EUROPEAN
COMMISSION

Bruxelles, 11.2.2015
C(2015)878 (final)

COMMISSION IMPLEMENTING DECISION

of 11.2.2015

withdrawing, at the holder's request, the marketing authorisation granted by Decision C(2011)1605(final) for "Pumarix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH TEXT IS AUTHENTIC)

COMMISSION IMPLEMENTING DECISION

of 11.2.2015

withdrawing, at the holder's request, the marketing authorisation granted by Decision C(2011)1605(final) for "Pumarix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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] ,

Having regard to the application submitted by GlaxoSmithKline Biologicals S.A. on 13 August 2014 with a view to the withdrawal of the marketing authorisation for the medicinal product "Pumarix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)",

Whereas:

(1) The placing on the market of the medicinal product "Pumarix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)", which is entered in the Community register of medicinal products under the numbers EU/1/10/664 was authorised by Commission Decision C(2011)1605(final) of 4 March 2011.

(2) Following the holder's request, that authorisation should be withdrawn,

HAS ADOPTED THIS DECISION:

Article 1

At the holder's request, the marketing authorisation granted by Decision C(2011)1605(final) of 4 March 2011 for the medicinal product "Pumarix - Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)" is withdrawn.

[1] OJ L 136, 30.4.2004, p. 1.

Article 2

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

Done at Brussels, 11.2.2015

For the Commission

Ladislav MIKO
Acting Director-General