



Malta, 13 October 2005  
Circular No. P17/2005

**RE: Post-licensing requirements with respect to submission of recently approved variations or ongoing variations which are not reflected in the dossier submitted for a Marketing Authorisation**

During the assessment phase for a marketing authorisation, approved variations not reflected in the submitted dossier should be notified to the Medicines Authority. Notification of approved variations should be made through a notification letter accompanied by the relevant national competent authority approval letter and the approved summary of product characteristics both as a hard and electronic copy. Once a Marketing Authorisation has been issued, any ongoing variations should be submitted as a national variation. Further information on how to vary a Marketing Authorisation can be obtained in the Post-Licensing section of this web site.