



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

Doc. Ref. EMEA/230384/2009  
P/74/2009

**EUROPEAN MEDICINES AGENCY DECISION**

**of 20 April 2009**

**on the granting of a product specific waiver for Bismuth subcitrate potassium / Metronidazole / Tetracycline hydrochloride (EMEA-000382-PIP01-08) 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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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 726/2004<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by Axcan Pharma SA on 5 December 2008 under Article 13 of Regulation (EC) No 1901/2006 as amended,

Having regard to the Opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 March 2009 in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended,

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

WHEREAS:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver,
- (2) It is therefore appropriate to adopt a Decision granting a waiver.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1

<sup>2</sup> OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

A waiver for Bismuth subcitrate potassium / Metronidazole / Tetracycline hydrochloride, capsule, oral 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 2*

This decision is addressed to Axcan Pharma SA, Route de Bû, 78550 – Houdan, France.

Done at London, 20 April 2009

For the European Medicines Agency  
Thomas Lönngren  
Executive Director

(Signature on file)



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

Doc. Ref. EMEA/PDCO/109806/2009  
EMEA-000382-PIP01-08

## **OPINION OF THE PAEDIATRIC COMMITTEE ON THE GRANTING OF A PRODUCT-SPECIFIC WAIVER**

### **Scope of the application**

Active substance(s):

Bismuth subcitrate potassium / Metronidazole / Tetracycline hydrochloride

Condition(s):

Helicobacter pylori infection

Pharmaceutical form(s):

Capsule

Route(s) of administration:

Oral use

Name/corporate name of the waiver applicant:

Axcan Pharma SA

### **Basis for opinion**

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Axcan Pharma SA submitted to the EMEA on 5 December 2008 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 8 January 2009.

## **Opinion**

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report, to grant a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the Agency, together with its annex and appendix.

London, 6 March 2009

On behalf of the Paediatric Committee  
Dr Daniel Brasseur, Chairman

(Signature on file)

**ANNEX I**  
**GROUNDS FOR THE GRANTING OF THE WAIVER**

## **GROUNDS FOR THE GRANTING OF THE WAIVER**

- **Condition**

Helicobacter pylori infection

The waiver applies to:

All subsets of the paediatric population from birth to less than 18 years of age for bismuth subcitrate potassium / metronidazole / tetracycline hydrochloride capsule for oral use on the grounds that the specific medicinal product is likely to be unsafe.