EUROPEAN
COMMISSION

Brussels, 25.7.2013
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COMMISSION IMPLEMENTING DECISION

of 25.7.2013

concerning, in the framework of Article 107i of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for medicinal products for human use containing "cyproterone acetate/ethinylestradiol (2mg/0.035mg)"

(Text with EEA relevance)

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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 Articles 34(1) and 107i thereof,

Having regard to the position of the majority of the Member States represented within the coordination group adopted on 29 May 2013,

Whereas:

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

(2) As a result of the evaluation of the pharmacovigilance data for the medicinal products for human use which contain the active substance "cyproterone acetate/ethinylestradiol (2mg/0.035mg)", the procedure under Articles 107i to 107k of Directive 2001/83/EC has been initiated.

(3) As the procedure resulted from the evaluation of data relating to pharmacovigilance, the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency issued a recommendation on 16 May 2013.

(4) As the procedure does not include any marketing authorisations granted in accordance with the centralised procedure provided for in Chapter 1 of Title II of Regulation (EC) No 726/2004[2], the recommendation of the Pharmacovigilance Risk Assessment Committee was forwarded to the coordination group in accordance with Article 107k(1) of Directive 2001/83/EC.

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1 OJ L 311, 28.11.2001, p. 67.
2 OJ L 136, 30.04.2004, p.1.

(5) In accordance with Article 107k(2) of Directive 2001/83/EC the position of the majority of the Member States represented within the coordination group was forwarded to the Commission. This position as set out in Annex II to this Decision, concludes that a decision should be taken amending the marketing authorisations for the medicinal products concerned.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The Member States concerned shall amend national 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 national marketing authorisations referred to in Article 1 shall be based on the amendments to the summary of the product characteristics and the package leaflet set out in Annex III and shall be subject to the conditions set out in Annex IV to this Decision.

Article 3

The Member States shall take account of the scientific conclusions set out in Annex II for the assessment of the efficacy and safety of medicinal products containing "cyproterone acetate/ethinylestradiol (2mg/0.035mg)" that are not included in Annex I.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 25.7.2013

For the Commission
Paola TESTORI COGGI
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION