EMA/656733/2010

European Medicines Agency decision

P/230/2010

of 23 November 2010

on the acceptance of a modification of an agreed paediatric investigation plan for moxifloxacin hydrochloride (Avalox and associated names; Octegra and associated names; Actimax and associated names; Actira and associated names), (EMEA-000288-PIP01-08-M02) 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 acceptance of a modification of an agreed paediatric investigation plan for moxifloxacin hydrochloride (Avalox and associated names; Octegra and associated names; Actimax and associated names; Actira and associated names), (EMEA-000288-PIP01-08-M02) 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 European Medicines Agency's decision P/96/2009 issued on 19 May 2009 and decision P/262/2009 issued on 23 December 2009,

Having regard to the application submitted by Bayer Schering Pharma AG on 30 July 2010 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 8 October 2010, 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.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the 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 (Avalox and associated names; Octegra and associated names; Actimax and associated names; Actira and associated names), film-coated tablet, solution for infusion, granules and solvent for oral suspension, oral use, intravenous use, 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 decision is addressed to Bayer Schering Pharma AG, Aprather Weg 18, 42096 Wuppertal, Germany.

Done at London, 23 November 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

EMA/PDCO/600203/2010

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

EMEA-000288-PIP01-08-M02

Scope of the application

Active substance(s):

Moxifloxacin hydrochloride

Invented name:

Avalox and associated names; Octegra and associated names; Actimax and associated names; 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

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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 European Medicines Agency on 30 July 2010 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/96/2009 issued on 19 May 2009, the decision P/262/2009 issued on 23 December 2009.

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

The procedure started on 12 August 2010.

Scope of the modification

The timelines of the initially agreed clinical studies are 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 in the scope set out in the Annex I of this opinion,

   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 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.

London, 8 October 2010

(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

Community Acquired Pneumonia

Acute Bacterial Sinusitis

Acute Exacerbation of Chronic Bronchitis

Complicated Skin and Skin Structure Infections

Pelvic Inflammatory Disease

Complicated Intra-Abdominal Infection

1.1. 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

1.2. 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

1.3. 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)

1.4. 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

1.5. 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

1.6. 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

2. Paediatric Investigation Plan

2.1. Condition: Pelvic Inflammatory Disease

2.1.1. Subset(s) of the paediatric population concerned by the paediatric development

Female adolescents from 12 to less than 18 years of age

2.1.2. Pharmaceutical form(s)

Film-coated Tablet, Oral use

Solution for Infusion, intravenous use

Granules and solvent for oral suspension

2.1.3. Studies

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

2.2. Condition: Complicated Intra-Abdominal Infection

2.2.1. Subset(s) of the paediatric population concerned by the paediatric development

From 3 months to less than 18 years

2.2.2. Pharmaceutical form(s)

Film-coated Tablet, Oral use

Solution for Infusion, intravenous use

Granules and solvent for oral suspension

2.2.3. 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.

3. Follow-up, completion and deferral of PIP

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 April 2013
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	Strength	Pharmaceutical form	Route of administration	Packaging	Content (concentration)	Package size
N/A	Avalox and associated names	400mg/ 250ml	film-coated tablets / solution for infusion	oral use / intravenous use	N/A	N/A	N/A
N/A	Octegra and associated names	400mg/ 250ml	film-coated tablets / solution for infusion	oral use / intravenous use	N/A	N/A	N/A
N/A	Actimax and associated names	400mg/ 250ml	film-coated tablets / solution for infusion	oral use / intravenous use	N/A	N/A	N/A
N/A	Actira and associated names	400mg/ 250ml	film-coated tablets / solution for infusion	oral use / intravenous use	N/A	N/A	N/A