

Ref: 36/11/gf

26th April 2011

RE: Training Session: Variations to Marketing Authorisation

Dear Stakeholder,

Variations are submitted by Marketing Authorisation Holders to vary the Marketing Authorisation, for instance, to add a new manufacturing site, to change the method of manufacture or to add a new indication. Variations are either Type IA or Type IB, or Type II, as defined in Commission Regulation 1234/2008. The Medicines Authority is organising a training session for Qualified Persons and individuals working in the field of regulatory affairs field who compile and/ or submit variations. The training will cover areas including:

- Changes to the submission of variation applications as a result of the new Variations Regulations
- Information on submission of application forms & supporting documentation for variations
- Information on submission of an application for a transfer

A question and answer session will be held at the end of the session.

Two identical sessions will be held on two different dates (Thursday 26th May 2011 between 09:00 and 11:30 and Tuesday 31st May 2011 between 13:00 and 15:30).

Participants may register by Monday 23rd May 2011 using the [registration form](#) and highlight which session they wish to attend. Participation is free of charge <https://spreadsheets.google.com/viewform?hl=en&formkey=dEZEbFRqeHZsMnFIcnNFSmJsLVZyMHc6MQ#gid=0>.

Prospective participants may highlight other training needs and / or issues in relation to variations which can be covered during this session by Friday 6th May 2011.

For more information please contact Ms. Cheryl Aquilina, Senior Pharmacist at the Medicines Authority on cheryl.aquilina@gov.mt.

Sincerely,

Gavril Flores
Operations and Regulatory Affairs Manager