European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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OVERVIEW OF COMMENTS RECEIVED ON
DRAFT GUIDELINE ON FOLLOW-UP OF PATIENTS ADMINISTERED WITH GENE THERAPY MEDICINAL PRODUCTS (EMEA/CHMP/GTWP/60436/2007)

Table 1: Organisations that commented on the draft Guideline as released for consultation

Name of Organisation or individual*	Country

* The organisation that commented on the draft Guideline as released for consultation has requested comments to be kept confidential and not to be published.

The main revisions to the guideline consisted in improving the complementarity with the overarching “Guideline on Safety and Efficacy Follow-up - Risk Management of advanced therapy medicinal products (EMEA/149995/2008)”, ensuring consistency with pharmacovigilance regulatory framework and clarifying, correcting considerations that may have led to misunderstandings.

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