ANNEX IV

Package leaflet referred to in Article 13

(a) For the identification of the advanced therapy medicinal product:

(i) the name of the advanced therapy medicinal product and, if appropriate, an indication of whether it is intended for babies, children or adults. The common name shall be included;

(ii) the therapeutic group or type of activity in terms easily understandable for the patient;

(iii) where the product contains cells or tissues, a description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin;

(iv) where the product contains medical devices or active implantable medical devices, a description of those devices and their specific origin;

(b) The therapeutic indications;

(c) A list of information which is necessary before the medicinal product is taken or used, including:

(i) contra-indications;

(ii) appropriate precautions for use;

(iii) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;

(iv) special warnings;

(v) if appropriate, possible effects on the ability to drive vehicles or to operate machinery;

(vi) the excipients, knowledge of which is important for the safe and effective use of the medicinal product and which are included in the detailed guidance published pursuant to Article 65 of Directive 2001/83/EC.

The list shall also take into account the particular condition of certain categories of users, such as children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions;

(d) The necessary and usual instructions for proper use, and in particular:

(i) the posology;

(ii) the method of use, application, administration or implantation and, if necessary, the route of administration;

and, as appropriate, depending on the nature of the product:

(iii) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;

(iv) the duration of treatment, where it should be limited;

(v) the action to be taken in case of an overdose (such as symptoms, emergency procedures);

(vi) information on what to do when one or more doses have not been taken;

(vii) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product;

(e) A description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly asked to communicate any adverse reaction which is not mentioned in the package leaflet to his doctor or pharmacist;

(f) A reference to the expiry date indicated on the label, with:

(i) a warning against using the product after that date;

(ii) where appropriate, special storage precautions;

(iii) if necessary, a warning concerning certain visible signs of deterioration;

(iv) the full qualitative and quantitative composition;

(v) the name and address of the marketing authorisation holder and, where applicable, the name of his appointed representatives in the Member States;

(vi) the name and address of the manufacturer;

(g) The date on which the package leaflet was last revised.