European Medicines Agency

London, 2 October 2009
Doc. Ref. EMEA/CHMP/150525/2009 rev.1
EMEA/H/A-29/1083

Questions and answers on the referral for Octegra solution for infusion containing moxifloxacin 400 mg/250 ml

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Octegra solution for infusion. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Octegra solution for infusion outweigh its risks, and the marketing authorisation granted in Germany can be recognised in other Member States of the EU, namely France and Portugal. However, the prescribing information for Octegra solution for infusion should be amended in all the Member States where it is authorised.
The review was carried out under an 'Article 29' referral[1].

What is Octegra solution for infusion?
Octegra solution for infusion is an antibiotic given by infusion (drip into a vein). It can be used to treat the following bacterial infections:
- community-acquired pneumonia (an infection of the lungs that is caught outside of hospital);
- complicated infections of the skin and the soft tissues below the skin. Complicated means that the infection is difficult to treat because it has spread to the deep tissues below the skin, treatment with surgery might be needed, or the patient has other conditions that might affect the response to treatment.

The active substance in Octegra solution for infusion, moxifloxacin, belongs to the group 'fluoroquinolones'. It works by blocking enzymes that bacteria use to make more DNA. By doing this, it stops the bacteria from growing and multiplying.

Why was Octegra solution for infusion reviewed?
Bayer Vital GmbH submitted Octegra solution for infusion for mutual recognition on the basis of the initial authorisation granted by Germany on 30 April 2002. The company wanted the authorisation to be recognised in France and Portugal (the 'concerned Member States'). However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 10 October 2008.

The grounds for the referral were concerns from France regarding the medicine's risk of causing problems with the heart rhythm (QT-interval prolongation).

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 Octegra solution for infusion outweigh its risks, and therefore the marketing authorisation for Octegra solution for infusion should be granted in all concerned Member States. The CHMP also recommended that the product information for the medicine should be amended in all the Member States where it is authorised. The amended information to healthcare professionals and patients is available here.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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The European Commission issued a decision on 2 October 2009.

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Co-Rapporteur:	Dr. Broich (Germany)
Referral start date:	23 October 2008
Company responses provided on:	26 January 2009; 27 April 2009; 28 May 2009
Opinion date:	25 June 2009