Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

ANNEX I

Manipulations referred to in the first indent of Article 2(1)(c)

cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions,...

ANNEX II

Summary of product characteristics referred to in Article 10

1. Name of the medicinal product.

2. Composition of the product:
   2.1. general description of the product, if necessary with explanatory drawings...
   2.2. qualitative and quantitative composition in terms of the active substances...

3. Pharmaceutical form.

4. Clinical particulars:
   - 4.1. therapeutic indications,
   - 4.2. posology and detailed instructions for use, application, implantation or administration...
   - 4.3. contra-indications,
   - 4.4. special warnings and precautions for use, including any special precautions...
   - 4.5. interaction with other medicinal products and other forms of interactions,...
   - 4.6. use during pregnancy and lactation,
   - 4.7. effects on ability to drive and to use machines,
   - 4.8. undesirable effects,
   - 4.9. overdose (symptoms, emergency procedures).

5. Pharmacological properties:
   - 5.1. pharmacodynamic properties,
   - 5.2. pharmacokinetic properties,
   - 5.3. preclinical safety data.

6. Quality particulars:
   - 6.1. list of excipients, including preservative systems,
   - 6.2. incompatibilities,
   - 6.3. shelf life, when necessary after reconstitution of the medicinal product...
   - 6.4. special precautions for storage,
   - 6.5. nature and contents of container and special equipment for use,...
   - 6.6. special precautions and instructions for handling and disposal of a...

7. Marketing authorisation holder.

8. Marketing authorisation number(s).

9. Date of the first authorisation or renewal of the authorisation....

10. Date of revision of the text.

ANNEX III

Labelling of outer/immediate packaging referred to in Article 11

The name of the medicinal product and, if appropriate, an...

ANNEX IV

Package leaflet referred to in Article 13

For the identification of the advanced therapy medicinal product: the...

(**1**) OJ C 309, 16.12.2006, p. 15.

(**2**) Opinion of the European Parliament of 25 April 2007 (not yet published in the Official Journal) and Council Decision of 30 October 2007.

(**3**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p. 1).

(**4**) OJ L 136, 30.4.2004, p. 1. Regulation as amended by Regulation (EC) No 1901/2006.

(**5**) OJ L 102, 7.4.2004, p. 48.

(**6**) OJ L 121, 1.5.2001, p. 34. Directive as amended by Regulation (EC) No 1901/2006.

(**7**) OJ L 91, 9.4.2005, p. 13.

(**8**) OJ L 262, 14.10.2003, p. 22.

(**9**) OJ L 169, 12.7.1993, p. 1. Directive as last amended by Directive 2007/47/EC of the European Parliament and of the Council (OJ L 247, 21.9.2007, p. 21).

(**10**) OJ L 189, 20.7.1990, p. 17. Directive as last amended by Directive 2007/47/EC.

(**11**) OJ L 33, 8.2.2003, p. 30.

(**12**) OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

(**13**) OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 1394/2007 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1(o)