

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:

The MAH commits to respond to a number of unresolved quality related issues by presenting relevant and adequate documents and data as outlined in the Letter of Undertaking dated 9 December 2009. To reduce administrative work, all response documents should be submitted as a single data package one year after the issue of the EC decision.