Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation

National competent authorities of Member State(s) coordinated by reference Member State(s) if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	Date
The MAHs should circulate the agreed DHPC in coordination with the NCAs according to the action plan agreed by CHMP.	Within 30 days following EC decision
The MAHs should update the risk management plan (RMP) for products with an existing RMP to include the additional risk minimisation measures and the additional pharmacovigilance activities agreed as part of this procedure. For products without an RMP, a RMP should be submitted.	Within 3 months following EC decision
The MAHs shall conduct a PASS to further characterise the safety concerns on the hypersensitivity reactions. The study will also have to be reflected in the updated/new RMP submission. Final study report by:	31 July 2016
The MAHs should submit annual cumulative reviews of hypersensitivity case reports, all fatal cases and all pregnancy cases, together with usage data yearly. In order to improve the overall product comparability, the MAHs should have: • same data lock point (31st of December of each year), • same exposure definition (expressed in 100,000 patients treated – daily dose of 100 mg equivalents), • same event definition (use of the specific PT "Hypersensitivity" and the narrow and broad scope SMQs for "Anaphylactic reactions and angioedema": the MAHs should confirm their coding convention for capturing symptoms and diagnosis as MedDRA terms) • and use the severity classification according to Ring and Messmer classification.	31 March 2014 and annually thereafter
The MAH(s) should provide within the risk management plan educational material for prescribers and patients. This will highlight the risks and warnings on hypersensitivity reactions (by e.g. a checklist, to be implemented at national level).	Within 3 months following EC decision