EUROPEAN
COMMISSION

Brussels, 19.12.2013
C(2013)9793 (final)

COMMISSION IMPLEMENTING DECISION

of 19.12.2013

concerning, in the framework of Articles 31 and 107i of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of "hydroxyethyl starch" (HES) containing medicinal products, solutions for infusion

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of 19.12.2013

concerning, in the framework of Articles 31 and 107i of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of "hydroxyethyl starch" (HES) containing medicinal products, solutions for infusion

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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[1], and in particular Articles 34(1) and 107k(2) third subparagraph thereof,

Having regard to the position of the majority of the Member States represented within the coordination group adopted on 23 October 2013,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) On 20 November 2012, Germany referred a question to the European Medicines Agency under Article 31(1) of Directive 2001/83/EC, in a specific case where the interests of the Union are involved, as to whether the marketing authorisations concerned should be maintained, varied, suspended or revoked.

(3) As the referral resulted from the evaluation of data relating to pharmacovigilance the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 13 June 2013. This recommendation was re-examined at the request of some marketing authorisation holders.

(4) On 27 June 2013, the United Kingdom considered that there was a need for urgent action at national level to protect public health and considered suspending the marketing authorisations for HES containing medicinal products. Therefore, the United Kingdom initiated the procedure under Articles 107i to 107k of Directive 2001/83/EC.

[1] OJ L 311, 28.11.2001, p. 67

(5) The Pharmacovigilance Risk Assessment Committee issued a final recommendation on re-examination of the referral under Article 31 of Directive 2001/83/EC and a recommendation following the referral under Article 107i of Directive 2001/83/EC on 10 October 2013. As the procedures do not include any marketing authorisations granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) No 726/2004[2], the recommendations of the Pharmacovigilance Risk Assessment Committee were forwarded to the coordination group in accordance with Article 107k(1) of Directive 2001/83/EC.

(6) The coordination group considered both recommendations of the Pharmacovigilance Risk Assessment Committee and has based its position on the recommendation following the referral procedure under Article 107i of Directive 2001/83/EC, which is the most complete and up-to-date evaluation of the available data relating to the hydroxyethyl starch (HES) containing medicinal products, solutions for infusion.

(7) In accordance with Article 107k(2) of Directive 2001/83/EC, the position of the majority of the Member States represented within the coordination group was forwarded to the Commission. This position, the conclusions of which are set out in Annex II to this Decision, shows that a decision should be taken varying the marketing authorisations for the medicinal products concerned in accordance with Article 116 of Directive 2001/83/EC.

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

HAS ADOPTED THIS DECISION:

Article 1

The Member States concerned shall vary national marketing authorisations for the medicinal products referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

Article 2

The national marketing authorisations referred to in Article 1 shall be based on the summary of the product characteristics and the package leaflet set out in Annex III.

Article 3

The conditions affecting the marketing authorisations are set out in Annex IV.

Article 4

The Member States shall take account of the scientific conclusions set out in Annex II for the assessment of the efficacy and safety of "hydroxyethyl starch" (HES) containing medicinal products, solutions for infusion that are not included in Annex I.

---

[2] OJ L 136, 30.04.2004, p. 1.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 19.12.2013

For the Commission
Paola Testori Coggi
Director-General