Amsterdam, 24 June 2020
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Co-ordination group for Mutual Recognition and Decentralised Procedures for Human Use
EMEA/H/A-31/1486

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

leuprorelin-containing depot medicinal products

Medicinal products: see Annex I

Basis for position

Pursuant to Article 31 of Directive 2001/83/EC, Germany initiated a procedure on 07 June 2019 based on concerns resulting from the evaluation of data from pharmacovigilance activities.

The procedure started on 14 June 2019.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 14 May 2020 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 leuprorelin-containing depot medicinal products should be varied.

   The Icelandic and the Norwegian CMDh members agree with the above-mentioned position of the CMDh.

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

[1] 10 July 2020

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

4. The conditions to the marketing authorisation(s) 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 leuprorelin (depot formulations) 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.