European Medicines Agency

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Questions and answers on the referral for Teicoplanin Hospira powder and solvent for injection containing 200 or 400 mg teicoplanin

On 25 June 2009, the European Medicines Agency (EMEA) completed an arbitration procedure following a disagreement among Member States of the European Union regarding the authorisation of the medicine Teicoplanin Hospira. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Teicoplanin Hospira do not outweigh its risks, and the marketing authorisation cannot be granted in Germany and in other Member States of the EU (Austria, Ireland, Italy, Portugal, Spain and the United Kingdom).
The company that makes Teicoplanin Hospira, Hospira UK Limited, requested a re-examination of the opinion. After having considered the grounds for this request, the CHMP re-examined the initial opinion, and confirmed the recommendation for the refusal of the marketing authorisation on 22 October 2009.
The review was carried out under an 'Article 29' referral[1].

What is Teicoplanin Hospira?

Teicoplanin Hospira is an antibiotic. It is use to treat patients with serious infections due to Gram-positive bacteria. Gram-positive bacteria include bacteria such as staphylocci (*Staphylococcus aureus*), streptococci (*Streptococcus pneumoniae*), *Listeria*, *Clostridium difficile*. These bacteria can cause skin infections, lung infections, joint and bone infections, heart infections or infections of the urinary tract (structures that carry urine). Teicoplanin Hospira can only be used in patients who cannot receive penicillin or cephalosporins antibiotics, or if these antibiotics have stopped working or the infection is due to a *Staphylococcus* that is resistant to other antibiotics.
Teicoplanin Hospira can also be used to prevent infections in patients undergoing surgery of the bones, joint or blood vessels.
The active substance in Teicoplanin Hospira, teicoplanin, is an antibiotic that belongs to the group 'glycopeptides'. It works by stopping the bacteria making their cell walls and by disrupting their cell membranes. Together, the cell wall and membrane form a barrier between the bacterial cell contents and the external environment. By disrupting this barrier, teicoplanin kills the bacteria that are causing the infection.
Teicoplanin Hospira is a generic medicine based on a 'reference medicine' authorised in Germany (Targocid 400 mg).

Why was Teicoplanin Hospira reviewed?

Hospira UK Limited submitted Teicoplanin Hospira to the German Regulatory Agency for a decentralised procedure. This is a procedure when one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view of granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Ireland, Italy, Portugal, Spain and the United Kingdom).
However, the Member States were not able to reach an agreement and the German Regulatory Agency referred the matter to the CHMP for arbitration on 8 October 2008.

[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 grounds for the referral were concerns from Ireland and the United Kingdom that Teicoplanin Hospira had not been shown to be bioequivalent to Targocid. Medicines are bioequivalent when they produce the same levels of the active substance in the body.
There were also concerns that the composition of the teicoplanin in Teicoplanin Hospira was different to that in Targocid, with a potential impact on the effectiveness of the medicine. This is because teicoplanin in Teicoplanin Hospira is made by fermentation, using a bacterium called *Actinoplanes* to produce the antibiotic. When an antibiotic is produced using a natural source, as in this instance, there can be some differences in the composition of the finished product.

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 Teicoplanin Hospira do not outweigh its risks, and therefore the marketing authorisation should not be granted in the concerned Member States. The CHMP opinion was confirmed after re-examination.

The European Commission issued a decision on 29 January 2010.

	Initial Assessment	Re-examination
Rapporteur:	Dr. Karl Broich	Dr Barbara Van Zwieten-Boot
Co-Rapporteur:	Dr. Patrick Salmon	Dr Ian Hudson
Referral start date:	23 October 2008	4 September 2009
Company responses provided on:	23 January 2009 and 27 May 2009	3 September 2009
Opinion date:	25 June 2009	22 October 2009