

Annex IV

Conditions to the marketing authorisation

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Post-authorisation safety study (PASS)

The MAH shall conduct a non-interventional post-authorisation safety study (PASS) to evaluate the safety of Targocid in adults with Gram-positive infections who are exposed to the higher loading dose of 12mg/kg twice a day (24 mg/kg/day).

The protocols, abstracts and final study reports shall be submitted in the format set out in Annex III of Commission Implementing Regulation (EC) No 520/2012.

The protocol of this non-interventional PASS shall be submitted within 2 months of the Commission Decision.

The study protocol shall be entered in the EU electronic register of post-authorisation studies (EU PAS Register) before the start of data collection.

Risk management plan

The MAH shall submit a RMP within 6 months of the Commission Decision.