No 1901/2006 of
the European Parliament and of the Council as amended**

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty establishing the European Community,

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 as amended 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 application submitted by Novartis Europharm Limited on 15 November 2007 under Article 16(1) of Regulation (EC) No 1901/2006 as amended also requesting a waiver under Article 13 of said Regulation and a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 17 October 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 of said Regulation and Article 21 of said Regulation,

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

WHEREAS:

- (1) The Paediatric Committee of the European Medicines Agency, has given a positive opinion.
- (2) It is therefore appropriate to adopt a Decision following the Paediatric Committee's opinion on the Paediatric Investigation Plan.
- (3) It is therefore appropriate to adopt a Decision granting a waiver.
- (4) It is therefore appropriate to adopt a Decision granting a 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

A Paediatric Investigation Plan for 3-(1H-indol-3-yl)-4-(2-(4-methyl-1-piperazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1), film-coated tablets, oral route, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A waiver for 3-(1H-indol-3-yl)-4-(2-(4-methyl-1-piperazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1), film-coated tablets, oral route, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A deferral for 3-(1H-indol-3-yl)-4-(2-(4-methyl-1-piperazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1), film-coated tablets, oral route, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Novartis Europharm Limited, Wimblehurst Road, Horsham, RH125AB, United Kingdom.

Done at London, 1 December 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)



European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

EMA/PDCO/520035/2008

EMA-000093-PIP01-07

**POSITIVE OPINION OF THE PAEDIATRIC COMMITTEE ON
A REQUEST FOR AGREEMENT OF
A PAEDIATRIC INVESTIGATION PLAN FOR**

Scope of the application

Active substance:

3-(1H-indol-3-yl)-4-(2-(4-methyl-1-piperazinyl)-4-quinazolinyl)-1H-pyrrole-2,5-dione acetate(1:1)

Condition:

Chronic plaque psoriasis

Pharmaceutical form(s):

Film-coated tablets

Route(s) of administration:

Oral route

Name/corporate name of the PIP applicant:

Novartis Europharm Limited

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Limited submitted for agreement to the EMA on 15 November 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 20 December 2007.

Supplementary information was provided by the applicant on 14 August 2008.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended,
- to grant a deferral in accordance with Article 21 of Regulation (EC) No 1901/2006 as amended,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended and concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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 agreed 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 Agency, together with its annex and appendix.

London, 17 October 2008

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

A. CONDITION(S)

Chronic plaque psoriasis

B. WAIVER

- **Condition**

Chronic plaque psoriasis

The waiver applies to:

- newborn infants (from birth to less than 28 days), infants and toddlers (from 28 days to less than 24 months), and children (from 2 to less than 6 years), for film-coated tablets, oral use, on the grounds that clinical studies cannot be expected to be of significant therapeutic benefit or fulfil a therapeutic need for the paediatric population.

C. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Chronic plaque psoriasis

- **Proposed PIP indication**

Chronic Plaque Psoriasis

- **Subset(s) of the paediatric population concerned by the paediatric development**

From 6 years to less than 18 years

- **Formulation(s)**

Film-coated tablets

- **Studies / Measures**

Area	Number of studies	Description
Quality		film-coated tablets
Non-clinical	1 1	Juvenile toxicity study in rats 39-week toxicity study in monkeys
Clinical	1 1	Pharmacokinetic-study in paediatric renal transplant recipients 6-17 years of age Randomised, double-blind, placebo controlled, multi-centre efficacy and safety study to assess efficacy and safety of AEB071 in paediatric (6-17 years of age) patients with plaque psoriasis

Measures to address long term follow-up on potential safety issues in relation to paediatric use: Yes

Deferral for initiation of some or all studies contained in the paediatric investigation plan: Yes

Deferral for completion of some or all studies contained in the paediatric investigation plan: Yes

Date of completion of the paediatric investigation plan: by June 2020