22 September 2011
EMA/CHMP/724015/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dificlir

fidaxomicin

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dificlir, 200mg, film-coated tablet intended in adults for the treatment of *Clostridium difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD). The applicant for this medicinal product is FGK Representative Service GmbH. 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 Dificlir is fidaxomicin, an antibacterial agent belonging to the macrocyclic class of antibacterials. Fidaxomicin is bactericidal and inhibits RNA synthesis by bacterial RNA polymerase. It interferes with RNA polymerase at a distinct site from that of rifamycins.

The benefits with Dificlir are its ability to cure populations suffering CDI. The efficacy of fidaxomicin was investigated in two Phase 3 trials which enrolled a total of 1164 subjects with CDI. In the pooled clinical trials, fidaxomicin was shown to be associated with a non inferior cure rate as compared to vancomycin. The most common side effects are nausea, vomiting and constipation.

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

The approved indication is: "DIFICLIR is indicated in adults for the treatment of *Clostridium difficile* infections (CDI) also known as *C. difficile*-associated diarrhoea (CDAD) (see section 5.1).

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

It is proposed that Dificlir be subject to medical prescription.

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.

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