22 January 2015
EMA/CHMP/780275/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vantobra

tobramycin

On 22 January 2015, the Committee for Medicinal Products for Human Use (CHMP) readopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vantobra 170 mg nebuliser solution intended for the management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis (CF).

The applicant for this medicinal product is PARI Pharma GmbH.

The active substance of Vantobra is tobramycin, an aminoglycoside antibacterial (J01GB01) which primarily affects the bacterial protein synthesis and result in rapid concentration-dependent killing.

Vantobra represents an alternative treatment option for cystic fibrosis patients with chronic *P.aeruginosa* lung infections. Young children (6-13 years old) and adults aged 20 years or older with poor lung function will benefit the most from the treatment.

A pharmacovigilance plan for Vantobra will be implemented as part of the marketing authorisation.

The approved indication is: "management of chronic pulmonary infection due to *Pseudomonas aeruginosa* in patients aged 6 years and older with cystic fibrosis (CF). Consideration should be given to official guidance on the appropriate use of antibacterial agents."

The CHMP had adopted an opinion for this medicinal product on 2 June 2014. However, following concerns raised regarding possible similarity with an orphan medicinal product, on 23 September 2014 the CHMP agreed to review the similarity assessment report for Vantobra vis-à-vis authorised orphan medicinal products based on the indication recommended on 02 June 2014. The CHMP concluded on 20 November 2014 that Vantobra was similar to TOBI Podhaler. Subsequently, the Applicant provided a delegation report justifying that Vantobra is clinically superior to the authorised orphan medicinal product, TOBI Podhaler, in the same therapeutic indication. On 22 January 2015 the CHMP concluded that Vantobra, although similar to TOBI Podhaler, is considered to be clinically superior due to greater safety in a substantial portion of the target population.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.