
Subject: FW: Essential Meds (Paediatrics) applications: AZT/3TC, abacavir, lamivudine scored forms

From: wendy.x.snowden
Sent: 06 June 2007 14:13
To: Hill, Suzanne
Subject: RE: Essential Meds (Paediatrics) applications: AZT/3TC, abacavir, lamivudine scored forms

Dear Suzanne,
Further to the applications for the scored tablets of AZT/3TC, lamivudine and abacavir for the WHO Essential Medicines list, which we understand will be discussed at an Experts Consultation meeting in July, we would like to update you on the Regulatory status of these products as we have recently recieved initial feedback from CHMP on our registration applications.

GSK have received a recommendation from CHMP that the type II variation for scored Combivir tablets 'could be approvable' providing satisfactory responses to a request for supplementary information (RSI) and revised SPC are provided. GSK are currently preparing responses to the request and therefore the earliest date for CHMP opinion has been delayed until the September CHMP meeting (there is no CHMP meeting in August).

GSK are expecting a similar delay in opinion for the variation for Scored Eпивir tablets, but have not yet received the formal documentation. The type II variation for Ziagen has been validated and is currently under review, no comments have yet been received from CHMP.

We will provide you with further updates when available.

Kind Regards,

Wendy

Wendy Snowden PhD
Clinical Development ID MDC
GlaxoSmithKline R&D
Bdg 38 -2/30, Greenford Rd
Greenford, Middlesex, UK
UB6 0HE

Phone +44 (0)208 966 4139
Mobile +44 (0)7717 801894
Fax +44 (0)208 966 8044