EUROPEAN
COMMISSION

Brussels, 24.11.2020
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# COMMISSION IMPLEMENTING DECISION

**of 24.11.2020**

**concerning, in the framework of Article 31 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 "ranitidine"**

(Text with EEA relevance)

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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 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 Article 34(1) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 30 April 2020 and on 17 September 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

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

(2) A question has been referred 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the Union are involved, as to whether the marketing authorisations concerned should be maintained, varied, suspended or withdrawn.

(3) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex II to this Decision, shows that, in the interests of the Union, a decision should be taken amending the marketing authorisations for the medicinal products concerned.

(4) Some of the medicinal products referred to in Annex I may be considered critical by the individual Member State(s), based on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State(s) and, as appropriate, the nature of the disease to be treated. Where a medicinal product is considered critical, the suspension of the concerned marketing authorisations may be then provisionally deferred.

(5) 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 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

*Article 1*

The Member States concerned shall suspend 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*

A Member State may defer the suspension of the marketing authorisation for the medicinal products referred to in Annex I, if it considers that a medicinal product is critical.

When a Member State considers whether a medicinal product is critical it shall base its decision on the evaluation of the potential unmet medical need, considering the availability of suitable alternative medicinal products in the respective Member State.

This period of deferral shall not exceed 12 months from the date of the adoption of this Decision. If during this period a Member State considers a medicinal product not being critical anymore, the Member State shall suspend the concerned marketing authorisation.

*Article 3*

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 "ranitidine" that are not included in Annex I.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 24.11.2020

*For the Commission*

*Sandra GALLINA*
*Director-General*

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For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION