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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): lamivudine (chronic hepatitis B)

Procedure No. EMEA/H/C/PSUSA/00001824/201507

Period covered by the PSUR: 01 August to 31 July 2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for lamivudine (chronic hepatitis B), the scientific conclusions of CHMP are as follows:

The product information of ZEFFIX should be adjusted to better reflect current guidelines for the management of lamivudine resistance. For that reason changes to SmPC section 4.2 for a switch to or addition of an alternative agent without cross-resistance to lamivudine based on therapeutic guidelines, were recommended by PRAC. Subsequent changes were deemed necessary in sections 4.4 and 5.1 of the SmPC to support this information. No changes were introduced to the package leaflet related to lamivudine resistance.

The MAH also has taken the opportunity to update the product information in accordance with the latest QRD v10 template, which is accepted.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing lamivudine were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for lamivudine (chronic hepatitis B) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lamivudine (chronic hepatitis B) is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.