

ANNEX IV

**CONCLUSIONS ON THE GRANTING OF THE MARKETING AUTHORISATION UNDER
EXCEPTIONAL CIRCUMSTANCES AND 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.