ANNEX II

Summary of product characteristics referred to in Article 10

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).

Status:
Point in time view as at 31/01/2020.

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.