

Safeguarding public health

10 SEP 2010

PA → MA



Dr P Bath
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08/09/2010

Dear Dr P Bath

NOTIFICATION OF AMENDMENT

Our Reference:	03057/0027/001-0010
Eudract Number:	2007-006749-42
Product:	Clopidogrel
Protocol number:	31350
Substantial Amendment Code Number:	SA04/10 31 August 2010 New UK sites and change of PI at existing sites.

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 1031

Thank you for your letter received on 03/09/2010. The proposed administrative amendment has been noted. It is assumed that the amendment will not be made until you have received a favourable opinion from the relevant ethics committee, in accordance with regulation 24 (9).

Please quote the above reference numbers in all communications.

Yours sincerely

Submissions
MHRA