European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 20 July 2008

on the application for agreement of a Paediatric Investigation Plan for Atorvastatin calcium (Sortis and associated names) EMEA-000073-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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on the application for agreement of a Paediatric Investigation Plan for Atorvastatin calcium, (Sortis and associated names) EMEA-000073-PIP00-07 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 726/2004[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 Pfizer Limited on 19 October 2007 under Article 16(1) also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 4 June 2008, in accordance with Article 18 of Regulation (EC) No 1901/2006 as amended, and Article 13 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.

[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 Atorvastatin calcium, (Sortis and associated names)**,** film-coated tablet, age-appropriate oral formulation, 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 agreed.

Article 2

A waiver for Atorvastatin calcium, (Sortis and associated names), film-coated tablet, age-appropriate oral formulation, oral use, the details of which are set out in the Opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ Sandwich .

Done at London, 20 July 2008

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

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

EMEA/PDCO/287022/2008
EMEA-000073-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:
Atorvastatin calcium

Invented name:
Sortis and associated names

Condition(s):
Pure hypercholesterolaemia (heterozygous, homozygous, or otherwise primary hypercholesterolaemia), combined (mixed) hyperlipidaemia; prevention of cardiovascular events

Pharmaceutical form(s):
Film-coated tablet
Age-appropriate oral formulation

Route(s) of administration:
Oral use

Name/corporate name of the PIP applicant:
Pfizer Limited

Information about the authorised medicinal product:
See Annex II.

Basis for opinion

Pursuant to Article 16.1 of Regulation (EC) No 1901/2006 as amended, Pfizer Limited submitted for agreement to the EMEA on 19 October 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 22 November 2007.

Supplementary information was provided by the applicant on 10 April 2007.

A meeting with the Paediatric Committee took place on 2 June 2008.

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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 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 annexes and appendices.

London, 4 June 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) / DISEASE(S)

Pure hypercholesterolaemia (heterozygous, homozygous, or otherwise primary hypercholesterolaemia), combined (mixed) hyperlipidaemia; prevention of cardiovascular events

B. WAIVER

- **Condition**

Heterozygous hypercholesterolaemia

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

    The waiver applies to children aged 0 to less than 6 years for the film-coated tablet and the age-appropriate formulation for oral use.

- **Condition**

Homozygous familial hypercholesterolaemia, combined (mixed) hypercholesterolaemia, primary hypercholesterolaemia; prevention of cardiovascular events

  - **Subset(s) of the paediatric population, pharmaceutical form(s) and route(s) of administration covered**

    The waiver applies to children aged 0 to less than 18 years for the film-coated tablet and the age-appropriate formulation for oral use.

C. PAEDIATRIC INVESTIGATION PLAN

Heterozygous hypercholesterolaemia

C.1. Condition to be investigated

Heterozygous hypercholesterolaemia

- **Subset(s) covered**

Children aged 6 to less than 18 years

- **Formulation(s)**

Film-coated tablet and age-appropriate oral formulation

- **Studies / Measures**

Study Number	Area	Subarea	Description
#1	Clinical	Bioequivalence	Bioequivalence study of the final age-appropriate oral atorvastatin formulation to the existing atorvastatin formulation in healthy adult volunteers
#2	Clinical	Pharmacokinetic, safety	Steady-state, eight week pharmacokinetic study of atorvastatin in children and adolescents (aged 6 years to less than 18 years) with heterozygous familial hypercholesterol-aemia using sparse PK sampling methodology and including flow-mediated artery dilatation assessments
#3	Clinical	Safety	A 3-year study of the safety and follow-up study of efficacy of atorvastatin treatment of children and adolescents (aged 6 years to less than 18 years) with heterozygous familial hypercholesterolaemia*

*** Study to be initiated by the date of completion of the paediatric investigation plan**

Date of completion of the paediatric investigation plan: 31 December 2009
Deferral compared to submission date: No

