<ANNEX IV

CONCLUSIONS ON THE GRANTING OF THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES AND <SIMILARITY AND DEROGATION> <AND> < THE REQUEST FOR ONE-YEAR <MARKETING PROTECTION> <DATA EXCLUSIVITY>> PRESENTED BY THE EUROPEAN MEDICINES AGENCY

Conclusions presented by the European Medicines Agency on:

[ For the status on marketing authorisation under exceptional circumstances and, in case of similarity and an accepted derogation, please select the statement(s) as provided below.]

* **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.>

* **<Similarity>**

<The CHMP is of the opinion that <name of product> is similar to authorised orphan medicinal product(s) within the meaning of Article 3 of Commission Regulation (EC) No. 847/2000 as further explained in the European Public Assessment Report. >

* **<Derogation>**

<The CHMP is of the opinion that pursuant to Article 8 of Regulation (EC) No. 141/2000 and <Article 3 of Commission Regulation (EC) No 847/2000> [only for the superiority derogation]the following derogation<s> laid down in Article 8.3 of the same Regulation apply(ies) as further explained in European Public Assessment Report :

<the holder of the marketing authorisation for <authorised orphan medicinal product> is unable to supply sufficient quantities of the medicinal product> <and>

<the applicant could establish in the application that the medicinal product, although similar to <authorised orphan medicinal product>, is safer, more effective or otherwise clinically superior (as defined in Article 3 of Commission Regulation (EC) No. 847/2000) for the same therapeutic indication> <and>

<the holder of the marketing authorisation for <authorised orphan medicinal product> has given his consent to the applicant.>

* **<one-year <marketing protection> <data exclusivity>>**

[Where one-year marketing protection/data exclusivity is accepted, please select the statement(s) as provided below, otherwise provide scientific conclusions and grounds.]

[For Art 14(11)] <The CHMP reviewed the data submitted by the Marketing Authorisation Holder, taking into account the provisions of Article 14(11) of Regulation (EC) No 726/2004, and considers that the new therapeutic indication brings significant clinical benefit in comparison with existing therapies as further explained in the European Public Assessment Report. >

[Art 10(5)]<The CHMP reviewed the data submitted by the Marketing Authorisation Holder, taking into account the provisions of Article 10(5) of Directive 2001/83/EC, and considers that <the <pre-clinical tests> <and> <clinical studies> carried out in relation to the new indication were significant as further explained in the European Public Assessment Report. >