European Medicines Agency

Doc. Ref. EMA/827815/2009
P/265/2009

EUROPEAN MEDICINES AGENCY DECISION

of 23 December 2009

on the acceptance of a modification of an agreed Paediatric Investigation Plan for moxifloxacin hydrochloride (Actira and associated names: Proflox) (EMEA-000493-PIP01-08-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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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[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 decision P/99/2009 of the European Medicines Agency on 19 May 2009,

Having regard to the application submitted by Bayer Schering Pharma AG on 1 October 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 11 December 2009, in accordance with Article 22 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 of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

[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 moxifloxacin hydrochloride, (Actira and associated names: Proflox), film-coated tablet, solution for infusion, granules and solvent for oral suspension, oral use, intravenous 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, are hereby accepted.

Article 2

This decision, that supersedes previous decision of the European Medicines Agency P/99/2009, as far as the agreed changes to the Paediatric Investigation Plan for moxifloxacin hydrochloride, (Actira and associated names: Proflox), are concerned, is addressed to Bayer Schering Pharma AG, Aprather Weg 18, 42096 Wuppertal, Germany.

Done at London, 23 December 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. EMA/PDCO/756166/2009
EMEA-000493-PIP01-08-M01

OPINION OF THE PAEDIATRIC COMMITTEE ON THE ACCEPTANCE OF A MODIFICATION OF AN AGREED PAEDIATRIC INVESTIGATION PLAN

Scope of the application

Active substance(s):
Moxifloxacin hydrochloride

(Invented) name:
Actira and associated names

Condition(s):
Community Acquired Pneumonia
Acute Bacterial Sinusitis
Acute Exacerbation of Chronic Bronchitis
Complicated Skin and Skin Structure Infections
Pelvic Inflammatory Disease
Complicated Intra-Abdominal Infection

Pharmaceutical form(s):
Film-coated tablet
Solution for infusion
Granules and solvent for oral suspension

Route(s) of administration:
Oral use
Intravenous use

Name/corporate name of the PIP applicant:
Bayer Schering Pharma AG

Information about the authorised medicinal product: see Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Bayer Schering Pharma AG submitted to the EMEA on 1 October 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the EMEA decision P/99/2009 of 19 May 2009. The application for modification proposed changes.

The procedure started on 15 October 2009.

Scope of the modification

The timelines and some measures of the initially agreed clinical studies are modified.

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E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

The Norwegian Paediatric Committee member 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 Agency, together with its annexes and appendix.

London, 11 December 2009

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman

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)

Community Acquired Pneumonia

Acute Bacterial Sinusitis

Acute Exacerbation of Chronic Bronchitis

Complicated Skin and Skin Structure Infections

Pelvic Inflammatory Disease

Complicated Intra-Abdominal Infection

B. WAIVER

- **Condition**

Community Acquired Pneumonia

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

- **Condition**

Acute Bacterial Sinusitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

- **Condition**

Acute Exacerbation of Chronic Bronchitis

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.

on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s)

- **Condition**

Complicated Skin and Skin Structure Infections

The waiver applies to:

- All subsets of the paediatric population from birth to less than 18 years of age.

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments

- **Condition**

Pelvic Inflammatory Disease

The waiver applies to:

- Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 24 months), Children (from 2 to less than 12 years), and males from 12 to less than 18 years

on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s), and
on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible

- **Condition**

Complicated Intra-Abdominal Infection

The waiver applies to:

- Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers, from 28 days to less than 3 months

on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible

C.1. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Pelvic Inflammatory Disease

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

Female adolescents from 12 to less than 18 years of age

- **Formulation(s)**

Film-coated Tablet, Oral use
Solution for Infusion, intravenous use
Granules and solvent for oral suspension

- **Studies**

Area	Number of studies	Description
Quality	0	
Non-clinical	0	
Clinical	1	Extrapolation of existing adult and paediatric data

C.2. PAEDIATRIC INVESTIGATION PLAN

- **Condition to be investigated**

Complicated Intra-Abdominal Infection

- **Proposed PIP indication**

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

From 3 months to less than 18 years.

- **Formulation(s)**

Film-coated Tablet, Oral use
Solution for Infusion, intravenous use
Granules and solvent for oral suspension

- **Studies**

Area	Number of studies	Description
Quality	1	Development of age appropriate oral formulation
Non-clinical	1	Subacute toxicity study in neonatal rats
Clinical	4	Comparative bioavailability study in healthy adult volunteers following non-blinded, randomised, single dose, cross over oral administration of the approved 400 mg moxifloxacin tablet and the paediatric oral formulations. Subprotocol for characterisation of oral pharmacokinetics of moxifloxacin and investigation of the absolute bioavailability in paediatric patients with complicated intra-abdominal infections Single dose safety, tolerability, and pharmacokinetics of moxifloxacin in paediatric patients Prospective, randomised, active-controlled, multi-national, multi-centre, clinical trial in paediatric patients with cIAI.

Measures to address long term follow-up of potential safety or efficacy issues in relation to paediatric use:	**No**
Date of completion of the paediatric investigation plan:	**By February 2012**
Deferral for some or all studies contained in the paediatric investigation plan:	**Yes**

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	**Invented name Name**	**Strength**	**Pharmaceutical Form**	**Route of administration**	**Packaging**	**Content (concentration)**	**Package size**
N/A	Actira and associated names	400mg/ 250ml	film-coated tablets / solution for infusion	oral use / intravenous use	N/A	N/A	N/A