European Medicines Agency

London, 17 March 2009
Doc. Ref. EMEA/CHMP/191900/2009
EMEA/H/A-29/1096

Questions and answers on the referral for Bleomycin, powder for solution for injection, 15 U/Vial, from Pharmachemie BV

The European Medicines Agency (EMEA) has completed a referral procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Bleomycin injection, from Pharmachemie BV. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Bleomycin injection, from Pharmachemie BV, outweigh its risks, and the marketing authorisation can be granted in the Member States of the European Union and the European Economic Area.
The review was carried out under an 'Article 29' referral[1] procedure.

What is Bleomycin?
Bleomycin is an anti-cancer medicine used to treat certain forms of cancer of the head or the neck, cervix (the neck of the womb) and external sexual organs; certain forms of lymphoma (cancer of the lymphatic system) such as Hodgkin's disease; and to treat cancer of the testicles. Bleomycin can also be used by injection directly inside the chest cavity to treat fluid accumulation in the lungs as a result of cancer.
Bleomycin is almost always used in combination with anti-cancer drugs or in combination with radiation.
Bleomycin is a cytostatic substance; this means that it stops the growth of cells. Bleomycin inserts itself within the strands of DNA, the genetic material of cells, making the strands break. As a result the cells cannot multiply.

Why was Bleomycin reviewed?
Pharmachemie BV submitted a Marketing Authorisation Application for Bleomycin powder for solution for injection 15 U/vial in the decentralised procedure on 10 July 2007, the Netherlands acting as the reference member state. The company wanted the authorisation to be granted in Austria, Belgium, Bulgaria, the Czech Republic, Denmark, Estonia, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Slovakia, Slovenia and Spain (the concerned Member States). These member states were not able to reach an agreement. On 3 November 2008, the Netherlands medicines regulatory agency, the Medicines Evaluation Board, referred the matter to the CHMP.

The grounds for the referral were that Germany was not in a position to accept some of the anti-cancer indications because they were not recognised as acceptable for bleomycin in the country. The indications 'head and neck carcinoma' and 'epidermoid carcinoma of external genitalia such as penile carcinoma, or cervix' had been deleted from the authorised indications for all bleomycin-containing products in Germany because the balance of benefit/risk for bleomycin in these indications was considered negative. Germany considered that the submitted data was insufficient for granting a marketing authorisation for the proposed indications. The RMS and the other positive CMSs were in favour of retaining these indications. Because consensus could not be reached, the procedure was

[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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referred to the CHMP. The CHMP assessed the available data in order to establish whether the two indications can be supported.

What are the conclusions of the CHMP?
Based on evaluation of the currently available data, including published literature and current treatment guidelines, and the scientific discussion within the Committee, the CHMP concluded that the benefits of Bleomycin injection, from Pharmachemie BV, outweigh its risks, and therefore the marketing authorisation for Bleomycin should be granted in all concerned member states.

The European Commission issued a decision on 12 March 2009.

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Referral start date:	20 November 2008
Opinion date:	18 December 2008