29 January 2016
EMA/55653/2016
EMEA/H/A-29/1428

Questions and answers on Tobramycin VVB and associated names (tobramycin, 300 mg/5 ml nebuliser solution)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 28 January 2015, 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 Tobramycin VVB. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that Tobramycin VVB can be granted marketing authorisation in Lithuania and in the following Member States of the EU: Bulgaria, Estonia, Hungary, Latvia, Poland and Romania.

What is Tobramycin VVB?

Tobramycin VVB is an antibiotic for treating long-term lung infection caused by the bacteria *Pseudomonas aeruginosa* in patients aged 6 years and older who have cystic fibrosis. Cystic fibrosis is an inherited disease in which there is an accumulation of thick mucus in the lungs that allows bacteria to grow more easily and cause infections. *P. aeruginosa* is a frequent cause of infections in cystic fibrosis patients.

Tobramycin VVB is to be available as a nebuliser solution (300 mg/5 ml) to be inhaled. The active substance in Tobramycin VVB, tobramycin, belongs to the group of antibiotics known as 'aminoglycosides'. It works by disrupting the production of proteins that *P. aeruginosa* needs to build its cell walls, resulting in damage to the bacteria which eventually kills them.

Tobramycin VVB is a 'hybrid medicine' that has been developed to be comparable to a 'reference medicine' containing tobramycin called Tobi (300 mg/5 ml nebuliser solution).

Why was Tobramycin VVB reviewed?

UAB VVB submitted Tobramycin VVB to the Lithuanian medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Lithuania) assesses a medicine with a view to 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 Bulgaria, Estonia, Hungary, Latvia, Poland and Romania).

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However, the Member States were not able to reach an agreement and the Lithuanian medicines regulatory agency referred the matter to the CHMP for arbitration on 14 October 2015.

The reason for the referral was a disagreement over whether Tobramycin VVB is clinically superior to Tobi Podhaler, another medicine containing tobramycin. Demonstration of clinical superiority is required because Tobi Podhaler is an orphan medicine and was granted market exclusivity in the EU at the time of its market authorisation in July 2011. This means that during the period of market exclusivity similar products, such as Tobramycin VVB, cannot be placed on the market; there are, however, exceptions such as where clinically superiority over Tobi Podhaler can be shown.

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 Tobramycin VVB is clinically superior to Tobi Podhaler because a substantial proportion of patients are intolerant to Tobi Podhaler but can be treated with Tobramycin VVB. The CHMP therefore recommended that Tobramycin VVB be granted marketing authorisation in Lithuania as well as in the other concerned Member States.

A European Commission decision on this opinion will be issued in due course.