EUROPEAN
COMMISSION

Bruxelles, 12.1.2016
C(2016)185 (final)

COMMISSION IMPLEMENTING DECISION

of 12.1.2016

maintaining, under Article 20 of Regulation (EC) no 726/2004 of the European Parliament and of the Council, the marketing authorisation, granted by Decision C(2006)4281, for "Gardasil - Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)" a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 20(3) and (8) thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 19 November 2015 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The placing on the market of the medicinal product "Gardasil - Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)" was authorised by Commission Decision C(2006)4281 of 20 September 2006.

(2) The Commission initiated a procedure in accordance with Article 20(2) of Regulation (EC) No 726/2004 and requested the opinion of the European Medicines Agency as to whether the marketing authorisation should be maintained, varied, suspended or withdrawn.

(3) In accordance with Article 20(8) of Regulation (EC) No 726/2004 the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 6 November 2015.

(4) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in the Annex to this Decision, shows that a decision should be taken maintaining the marketing authorisation for the medicinal product concerned.

(5) Decision C(2006)4281 should therefore be maintained and the Community Register of Medicinal Products should be updated.

(6) 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.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2006)4281 of 20 September 2006 for the medicinal product "Gardasil - Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)" is maintained, on the basis of the scientific conclusions set out in the Annex to this Decision.

Article 2

This Decision is addressed to Sanofi Pasteur MSD SNC, 162 avenue Jean Jaurès, 69007 Lyon, France.

Done at Brussels, 12.1.2016

For the Commission

Xavier PRATS MONNÉ
Director-General