20 September 2018
EMA/CHMP/619927/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pifeltro

doravirine

On 20 September 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pifeltro, intended for the treatment of HIV-1 infection. The applicant for this medicinal product is Merck Sharp & Dohme B.V.

Pifeltro will be available as 100-mg film-coated tablets. The active substance of Pifeltro is doravirine, a new non-nucleoside reverse transcriptase inhibitor (NNRTI) which inhibits HIV-1 replication by non-competitive inhibition of HIV-1 reverse transcriptase (ATC code: J05AG).

The benefits with Pifeltro are its ability to achieve a potent antiretroviral response in a once daily, single pill regimen. The most common side effects are nausea and headache.

The full indication is: "Pifeltro is indicated, in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class (see sections 4.4 and 5.1)."

It is proposed that Pifeltro be prescribed by physicians experienced in the management of HIV infection.

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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