18 December 2014
EMA/CHMP/676678/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Quinsair

levofloxacin

On 18 December 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Quinsair, 240 mg, nebuliser solution intended for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis.

Quinsair was designated as an orphan medicinal product on 23 September 2008. The applicant for this medicinal product is Aptalis Pharma SAS. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Quinsair is levofloxacin, a fluoroquinolone antibacterial: J01MA12, acting by inhibition of bacterial DNA gyrase and topoisomerase IV enzymes.

The benefits with Quinsair are its ability to prevent deterioration of respiratory function in cystic fibrosis patients, mainly based on data derived from one Phase 2 (MPEX 204) and two Phase 3 studies (MPEX 207-209). The most common side effects are cough/productive cough, dysgeusia and fatigue/asthenia. Due to substantial systemic exposure observed with Quinsair, it is cautioned that the use of the product might be associated with treatment emerging adverse events (TEAEs) recognised to occur with systemic doses of levofloxacin.

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

The approved indication is:

"Indicated for the management of chronic pulmonary infections due to Pseudomonas aeruginosa in adult patients with cystic fibrosis (CF, see section 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents."

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

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Quinsair and therefore recommends the granting of the marketing authorisation.