European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

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EMEA PUBLIC STATEMENT

Use of antiretroviral treatment in HIV-patients with hepatic impairment and/or HBV/HCV co-infection

During 2002, the EMEA's Committee for Proprietary Medicinal Products (CPMP) requested the Marketing Authorisation Holders (MAHs) for all licensed antiretroviral medicinal products in Europe to conduct a retrospective review from clinical trials and post marketing data in HIV patients with hepatic impairment and/or HBV/HCV co-infection, with the aim to review pharmacokinetic and safety data, and to propose measures to improve the availability of relevant data from these patients. The focus on this issue provided new information which has been incorporated into the relevant sections of the Summary of Product Characteristics of antiretroviral products, the enrolment of co-infected patients in ongoing and planned clinical trials, an improved surveillance of hepatic safety in these patients and the planning of epidemiological studies.

After an assessment of initial responses by CPMP in April 2004, the MAHs jointly established a Steering Committee (HIV/Hepatitis Co-infection Cohort Collaboration- HIVCO), to set up a plan on how to obtain information on the hepatic safety of highly active antiretroviral treatment (HAART) in co-infected patients**,** which reported in March 2005. At the CHMP[1] and Pharmacovigilance Working party meeting in June 2005, the preliminary assessment of this response was discussed and the Marketing Authorisation Holders made a presentation of their data and proposals. The conclusions from this meeting were formally adopted by the CHMP in its July 2005 meeting.

The CHMP endorsed the proposal of the HIVCO committee that the D.A.D. Study[2] should be used for the evaluation of liver related death in co-infected patients, which the Marketing Authorisation Holders also have committed to support for three years.

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[1] Previously known as CPMP
[2] A large multi-cohort prospective study to evaluate cardiovascular risk know as The Data Collection on Adverse Events of Anti-HIV Drugs.