Annex IV

Condition to the marketing authorisation

Condition to the marketing authorisation

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):

The MAHs shall submit an EU risk management plan for the products according to the EU Good Vigilance Practices and including the following measures:

- Shortening of PSUR cycle from 3 yearly to 6-monthly PSURs until 2016. Safety reports focused on cardiovascular adverse events, haemorrhagic adverse events and off-label use should be submitted together with the 6-monthly PSURs.

  First Data Lock Point (DLP) = 30 August 2013
- Conduct of a drug utilization study to describe the characteristics of new users of cilostazol and the duration of the use of cilostazol and discontinuation patterns. The study will also aim to quantify off-label use, describe dosage patterns and identify the medical specialties of physicians prescribing cilostazol.

  Deadline for submission of the Final study report: 30 June 2014.
- The MAH should perform a drug utilization study to evaluate the effectiveness of the implemented risk minimisation measures in terms of the mitigation of off-label use and adherence of prescribers to the SmPC.

  Deadline for submission of the Final study reports: 31 December 2016.