

Malta, 24 April 2009
Circular No. P07/2009

Re: Abacavir and the risk of heart attack – Update

Abacavir is a nucleoside reverse transcriptase inhibitor (NRTI) indicated in antiretroviral combination therapy for the treatment of HIV infection. In the European Union, it is available as Ziagen, in combination with lamivudine as Kivexa, and in combination with lamivudine and zidovudine as Trizivir.

Finalising a review of recent data on the risk of heart attack (myocardial infarction) associated with the use of abacavir in HIV-infected patients, the CHMP has concluded that there is insufficient evidence to recommend changes to the therapeutic management of patients. This follows the Committee's review of findings from the D:A:D study in April 2008, which concluded that further data were needed to determine this risk.

Data from observational studies that have become available since April 2008, including the French Hospital Database on HIV, have continued to show a possible link between myocardial infarction and the use of abacavir. Data from clinical trials showed low numbers of myocardial infarction and could not exclude a small increase in risk.

However, the CHMP has concluded that there were inconsistencies between the different studies' findings and that a causal relationship between treatment with abacavir and the risk of myocardial infarction can neither be confirmed nor refuted. To date, there is no established biological mechanism that could explain a potential increase in risk.

Nevertheless, when prescribing abacavir-containing medicines, prescribers should take action to minimise modifiable risk factors, such as smoking, high blood pressure and high blood fat levels. The product information for abacavir-containing medicines will be updated to reflect this information.

The press release from April 2008 is available [here](#).

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the full [press release](#) issued by the EMEA, attached here for your perusal.