EUROPEAN
COMMISSION

Brussels, 10.5.2024
C(2024) 3294 final

# COMMISSION IMPLEMENTING DECISION

**of 10.5.2024**

**concerning, in the framework of Article 29 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for "Ibuprofen NVT and associated names", medicinal products for human use which contain the active substance "ibuprofen"**

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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 opinion of the European Medicines Agency, formulated on 22 February 2024 by the Committee for Medicinal Products for Human Use, whose opinion was requested on 14 December 2023,

Whereas:

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

(2) During the repeat use procedure for the marketing authorisations for "Ibuprofen NVT and associated names" in accordance with Directive 2001/83/EC, on grounds of a potential serious risk to public health, Spain could not approve the assessment report, the summary of product characteristics, the labelling or the package leaflet. The Member States did not reach an agreement within the coordination group in accordance with Article 29 of that Directive and Lithuania referred the matter to the Committee for Medicinal Products for Human Use.

(3) The scientific assessment by the Committee, the conclusions of which are set out in Annex II to this Decision, shows that a decision should be taken suspending the marketing authorisations or refusing the applications for the marketing authorisations for the medicinal products concerned.

(4) 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 or refuse the applications for the 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 condition for the lifting of the suspension of the national marketing authorisations is set out in Annex III.

*Article 3*

This Decision is addressed to the Member States.

Done at Brussels, 10.5.2024

*For the Commission*

*Sandra GALLINA*
*Director-General*

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For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION