

**ANNEX IV**

**CONDITIONS OF THE MARKETING AUTHORISATIONS**

National Competent Authorities shall ensure that the following condition is fulfilled by the Marketing Authorisation Holders:

The MAHs should provide within three months a detailed protocol (e.g. drug utilisation studies or survey done by record linkage) for the long term follow-up on the adherence to and effectiveness of the changes to the product information adopted by the CHMP as part of the referral procedure EMEA/H/A-31/881.