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EMA recommends authorisation of Perlinring (etonogestrel / ethinylestradiol vaginal ring) in the EU

EMA completes review following disagreement among EU Member States

On 18 October 2018, the European Medicines Agency completed a review of Perlinring following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of Perlinring outweigh its risks, and the marketing authorisation can be granted in the United Kingdom and in the following Member States of the EU: Austria, Belgium, Croatia, Czech Republic, Denmark, Estonia, Spain, Finland, France, Germany, Hungary, Ireland, Italy, Lithuania, Latvia, the Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia and Sweden, plus Iceland and Norway.

What is Perlinring?

Perlinring is a contraceptive vaginal ring used to prevent pregnancy. Each ring contains two hormones, etonogestrel and ethinylestradiol, which are slowly released into the blood circulation and prevent the release of eggs from the ovaries. Perlinring is used for 21 days (3 weeks) in a row, followed by a 7-day break, after which a new ring should be used.

Perlinring was developed as a generic medicine. This means that Perlinring was developed to contain the same active substance and work in the same way as a 'reference medicine' already authorised in the EU called Nuvaring.

Why was Perlinring reviewed?

Actavis Group PTC EHF submitted Perlinring to the UK medicines agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the United Kingdom) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned' Member States, see list above) where the company has applied for a marketing authorisation.

However, the Member States were not able to reach an agreement and the UK medicines regulatory agency referred the matter to EMA for arbitration on 7 August 2018.

In its application, the company for Perlinring provided data demonstrating that Perlinring is 'bioequivalent' to Nuvaring over a period of 3 weeks, which is the authorised length of treatment. Two

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medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

The grounds for the referral relate to concerns raised by Germany, France and the Netherlands, that the Nuvaring product information for doctors and patients states that the product continues to be effective if it is used for an additional 4th week. Although the bioequivalence data submitted were sufficient to show that Perlinring is bioequivalent to Nuvaring over a period of 3 weeks, they did not cover the additional 4th week during which the contraceptive ring may still be used, even though this use is not recommended.

Bioequivalence data for week 4 were considered necessary by Germany, France and the Netherlands as Perlinring is expected to be used in the same way as Nuvaring.

What is the outcome of the review?

Based on evaluation of the currently available data, the Agency considered that bioequivalence to the reference medicinal product has been shown for the authorised duration of treatment (3 weeks). In addition, there is enough evidence to expect that Perlinring continues to be effective for an additional 4th week, as is the case for Nuvaring. The Agency therefore concluded that the benefits of Perlinring outweigh its risks and recommended that the marketing authorisation be granted in all concerned Member States.

More about the procedure

The review of Perlinring was initiated at the request of the United Kingdom, under Article 29 of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on 18 December 2018.