EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2010
EMA/CHMP/56057/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Baraclude

entecavir

On 20 January 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Baraclude. The marketing authorisation holder for this medicinal product is Bristol-Myers Squibb Pharma EEIG. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a new indication as follows:
"Baraclude is indicated for the treatment of chronic hepatitis B virus (HBV) infection (see section 5.1) in adults with:

- decompensated liver disease (see section 4.4)".

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full indications for Baraclude will be as follows[2]:

Baraclude is indicated for the treatment of chronic hepatitis B virus (HBV) infection (see section 5.1) in adults with:

- compensated liver disease and evidence of active viral replication, persistently elevated serum alanine aminotransferase (ALT) levels and histological evidence of active inflammation and/or fibrosis.
- **decompensated liver disease (see section 4.4)**

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

[2] The text in bold represents the new or the amended indication.

For both compensated and decompensated liver disease, this indication is based on clinical trial data in nucleoside naive patients with HBeAg positive and HBeAg negative HBV infection. With respect to patients with lamivudine-refractory hepatitis B, see sections 4.4 and 5.1.