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 and pictures,

2.2. qualitative and quantitative composition in terms of the active substances and other constituents of the product, knowledge of which is essential for proper use, administration or implantation of the product. Where the product contains cells or tissues, a detailed description of these cells or tissues and of their specific origin, including the species of animal in cases of non-human origin, shall be provided,

For a list of excipients, see point 6.1.

3. Pharmaceutical form.

4. Clinical particulars:

4.1. therapeutic indications,

4.2. posology and detailed instructions for use, application, implantation or administration for adults and, where necessary, for children or other special populations, if necessary with explanatory drawings and pictures,

4.3. contra-indications,

4.4. special warnings and precautions for use, including any special precautions to be taken by persons handling such products and administering them to or implanting them in patients, together with any precautions to be taken by the patient,

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 or when the immediate packaging is opened for the first time,

6.4. special precautions for storage,

6.5. nature and contents of container and special equipment for use, administration or implantation, if necessary with explanatory drawings and pictures,

6.6. special precautions and instructions for handling and disposal of a used advanced therapy medicinal product or waste materials derived from such product, if appropriate and, if necessary, with explanatory drawings and pictures.

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.

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)