Amsterdam, 26 March 2020
EMA/CMDh/90487/2020
Co-ordination group for Human Use
EMEA/H/A-31/1488

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

cyproterone-containing medicinal products

Medicinal products: see Annex I

Basis for position

Pursuant to Article 31 of Directive 2001/83/EC, France initiated a procedure on 02 July 2019 based on concerns resulting from the evaluation of data from pharmacovigilance activities.

The procedure started on 11 July 2019.

The Pharmacovigilance Risk Assessment Committee (PRAC) recommendation was adopted on 13 February 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 cyproterone-containing products should be varied.

   The Icelandic and the Norwegian CMDh member(s) agree(s) 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 cyproterone-containing products 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 medicinal products containing cyproterone 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 and Norway and to the marketing authorisation holder(s) for the above mentioned medicinal product(s), together with its annexes and appendices.