AWTORITA' DWAR IL-MEDIĆINI

Malta, 9 April 2008 Circular No. P07/2008

Dear Healthcare Professional,

Re: Further data needed to determine risk of heart attack with abacavir

The Committee for Medicinal Products for Human Use (CHMP) has concluded at its March 2008 meeting that the data from the D:A:D ('Data collection of Adverse effects of anti-HIV Drugs') study, do not allow for a definitive conclusion to be drawn on the association between the use of abacavir and an increased risk of myocardial infarction. At present no changes to the prescribing information for abacavir-containing medicines are required, but further information is needed to determine the risk of myocardial infarction with abacavir-containing medicines. The CHMP is requesting information from ongoing epidemiological studies to determine this risk. The Medicines Authority has participated in these discussions held at the European Medicines Agency (EMEA) and is in agreement with the press release and Q&A document issued by the EMEA, attached here for your perusal.