Amsterdam, 10 November 2022
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Co-ordination group for Human Use
EMEA/H/A-31/1514

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

Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome

Medicinal products: see Annex I

Basis for position

Pursuant to Article 31 of Directive 2001/83/EC, Denmark initiated a procedure on 22 December 2021 based on concerns resulting from the evaluation of data from pharmacovigilance activities.

The procedure started on 13 January 2022.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 29 September 2022 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 terlipressin-containing medicinal products indicated in the treatment of type 1 hepatorenal syndrome (type 1 HRS) should be varied.

   The CMDh members of Iceland and Norway agree with the above-mentioned position of the CMDh.

[1] 2 December2022

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

3. The amendments to be introduced to the product information of terlipressin-containing medicinal products indicated in the treatment of type 1 HRS are set out in Annex III.

4. The timetable for the implementation of the CMDh position is set out in Annex IV.

To the extent that other terlipressin-containing medicinal products indicated in the treatment of type 1 HRS not included in Annex I are currently authorised in the 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.