

#### **Annex IV**

**Conclusions on the granting of the marketing authorisation under exceptional circumstances  
presented by the European Medicines Agency**

**Conclusions presented by the European Medicines Agency on:**

- **Marketing authorisation under exceptional circumstances**

The CHMP having considered the application is of the opinion that the risk-benefit balance is favourable to recommend the granting of the marketing authorisation under exceptional circumstances as further explained in the European Public Assessment Report.