ANNEX IV

CONDITIONS OF THE MARKETING AUTHORISATIONS

The National Competent Authorities, coordinated by the Reference Member State, shall ensure that the following conditions are fulfilled by the Marketing Authorisation Holders:

1. The MAH commits to conduct an epidemiological study on the risk of falls and fractures and to provide the results of this study by Q2 of 2011. The MAH commits to amend the product information as relevant based on the outcome of the study.

2. The MAH commits to respond to the following unresolved quality issues by discussing and implementing as relevant in the context of an update of the CTD documentation in May 2010.

All formulations	The MAH commits to provide the supporting documents and data regarding the stability of the modification of the drug substance omeprazole magnesium and omeprazole. The MAH commits to develop and introduce a second identification method for the drug substance omeprazole.
MUPS and capsules	The MAH commits to provide the supporting documents regarding bioequivalence to the biobatch. The MAH commits to update the dossier according to the various regulations and the EU Directive 2001/83/EC. The MAH commits to provide stability data for the intermediate/bulk product. The MAH commits to update the specifications with the test uniformity of dosage units.
MUPS	The MAH commits to investigate, justify and introduce the limits for impurities in accordance with the guideline *ICH Topic Q3B: Impurities in new Drug Products*
MUPS	The MAH commits to provide the supporting documents regarding the limits of quantifications of the drug product
Capsules and solution for injection and solution for infusion	The MAH commits to investigate, justify and introduce limits for a number of degradation products.
Solution for injection and solution for infusion	The MAH commits to clarify the activities of the drug product manufacturer. The MAH commits to provide the supporting documents regarding the shelf-life specification of the finished product. The MAH commits to provide the supporting documents regarding TSE (Transmissible Spongiform Encephalopathies) safety. The MAH commits to update the document ’P3-03 Description of Manufacturing Process and Process Controls for Drug Product’