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Questions and answers on Priligy (dapoxetine, 30 mg and 60 mg tablets)

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

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of Priligy tablets. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of the 60 mg tablet (over which there was disagreement) do outweigh its risks and that the marketing authorisation for Priligy granted in Sweden can be recognised in other Member States of the EU.

What is Priligy?

Priligy is a medicine used to treat premature ejaculation in men aged 18 to 64 years old.

Priligy is believed to increase the time it takes to ejaculate by increasing the amount of a neurotransmitter between the nerve cells.

The active substance, dapoxetine, is a selective serotonin re-uptake inhibitor (SSRI) and it works by preventing the neurotransmitter 5-hydroxytryptamine (also called serotonin) from being taken back up into nerve cells in the brain and spinal cord, thereby increasing the amount of serotonin between nerve cells.

Why was Priligy reviewed?

The company that markets Priligy in Sweden, Janssen-Cilag AB, submitted an application to market Priligy (30 mg and 60 mg tablets) through the mutual recognition procedure based on the initial authorisation granted by Sweden on 6 February 2009. The company wanted the authorisation to be recognised in Belgium, Bulgaria, Cyprus, Czech, Denmark, Estonia, Greece, France, Hungary, Ireland, Iceland, Lithuania, Luxembourg, Latvia, Malta, Netherlands, Norway, Poland, Romania, Slovenia, Slovakia and the United Kingdom (the 'concerned Member States').

However, the Member States were not able to reach an agreement and the Swedish medicines regulatory agency referred the matter to the CHMP for arbitration on 24 February 2011.

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The grounds for the referral were concerns over the benefit-risk balance of the 60 mg tablet by some Member States, who considered its additional benefit compared with the 30 mg tablet to be too modest when weighed against the increased risk of severe cases of syncope (fainting) seen in studies with the medicine.

What are the conclusions of the CHMP?

Based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Priligy 60 mg outweigh its risks, and that therefore the marketing authorisation for Priligy (30 mg and 60 mg) should be granted in all concerned Member States. The CHMP also concluded that the potential increased risk for syncope has been proven to be manageable. Patients should not start treatment with 60 mg tablets, and may only be switched to 60 mg if they have not responded sufficiently to the 30 mg tablets and have not experienced moderate or severe adverse reactions or symptoms suggestive of syncope.

The European Commission issued a decision on 20 January 2012.