Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisations

National Competent Authorities (NCAs) of Member State(s) or Reference Member State(s) (RMS) where applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	**Date**
DHPC Communication circulation according to the CHMP agreed action plan and conditions.	Within 30 days after Commission Decision
Clinical/safety The MAH should perform a PK study assessing the effect of renal impairment and age on trimetazidine pharmacokinetics according to the CHMP agreed protocol. The final study results will be submitted to NCAs/RMS by:	30 September 2014.
PhV 1 The MAH should perform a drug utilization study to verify the compliance of prescribers regarding the restricted indication after marketing authorisation changes. The final study protocol will be submitted within 60 days from Commission decision to MSs/RMS to be finally agreed prior to starting the study. The final study report will be submitted to NCAs/RMS by:	30 September 2014
PhV 2 The MAH will perform a PASS study to address all important, potential and identified risks, particularly Parkinsonism. The full study protocol for the nested case-control study within the European Society of Cardiology cohort, to investigate the potential association between extrapyramidal symptoms (EPS) and trimetazidine will be submitted to the MSs/RMS within 60 days after Commission Decision to be finalised prior to starting the study. The final study report will be submitted to MSs/RMS by:	31 March 2015:pilot study 31 December 2016: main cohort (1 year results)