Conditions of the marketing authorisation as adopted by the CHMP with all information of a commercially confidential nature redacted (black box in text: [redacted])

Annex III

Conditions of the marketing authorisation

National Competent Authorities shall ensure that the following conditions are fulfilled by the MAH(s):

QUALITY

The variation to the marketing authorisations concerning changes to the manufacturing process:

- a routine adsorption step [redacted] (as previously optional);
- Results of NaPTT testing to be provided within the documentation being submitted in support of the official control authority batch release procedure and will cover all dilutions [redacted].
- A maximum of [redacted] adsorption for C1 Esterase Inhibitor [redacted].

PHARMACOVIGILANCE

The MAH is requested to submit a revised RMP to the NCAs within one month following Commission Decision. The revised version of the RMP should be amended for the important potential risk of TEE detailing routine risk minimisation activities for TEE as *"Included in the precautions section of the SmPC (section 4.4), and included in the adverse effects section of the SmPC (section 4.8)."*