28 September 2012
EMA/265750/2012 Rev. 1
EMEA/H/A-29/1330

Questions and answers on Yvidually and associated names (ethinylestradiol / drospirenone, 0.02 mg/3 mg tablets)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

On 19 April 2012, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Yvidually and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Yvidually outweigh its risks, and the marketing authorisation can be granted in all EU Member States as well as Iceland and Norway.

What is Yvidually?

Yvidually is a combined contraceptive pill. It contains 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. Yvidually works 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).

Yvidually is an 'extended use' oral contraceptive, which means that it can be taken daily for up to 120 days. The option of a tablet-free interval at any time during day 25 to 120 of the treatment cycle is also allowed.

Yvidually will be available as tablets in an automated tablet dispenser device with a reminder function for when the next pill has to be taken. This medicine will be marketed also as Flexyess.

Why was Yvidually reviewed?

Bayer B.V. submitted Yvidually to the Netherlands medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the Netherlands) 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', in this instance Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Germany, Greece, Finland,

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

© European Medicines Agency, 2012. Reproduction is authorised provided the source is acknowledged.

France, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom).

However, the Member States were not able to reach an agreement and the Netherlands referred the matter to the CHMP for arbitration on 23 February 2012.

The grounds for the referral were concerns by France about the effectiveness of the proposed extended use of the medicine and the irregular bleeding episodes that might occur during the days of intake of the pill. France was also concerned that the tablet dispenser had not been used in the main clinical studies.

What are the conclusions of the CHMP?

Based on evaluation of the available data and the scientific discussion within the Committee, the CHMP concluded that the contraceptive effectiveness during an extended use had been demonstrated. While different bleeding patterns had been reported during the days of pill intake, these bleeding episodes seemed to be well tolerated. The CHMP also noted that the concerns over the tablet dispenser had been adequately addressed, as an additional study provided by the company showed that women find the dispenser easy to use and that there were no problems with posology compliance. The CHMP therefore concluded that the benefits of Yvidually outweigh its risks, and therefore the marketing authorisation for Yvidually should be granted in all concerned Member States.

The European Commission issued a decision on 28 September 2012.