European Medicines Agency

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Questions and answers on the referral for Avalox 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 Avalox solution for infusion. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Avalox solution for infusion outweigh its risks, and the marketing authorisation granted in Germany can be recognised in other Member States of the EU, namely Cyprus, the Czech Republic, France, Italy, Poland, Portugal, Spain and the United Kingdom. However, the prescribing information for Avalox 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 Avalox solution for infusion?
Avalox solution for infusion is an antibiotic given by infusion (drip into a vein). It is 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 Avalox 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 Avalox solution for infusion reviewed?
Bayer Vital GmbH submitted Avalox 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 Cyprus, the Czech Republic, France, Italy, Poland, Portugal, Spain and the United Kingdom (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 expressed by the United Kingdom that the use of intravenous moxifloxacin in community acquired pneumonia and complicated skin and soft tissues infections should be limited to when the standard treatments for these infections are not appropriate, and concerns from France regarding the medicine's risk of causing problems with the heart rhythm (QT-interval prolongation).

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

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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 Avalox solution for infusion outweigh its risks, and therefore the marketing authorisation for Avalox 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.

The European Commission issued a decision on 2 October 2009.

Rapporteur:	Dr. Hudson (United Kingdom)
Co-Rapporteur:	Dr. Broich (Germany)
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