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Questions and answers on Mifepristone Linepharma and associated names (mifepristone, 200 mg tablet)

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

On 21 June 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 Mifepristone Linepharma. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Mifepristone Linepharma outweigh its risks, and recommended that the marketing authorisation granted in Sweden be recognised in other Member States of the EU.

What is Mifepristone Linepharma?

Mifepristone Linepharma is a medicine used for terminating pregnancy. It contains the active substance mifepristone, which works by blocking the effects of the hormone progesterone, which plays an important role in the maintenance of pregnancy.

Mifepristone Linepharma is given as a single dose of 200 mg, followed 36 - 48 hours later by a dose of another medicine called gemeprost.

Mifepristone Linepharma is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' called Mifegyne containing the same active substance. Both medicines are available as 200 mg tablets but whereas Mifegyne was authorised to be given at doses of 600 mg and 200 mg, Mifepristone Linepharma was only authorised at the 200 mg dose.

Mifepristone Linepharma is already authorised through a decentralised procedure in Denmark, Finland, Island, Norway and Sweden.

Why was Mifepristone Linepharma reviewed?

Linepharma France submitted an application for Mifepristone Linepharma for mutual recognition on the basis of the initial authorisation granted by Sweden on 3 December 2010. The company wanted the authorisation to be recognised in France and the United Kingdom (the 'concerned Member States').

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

The grounds for the referral were that Mifepristone Linepharma had not been shown to be bioequivalent to the reference medicine, Mifegyne 200 mg. In addition, the available data on the safety and effectiveness of the medicine were not sufficient to compensate for the lack of bioequivalence. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the conclusions of the CHMP?

The CHMP noted that the data submitted by the company showed a small deviation of Mifepristone Linepharma from the acceptable range for bioequivalence with the reference medicine, with Mifepristone Linepharma 200 mg producing slightly higher levels of active substance in the body than Mifegyne 200 mg. However, the difference was not considered to be of concern as the safety and effectiveness of mifepristone at much higher doses of up to 600 mg is well established and has been confirmed by the supportive studies with Mifepristone Linepharma.

Therefore, based on the evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Mifepristone Linepharma outweigh its risks and recommended that the marketing authorisation for Mifepristone Linepharma be granted in all concerned Member States. The CHMP also concluded that the product information should include a statement that doses higher than 200 mg should not be given. In addition, the Committee recommended that a prospective observational study should be performed to monitor how Mifepristone Linepharma is prescribed.

The European Commission issued a decision on 11 September 2012.