COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.3.2009
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NOT FOR PUBLICATION

**COMMISSION DECISION**

**of 30.3.2009**

**granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for "Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed)", a medicinal product for human use**

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A., on 30 January 2008, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 January 2009,

Whereas:

(1) The medicinal product "Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed)" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) It is therefore appropriate to authorise its placing on the market.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

*Article 1*

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed)", the characteristics of which are summarised in Annex I to this Decision. "Synflorix - Pneumococcal polysaccharide conjugate vaccine (adsorbed)" shall be registered in the Community register of medicinal products under number(s)

| | |
|---|---|
| EU/1/09/508/001 | Synflorix-Suspension for injection-Intramuscular use-pre-filled syringe (glass)-0.5 ml-1 pre-filled syringe |
| EU/1/09/508/002 | Synflorix-Suspension for injection-Intramuscular use-pre-filled syringe (glass)-0.5 ml-10 pre-filled syringes |
| EU/1/09/508/003 | Synflorix-Suspension for injection-Intramuscular use-pre-filled syringe (glass)-0.5 ml-1 pre-filled syringe + 1 needle |
| EU/1/09/508/004 | Synflorix-Suspension for injection-Intramuscular use-pre-filled syringe (glass)-0.5 ml-10 pre-filled syringes + 10 needles |
| EU/1/09/508/005 | Synflorix-Suspension for injection-Intramuscular use-pre-filled syringe (glass)-0.5 ml-1 pre-filled syringe + 2 needles |
| EU/1/09/508/006 | Synflorix-Suspension for injection-Intramuscular use-vial (glass)-0.5 ml-1 vial |
| EU/1/09/508/007 | Synflorix-Suspension for injection-Intramuscular use-vial (glass)-0.5 ml-10 vials |
| EU/1/09/508/008 | Synflorix-Suspension for injection-Intramuscular use-vial (glass)-0.5 ml-100 vials |
| EU/1/09/508/009 | Synflorix-Suspension for injection-Intramuscular use-vial (glass)-1.0 ml-100 vials (multidose) |

*Article 2*

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

*Article 3*

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

*Article 4*

The period of validity of the authorisation shall be five years from the date of notification of this Decision.

*Article 5*

This Decision is addressed to GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, 1330 Rixensart, Belgique.

Done at Brussels, 30.3.2009

*For the Commission*
*Heinz ZOUREK*
*Director-General*