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Questions and answers on Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 (ethinylestradiol / drospirenone, 0.02 mg/3 mg tablets)

Outcome of a procedure under Article 6(12) of Regulation (EC) 1084/2003 as amended

On 19 April 2012, the European Medicines Agency completed an arbitration procedure for Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4. The Agency's Committee for Medicinal Products for Human Use (CHMP) had been asked to consider a proposed change to the marketing authorisations for these medicines to include a new indication for the treatment of moderate acne in women seeking oral contraception. The Committee concluded that the change to the marketing authorisations cannot be granted.

What are Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4?

Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 are combined contraceptive pills. They contain two active substances, ethinylestradiol and drospirenone, which are derived from natural hormones produced in the ovaries: ethinylestradiol is derived from oestrogen and drospirenone is derived from progesterone. Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 work by changing the body's hormonal balance to prevent ovulation, by altering the mucus in the cervix (neck of the womb) and by thinning the endometrium (the lining of the womb).

The company that markets Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 is Bayer B.V.

Why were Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 reviewed?

Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 are authorised in several Member States of the European Union (EU)[1] under a mutual recognition procedure on the basis of an initial authorisation granted by the Netherlands. The company applied for a change to the marketing authorisations of these medicines to extend their use to include the 'treatment of moderate acne vulgaris only in women seeking oral contraception'. This change was to be recognised in the Netherlands and all other

[1] Yaz is authorised in all EU Member States except Hungary, and Ethinylestradiol-Drospirenone 24+4 is authorised in the following Member States: Austria, Bulgaria, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Malta, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

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concerned Member States. Because the Member States were not able to reach an agreement on this new indication, on 28 and 29 June 2011 the Italian and Swedish medicines regulatory agencies referred the matter to the CHMP for arbitration.

The grounds for the referral were concerns over whether the medicines' benefits in the combined indication outweighed their risks, particularly the risk of venous thromboembolism (VTE, formation of blood clots in the veins).

What are the conclusions of the CHMP?

The Committee reviewed the two main studies presented by the company to support the new indication. The CHMP noted the overall effectiveness of Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 compared with placebo in the treatment of acne.

The Committee also considered the known risks with Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4, including VTE. Since acne is a common problem in young women, the CHMP was concerned that the measures proposed by the company to ensure that these medicines would be used to treat acne only in women seeking oral contraception were not sufficient. Women not seeking contraception would therefore be unnecessarily exposed to the risks of Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 when alternative acne treatments are available.

Therefore, based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP considered that the benefits of Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4 did not outweigh their risks in the proposed new indication. The Committee concluded that the variation to the marketing authorisations for these medicines cannot be approved.

The European Commission issued the decisions on 3 July 2012 (Yaz 24+4) and 6 July 2012 (Ethinylestradiol-Drospirenone 24+4).