European Medicines Agency
Evaluation of Medicines for Human Use

London, 17 June 2008
EMEA/CHMP/332403/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 5(11)[1] REFERRAL FOR

Belanette and associated names (see Annex I)

International Non-Proprietary Name (INN): Drospirenone + Ethinylestradiol

BACKGROUND INFORMATION

Belanette and associated names, is a combined oral contraceptive containing 0.02 mg of ethinylestradiol and 3 mg of drospirenone.

The MAH submitted variation application subject to the Mutual Recognition Procedure to the Marketing Authorisations of the medicinal product in the framework of Article 5 of Commission Regulation (EC) No 1084/2003. The Mutual Recognition Procedure started on 18 June 2007. The Reference Member State was Netherlands and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Slovakia, Slovenia, Spain and Sweden. These Member States were not able to reach an agreement in respect of the variation to the Marketing Authorisation within the time frame as referred to in Article 5(6) of Commission Regulation (EC) No 1084/2003. Hungary referred the reasons for disagreement to the EMEA on 12 October 2007.

The proposed package concept, the so-called wallet with the product and package leaflet wrapped in transparent cellophane was considered to be a serious public concern. The cellophane wrapping could not be accepted as an outer packaging due to the risk that during usage the product (wallets) would get separated from the package leaflet. Furthermore the Braille text could not be read through the outer packaging as the cellophane is slippery and moves when touched.

The arbitration procedure started on 18 October 2007. The Rapporteur was Dr Jean-Louis Robert and Co-Rapporteur was Dr Janos Borvendeg.

During their December 2007 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Yasminelle and associated names, that the objections raised by Hungary should not prevent the approval of the variation applied for and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be the final versions achieved during the Coordination group procedure. A positive opinion was adopted by majority on 13 December 2007.

The list of the product names concerned is given in Annex I.

The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 17 June 2008.

[1] Article 5(11) of Commission Regulation (EC) No 1084/2003

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