EUROPEAN
COMMISSION

Brussels, 24.5.2022
C(2022) 3591 final

COMMISSION IMPLEMENTING DECISION

of 24.5.2022

concerning, in the framework of Article 107p of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substance "hydroxyethyl starch (HES), solutions for infusion" following an assessment of a post authorisation safety study

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of 24.5.2022

concerning, in the framework of Article 107p of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substance "hydroxyethyl starch (HES), solutions for infusion" following an assessment of a post authorisation safety study

(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 107p thereof,

Having regard to the position of the majority of the Member States represented within the coordination group adopted on 23 February 2022,

Whereas:

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

(2) In accordance with Article 107p of Directive 2001/83/EC, the marketing authorisation holders submitted a final study report for non-interventional imposed post-authorisation safety study for the nationally authorised medicinal products containing the active substance hydroxyethyl starch. The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency considered the results of the study in accordance with Article 107q(1**)** of Directive 2001/83/EC and concluded that non-adherence to the product information remains, despite the extensive additional risk minimisation measures implemented as an outcome of the referral procedure concluded in 2018.

(3) The PRAC considered the seriousness of the safety issues and the fact that the proportion of patients who are exposed to these risks in the absence of effective risk minimisation measures could have important public health consequences, including a potentially increased mortality.

(4) The PRAC concluded that the risks related to the use of HES outweigh their benefits and thus the benefit-risk balance of HES solutions for infusion is no longer favourable. It therefore recommended on 10 February 2022 the suspension of the marketing authorisations for the medicinal products mentioned above, and forwarded the recommendation to the coordination group in accordance with Article 107q(2) first subparagraph of Directive 2001/83/EC.

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

(5) In accordance with Article 107q(2) fifth subparagraph 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, which is set out in Annex II to this Decision, concludes that, in the interests of the Union, a decision should be taken suspending the marketing authorisations for the medicinal products concerned.

(6) Exceptionally, taking into account public health considerations in their territory, Member States may defer provisionally the suspension of the concerned marketing authorisations, provided that certain conditions are fulfilled to safeguard patients and that the previously agreed risk minimisation measures are maintained and monitored. Such action should be conducted under the responsibility of Member States and that of the marketing authorisation holders.

(7) 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 suspend the national marketing authorisations for the medicinal products referred to in Annex I on the basis of the scientific conclusions set out in Annex II.

The conditions for lifting the suspension are set out in Annex III.

Article 2

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

Article 3

A Member State may exceptionally defer the application of Article 1 for a period not exceeding 18 months from the date of adoption of this Decision. In such case, the Member State concerned shall ensure that the following conditions are fulfilled:

(a) The deferral is considered necessary taking into account public health considerations in the Member State concerned;

(b) The marketing authorisation holder continues to adhere to the risk minimisation measures implemented as an outcome of the 2018 referral in Commission Decision C(2018)4832 final;

(c) The marketing authorisation holder immediately suspends the supply of the product to an accredited hospital if information becomes available that the hospital does not adhere to the risk minimisation measures;

(d) The Member State concerned has the appropriate measures in place to enforce and monitor the implementation of the risk minimisation measures.

A Member State making use of the possibility provided by this Article shall notify the European Medicines Agency within one month from the adoption of this Decision.

If a Member State making use of the deferral takes the view that the above conditions cease to be fulfilled during the period of the deferral, it shall take the appropriate steps to suspend without delay the marketing authorisation concerned in accordance with Article 1.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 24.5.2022

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION