EMA/651486/2010

European Medicines Agency decision

P/227/2010

of 28 October 2010

on the agreement of a paediatric investigation plan and on the granting of a deferral for partially purified bromelain (EMEA-000142-PIP02-09) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for partially purified bromelain (EMEA-000142-PIP02-09) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by Teva Pharma GmbH on 12 April 2010 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 8 October 2010, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) 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 partially purified bromelain, powder and gel vehicle, cutaneous use, 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 deferral for partially purified bromelain, powder and gel vehicle, cutaneous use, 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

This decision is addressed to Teva Pharma GmbH, Kandelstasse 10, 79199 – Kirchzarten, Germany.

Done at London, 28 October 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director
(Signature on file)

EMA/PDCO/576230/2010

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000142-PIP02-09

Scope of the application

Active substance(s):

Partially purified bromelain

Condition(s):

Treatment of burns

Pharmaceutical form(s):

Powder and gel vehicle

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Teva Pharma GmbH

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Teva Pharma GmbH submitted for agreement to the European Medicines Agency on 12 April 2010 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 20 May 2010.

Supplementary information was provided by the applicant on 2 August 2010.

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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 said Regulation,
   - to grant a deferral in accordance with Article 21 of said Regulation.

   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 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, 8 October 2010

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 burns of external body surface.

2.1.1. Indication(s) targeted by the PIP

Removal of eschar in deep partial and/or full thickness burns.

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 and gel vehicle

2.1.4. Studies

Area	Number of studies	Description
Quality	-	Not applicable.
Non-clinical	2	*Study 1* Single dose toxicity study of partially purified bromelain powder administered intravenously to minipigs with a 14-day observation period. *Study 2* 14-Day repeated intravenous dose study in juvenile pigs with collection of toxicokinetic data.
Clinical	3	*Study 3* Multicentre trial to assess long-term scar formation and quality of life in adults and children aged from 4 to less than 18 years comparing debridement of burn wounds with partially purified bromelain to standard of care. *Study 4* Open-label, randomised, multicentre trial to evaluate pharmacokinetics, safety, efficacy and immunogenicity of partially purified bromelain for debridement of partial thickness and full thickness thermal burns compared to standard of care in children aged from birth to less than 18 years.

Area	Number of studies	Description
		Study 5 Multicentre trial to assess long-term scar formation and quality of life children after participating in study 4 comparing debridement with partially purified bromelain to standard of care in children aged from birth to less than 18 years.

3. Follow-up, completion and deferral of PIP

Measures to address long term follow-up of potential safety issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2019
Deferral for one or more studies contained in the paediatric investigation plan:	Yes