- **Specific safety concern(s) / monitoring**

Need for a EU-RMP: Yes

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

Country	Invented Name	Strength	Pharmaceutical form	Route of administration
AT	Sortis	80 mg	film-coated tablet	oral
AT	Sortis	10, 20, 40 mg	film-coated tablet	oral
BE	Lipitor	10, 20, 40 mg	film-coated tablet	oral
BE	Lipitor	80 mg	film-coated tablet	oral
BG	Sortis	80 mg	film-coated tablet	oral
BG	Sortis	10, 20, 40 mg	film-coated tablet	oral
CY	Lipitor	10, 20, 40 mg	film-coated tablet	oral
CZ	Sortis	10, 20, 40 mg	film-coated tablet	oral
CZ	Sortis	80 mg	film-coated tablet	oral
DE	Sortis	10, 20, 40 mg	film-coated tablet	oral
DE	Sortis	80 mg	film-coated tablet	oral
DK	Zarator	80 mg	film-coated tablet	oral
DK	Zarator	10, 20, 40 mg	film-coated tablet	oral
EE	Sortis	80 mg	film-coated tablet	oral
EE	Sortis	10, 20, 40 mg	film-coated tablet	oral
ES	Cardyl	10 mg	film-coated tablet	oral
ES	Cardyl	20, 40 mg	film-coated tablet	oral
ES	Zarator	10 mg	film-coated tablet	oral
ES	Zarator	80 mg	film-coated tablet	oral
ES	Cardyl	80 mg	film-coated tablet	oral
ES	Zarator	10 mg	film-coated tablet	oral
ES	Zarator	20, 40 mg	film-coated tablet	oral
FI	Lipitor	10, 20, 40 mg	film-coated tablet	oral
FI	Lipitor	80 mg	film-coated tablet	oral
FR	Tahor	80 mg	film-coated tablet	oral
FR	Tahor	10, 20, 40 mg	film-coated tablet	oral
GB	Lipitor	80 mg	film-coated tablet	oral
GB	Lipitor	10, 20, 40 mg	film-coated tablet	oral
GR	Lipitor	10, 20, 40 mg	film-coated tablet	oral
GR	Lipitor	80 mg	film-coated tablet	oral
GR	Zarator	10, 20, 40 mg	film-coated tablet	oral
HU	Sortis	80 mg	film-coated tablet	oral
HU	Sortis	10, 20, 40 mg	film-coated tablet	oral
HU	Liprimar	80 mg	film-coated tablet	oral
HU	Liprimar	10, 20, 40 mg	film-coated tablet	oral
IE	Lipitor	10, 20, 40 mg	film-coated tablet	oral
IE	Lipitor	80 mg	film-coated tablet	oral
IS	Zarator	10, 20, 40 mg	film-coated tablet	oral
IS	Zarator	80 mg	film-coated tablet	oral
IT	Totalip	80 mg	film-coated tablet	oral
IT	Xarator	80 mg	film-coated tablet	oral
IT	Torvast	80 mg	film-coated tablet	oral
IT	Xarator	10, 20, 40 mg	film-coated tablet	oral
IT	Lipitor	10, 20, 40 mg	film-coated tablet	oral
IT	Totalip	10, 20, 40 mg	film-coated tablet	oral
IT	Torvast	10, 20, 40 mg	film-coated tablet	oral
IT	Lipitor	80 mg	film-coated tablet	oral
LT	Sortis	10, 20, 40 mg	film-coated tablet	oral
LT	Sortis	80 mg	film-coated tablet	oral
LU	Lipitor	80 mg	film-coated tablet	oral
LU	Lipitor	10, 20, 40 mg	film-coated tablet	oral
LV	Sortis	10, 20, 40 mg	film-coated tablet	oral
LV	Sortis	80 mg	film-coated tablet	oral
MT	Lipitor	10, 20, 40 mg	film-coated tablet	oral

MT	Lipitor	80 mg	film-coated tablet	oral
NL	Lipitor	10, 20, 40 mg	film-coated tablet	oral
NL	Lipitor	80 mg	film-coated tablet	oral
NO	Lipitor	80 mg	film-coated tablet	oral
NO	Lipitor	10, 20, 40 mg	film-coated tablet	oral
PL	Sortis	10, 20, 40 mg	film-coated tablet	oral
PL	Sortis	80 mg	film-coated tablet	oral
PT	Sortis	10, 20, 40 mg	film-coated tablet	oral
PT	Zarator	10, 20, 40 mg	film-coated tablet	oral
PT	Zarator	80 mg	film-coated tablet	oral
RO	Sortis	10, 20 mg	film-coated tablet	oral
RO	Sortis	40, 80 mg	film-coated tablet	oral
SE	Lipitor	10, 20, 40 mg	film-coated tablet	oral
SE	Lipitor	80 mg	film-coated tablet	oral
SI	Sortis	10, 20, 40 mg	film-coated tablet	oral
SK	Sortis	80 mg	film-coated tablet	oral
SK	Sortis	10, 20, 40 mg	film-coated tablet	oral