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# Questions and answers on Seasonique and associated names (levonorgestrel / ethinylestradiol)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 26 June 2014, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the oral contraceptive Seasonique. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Seasonique outweigh its risks and that marketing authorisation should be granted in France and in the following EU Member States: Austria, Belgium, Germany, Italy, Poland, Romania, Slovakia and Slovenia.

## What is Seasonique?

Seasonique is an oral contraceptive for women. It is available as blister packs containing 91 tablets to be taken once a day in the order shown on the pack. For 84 days the woman takes the tablets containing levonorgestrel and ethinylestradiol and then for the remaining 7 days she takes tablets containing only ethinylestradiol.

Levonorgestrel (a progestogen) and ethinylestradiol (an oestrogen) are both hormones and Seasonique is what is known as a 'combined hormonal contraceptive'. Combined hormonal contraceptives work by stopping the release of eggs from the ovaries and by causing changes in the cervix and the lining of the womb that make it harder for a sperm to reach an egg and for a fertilised egg to implant in the womb.

Because the treatment cycle of 91 days is longer than that of most other combined contraceptives (which is normally 28 days), Seasonique is known as an extended cycle oral contraceptive. Women taking Seasonique will have longer intervals between withdrawal bleeding but may experience more irregular bleeding.

## Why was Seasonique reviewed?

Teva Pharma submitted an application to the French medicines agency (ANSM) for Seasonique to be authorised in a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance France) assesses a medicine with a view to granting a marketing authorisation that will be valid in that country as well as in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Germany, Italy, Poland, Romania, Slovakia and

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Slovenia). However, the Member States were not able to reach an agreement and the French medicines agency referred the matter to the CHMP for arbitration on 3 February 2014.

The grounds for the referral related to concerns raised by the German medicines agency about the effectiveness of Seasonique in preventing pregnancy and the irregular bleeding experienced by women taking the contraceptive.

## What are the conclusions of the CHMP?

After evaluating data from studies and post-marketing data from outside the EU, the CHMP was of the view that there was adequate evidence that Seasonique is an effective contraceptive. The Committee also noted that the irregular bleeding reported with Seasonique has not made women less likely to keep to their treatment and adequate information about the risk of irregular bleeding is included in the package leaflet.

The Committee therefore concluded that the benefits of Seasonique outweigh its risks and recommended that marketing authorisation be granted in the reference and concerned Member States.

The European Commission issued an EU-wide legally binding decision on 12 January 2015.