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Co-ordination group for Human Use
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Position of the Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use, pursuant to Article 107k(1) and (2) of Directive 2001/83/EC for

Topiramate-containing medicinal products

Medicinal products: see Annex I

Basis for position

Pursuant to Article 31 of Directive 2001/83/EC, France (ANSM) initiated a procedure on 22 August 2022 based on concerns resulting from the evaluation of data from pharmacovigilance activities.

The procedure started on 01 September 2022.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 31 August 2023 and is appended to this position.

The steps taken for the assessment and the notification for the procedure are included in the appended PRAC recommendation.

The Co-ordination Group for Mutual Recognition and Decentralised Procedures for human use (CMDh) has considered the recommendation of PRAC in accordance with Article 107k(1) and (2) of Directive 2001/83/EC.

Position

1. The CMDh, having considered the PRAC recommendation, reached the position by consensus that the marketing authorisations for topiramate-containing medicinal products should be varied.

   The CMDh member(s) of Iceland and Norway agree with the above-mentioned position of the CMDh.

2. The scientific conclusions are set out in Annex II.

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3. The amendments to be introduced to the product information of topiramate-containing medicinal products are set out in Annex III.

4. The conditions to the marketing authorisation(s) of topiramate-containing medicinal products are set out in Annex IV.

5. The timetable for the implementation of the CMDh position is set out in Annex V.

To the extent that other medicinal products containing topiramate not included in Annex I are currently authorised in the European Union (EU), or are subject to future authorisation procedures by the Member States, the CMDh recommends that the Member States concerned take due consideration of the scientific conclusions set out in Annex II.

This position is forwarded to the Member States, to Iceland, Liechtenstein and Norway and to the marketing authorisation holder(s) for the above mentioned medicinal product(s), together with its annexes and appendices.