EUROPEAN COMMISSION

Brussels, 30.9.2010
C(2010)6910

COMMISSION DECISION

of 30.9.2010

amending, 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)602, for "Rotarix - Rotavirus vaccine, live" a medicinal product for human use

(ONLY THE FRENCH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

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) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 July 2010,

Whereas:

(1) The placing on the market of the medicinal product "Rotarix - Rotavirus vaccine, live", which is entered in the Community register of medicinal products under the numbers EU/1/05/330/001-011 was authorised by Commission Decision C(2006)602 of 21 February 2006.

(2) The Commission requested the opinion of the Committee on Medicinal Products for Human Use in accordance with Article 20 (2) of Regulation (EC) N° 726/2004.

(3) The scientific assessment by the Committee, the conclusions of which are set out in the Annex IV to this Decision, has shown that a Decision should be adopted amending the marketing authorisation for the medicinal product concerned.

(4) Decision C(2006)602 should therefore be amended accordingly.

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

(6) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2006)602 should therefore be replaced,

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

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2006)602 of 21 February 2006 for the medicinal product “Rotarix - Rotavirus vaccine, live” is amended, on the basis of the scientific conclusions set out in the Annex IV to this Decision.

Article 2

Decision C(2006)602 is amended as follows:

Annex II is replaced by the text set out in the Annex II to this Decision.

Article 3

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

Done at Brussels, on 30.9.2010.

For the Commission
Paola TESTORI COGGI
Director-General