European Medicines Agency

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EUROPEAN MEDICINES AGENCY DECISION

of 16 May 2008

on the application for agreement of a Paediatric Investigation Plan for Docetaxel, Taxotere (EMEA-000029-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)

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 application submitted by Aventis Pharma SA on 26 July 2007 under Article 16.1 of Regulation (EC) No 1901/2006 as amended also including a request for a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, formulated on 15 February 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, which became final on 5 May 2008.

(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 Docetaxel, Taxotere, concentrate and solvent for solution for infusion, 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, is hereby agreed.

Article 2

A waiver for Docetaxel, Taxotere, concentrate and solvent for solution for infusion, intravenous 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 Aventis Pharma SA, 20 Avenue Raymond Aron, F 92165, Antony cedex, France.

Done at London, 16 May 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/244977/2008
EMEA-000029-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:
Docetaxel

Invented name:
Taxotere

Condition:
Nasopharyngeal carcinoma

Pharmaceutical form:
Concentrate and solvent for solution for infusion

Route of administration:
Intravenous use

Name/corporate name of the PIP applicant:
Aventis Pharma SA

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, Aventis Pharma SA submitted for agreement to the EMEA on 26 July 2007 a paediatric investigation plan for the above mentioned medicinal product.

The procedure started on 30 August 2007.

Supplementary information was provided by the applicant on 20 December 2007.

A meeting with the Paediatric Committee took place on 14 February 2008.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 40
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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)(b) of Regulation (EC) No 1901/2006 as amended, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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 subsets of the paediatric population and conditions 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, 15 February 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 SUBSETS OF THE PAEDIATRIC POPULATION AND CONDITIONS COVERED BY THE WAIVER

A. CONDITION(S) / DISEASE(S)

Nasopharyngeal carcinoma

B. WAIVER

- **Condition**

Nasopharyngeal carcinoma

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

    The waiver applies to:

    Preterm newborn infants and term newborn infants (0-27 d) for the concentrate and solvent for solution for infusion for intravenous route

- **Condition**

Breast cancer

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

    The waiver applies to:

    Preterm newborn infants, term newborn infants (0-27 d), infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y) for the concentrate and solvent for solution for infusion for intravenous route

- **Condition**

Non-small cell lung cancer

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

    The waiver applies to:

    Preterm newborn infants, term newborn infants (0-27 d), infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y) for the concentrate and solvent for solution for infusion for intravenous route

- **Condition**

Prostate cancer

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

    The waiver applies to:

Preterm newborn infants, term newborn infants (0-27 d), infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y) for the concentrate and solvent for solution for infusion for intravenous route

- **Condition**

Gastric adenocarcinoma

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

The waiver applies to:

Preterm newborn infants, term newborn infants (0-27 d), infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y) for the concentrate and solvent for solution for infusion for intravenous route

- **Condition**

Head and neck cancer, not including type II and III less differentiated nasopharyngeal carcinoma

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

The waiver applies to:

Preterm newborn infants, term newborn infants (0-27 d), infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y) for the concentrate and solvent for solution for infusion for intravenous route

C. PAEDIATRIC INVESTIGATION PLAN

C.1. Conditions to be investigated

Nasopharyngeal carcinoma

- **Subset(s) covered**

Infants & toddlers (28 d-23 m), children (2-11 y) and adolescents (12-18 y)

- **Formulation(s)**

Concentrate and solvent for solution for infusion for intravenous use

- **Studies / Measures**

Area	Subarea	Number	Description
Clinical	Safety and efficacy	1	Randomised, parallel-group, open-label, multi-centre, multiple-dose, comparative phase 2 study of the safety, efficacy and quality of life

Need for paediatric measures to be included in the EU-RMP: Yes
Date of completion of the paediatric investigation plan: September 2009
Deferral compared to submission date for non-paediatric data: No

ANNEX II

INFORMATION ABOUT THE AUTHORISED MEDICINAL PRODUCT

EU Number	Invented name	Strength	Pharmaceutical Form	Route of administration	Packaging	Content (concentration)	Package size
EU/1/95/002/001	Taxotere	20 mg	Concentrate and solvent for solution for infusion	Intravenous use	Concentrate: vial (glass) Solvent: vial (glass)	Concentrate: 0.5 ml Solvent: 1.5 ml	1 vial + 1 vial
EU/1/95/002/002	Taxotere	80 mg	Concentrate and solvent for solution for infusion	Intravenous use	Concentrate: vial (glass) Solvent: vial (glass)	Concentrate: 2 ml Solvent: 6 ml	1 vial + 1 vial